NEW YORK STATE | Department of Health | Medicaid Redesign Team

Regulatory Impact Subcommittee

Meeting #3

September 21, 2015

Today's Agenda

Today's Agenda includes the following:

Agenda Item	Time
Welcome and Introduction	1:00 pm
Recap: Final Recommendations from Meeting #2	1:10 pm
Policy Questions and Options: Model Contract and Provider Guidelines	1:40 pm
Introduction to Self-Referral (Stark Law), Anti-kickback, Prompt Payment, and Civil Monetary Penalties	2:30 pm
Closing	3:45 pm

Recap of Meeting #2: Final Recommendations*

Recommendation #1 - Provider Risk Sharing – Option 1 – Leave Regulation 164 as it currently stands. Apply the requirements of Regulation 164 to higher risk, Level Three Arrangements but not to Level Two arrangements.

Recommendation #2 - Default Risk Reserves – Option 2B – Allow providers to engage in VBP Level Two arrangements without a financial security deposit, but require additional safeguards to mitigate risk.

Recommendation #3 – Contracting Entities (PPS) – Do not formally recognize PPSs as a legal entity capable of contracting. Instead, keep the status quo utilizing existing legal frameworks (e.g. IPAs) for contracting.

Recommendation #4 – Provider Contract Review – Revise provider contract review guidelines to create three review Tiers aligned with the VBP Roadmap levels. High and medium risk contracts would be subject to DFS or DOH review. Low risk contracts would only require DOH notification.

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

Recommendation #4: Provider Contract Review

At the August 27th meeting, the SC requested a simplified guide outlining when DOH or DFS would review a provider contract.

- A detailed MOU will be created detailing the specifics of the DOH and DFS provider contract review process.

The next slide highlights three Tiers of review for Recommendation #4 (Provider Contract Review).

These three Tiers present a proposed high-level structure for steering who reviews a provider contract and what requirements those contracts must meet.*

**Refer to the Meeting #2 Recommendations document for full detail.*

Provider Contract Review

The SC recommends the following three Tiers of provider contract review:*

Tier	Owner	Description
3 - Highest	DFS DOH	**The existing DFS contract review process under Regulation 164 would apply.** This tier would generally apply to **higher risk VBP Level 3** arrangements.
2 - Middle	DOH	**The existing DOH contract review process would apply**. 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 **higher risk VBP Level 2 and lower risk Level 3 arrangements.**
1 - Lowest	DOH	**No explicit approval from DOH is required** 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 **VBP Level 1 and lower risk Level 2/3 arrangements**.

**Refer to the Meeting #2 Recommendations document for full detail.*

Model Contract and Provider Guidelines

At the August 27th meeting, the SC was asked to provide feedback for potential changes to the Medicaid Managed Care Model Contract and Provider Contract Guidelines.

- The deadline to submit comments has been extended to September 25
- This topic will be finalized in a future Subcommittee meeting

Model Contract and Provider Guidelines

Potential Sections Subject to Revision:

- **MC Section 3** - Compensation
- **MC Section 18/19** – Contractor Reporting & Audit Rights
- **MC Section 21** – Network Adequacy
- **MC Section 22** – Subcontracts and Provider Agreements
- **PG Section V.B** – Risk Sharing Requirements
- **PG Section VI** – Financial Review of MCO Contracts

Introducing the New Policy Questions:

Policy Question #6

SELF REFERRAL

Should NYS laws and regulations be harmonized with federal laws and regulations?

Policy Question #7

ANTI KICKBACK

What revisions, if any, should be made to state anti-kickback laws and regulations?

Policy Question #8

PROMPT PAYMENT

What revisions should be made to state laws and regulations to govern bonus reconciliations and payments?

Policy Question #9

CIVIL MONETARY PENALTIES

Should state laws and regulations be changed to enhance violations which may be more prevalent under VBP?

Policy Question #6: Stark Law (Self-Referral)

Federal and state laws prohibit physicians from referring patients for certain designated health services (DHS) which the physician (or immediate family) has a financial interest.

Key Federal Law Considerations

- Violations can be triggered in many ways such as (a) leases of office space or equipment, (b) referral arrangements, or (c) fee splitting.
- Physicians are not able to bill or submit a claim for DHS furnished as a result of a prohibited referral.
- Intent is irrelevant. Even an inadvertent violation is still a violation.

Key State Law Considerations

- Expands federal Stark to include all payers and expands the prohibition beyond physicians to include additional practitioners such as nurses, physician assistants, and nurse practitioners.
- Currently has fewer exceptions than federal Stark such as no specific exception for fair market value compensation arrangements, indirect compensation arrangements, nor any temporary non-compliance grace period to correct errors.

Stark Law (Self-Referral)

Potential exceptions to federal law which may mitigate the risk of a violation:

- **Physician Incentive Plan**: Most useful for VBP Levels 1 and 2, but there are limitations on the upside bonus and downside risk
- **Risk-Sharing Arrangements**: Useful for payments between an MCO and provider or IPA and provider, but must still comply with the Anti-kickback laws
- **Fair Market Value**: A useful exception for payments between providers (e.g. fee splitting, leases for integrated care), but there are strict requirements

Stark Law (Self-Referral)

Compliance with NYS Law

New York's version of the federal law is broader in scope and contains fewer exceptions. Therefore, New York law is more restrictive and affords less flexibility for providers compared to federal law. VBP contracting may be hindered due to current state law.

***Policy Question 6**: Should New York state law be amended to more fully align (harmonize) with federal Stark law OR should individual state exceptions be expanded (e.g. the Medicaid ACO exceptions)?*

Policy Question #7: Anti-Kickback (Fee-splitting)

Federal Anti-Kickback statute (AKS) prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals (including self-referrals) or generate federal health care program business.

Key considerations:

- Unlike Stark law, AKS is intent-based and can carry both civil and criminal penalties.
- Federal and state AKS laws are largely similar (unlike Stark law). Some exceptions exist where state law is broader.
- There are several “safe harbors” that act as exemptions to AKS, but VBP arrangements are not currently included at either the federal or state level.

Anti-Kickback (Fee-splitting)

AKS Compliance Considerations:

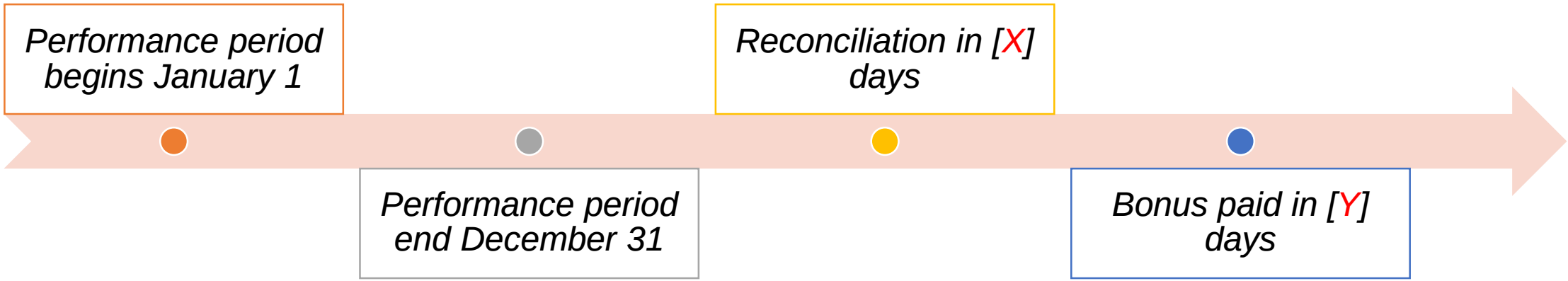
Absent any safe harbors for VBP arrangements, no purpose of remuneration can be to induce referrals payable by federal health care programs	The OIG is very active in monitoring potential kickbacks and issuing opinions and prosecuting cases	Areas to consider are; leases of space, leases of equipment, splitting of fees, contractual compensation arrangements between providers	A central inquiry will be whether the remuneration is for fair market value without regard to any referrals between the providers

***Policy Question 7**: How can NYS minimize the risks that VBP arrangements violate federal and NYS Anti-kickback laws in a VBP system, and what changes, if any, should be made to NYS laws and regulations to address VBP payment arrangements?*

Policy Question #8: Prompt Payment – VBP Bonuses

Prompt Payment laws and regulations typically require MCOs to pay claims submitted by providers within 30 days (electronic filing) or 45 days (paper filing); however, bonus payments are not addressed in current statute and regulations.

***Policy Question 8**: VBP Level 1 and 2 arrangements require the MCO to reconcile and calculate the shared savings to be paid to a provider over a contractual performance period. How long should this bonus reconciliation and payment process take between MCOs and providers?*



Policy Question #9: Civil Monetary Penalties

Federal and state laws penalize and sanction plans and providers for violations such as:

- ❑ Submitting false claims and false patient health data
- ❑ Offering remuneration to influence a patient to go to a particular provider
- ❑ Payment by a hospital to a physician to artificially reduce services to a Medicaid member
- ❑ Falsification of member applications
- ❑ Utilization of an excluded provider

***Policy Question 9**: Should state laws and regulations be changed to enhance violations which may be more prevalent under 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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