HIPAA and State Patient Privacy: Options and Considerations

Executive Summary

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and related NYS privacy laws and regulations are key components of Value-Based Payment (VBP) arrangements. The Regulatory Impact Subcommittee (Subcommittee) is tasked with providing recommendations regarding the policy question and related policy options discussed below which deal with the regulatory and procedural framework surrounding HIPAA and NYS privacy and security.

Current NYS privacy laws and regulations are more restrictive and provide less flexibility than federal HIPAA laws and regulations. These additional restrictions may prevent providers from sharing information for the purpose of coordinating care and evaluating the outcome of care, both of which are critical to successful VBP arrangements.

In some cases, the recommended method will be to align NYS and federal policies while maintaining sufficient protections to prevent the unnecessary sharing of individuals' Protected Health Information (PHI). Furthermore, there may need to be additional training for providers on any changes to the laws in order to support appropriate information sharing for the purpose of coordinating care while still protecting the confidentiality of this information. In other cases, the recommendation may be to retain NYS laws and regulations due to state policy reasons, yet create specific exceptions or alternative processes to accomplish the purposes of VBP.

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

A thorough review of five scenarios below depict various VBP challenges under current NYS law. The scenarios describe examples of the significant data privacy issues that may arise in a VBP setting. Each scenario depicts 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.[1]

Each of the five scenarios described in this brief should be considered on an individual basis with at least the three options described here (suggestions for alternative options are encouraged). The options below attempt to take into account potential changes in Medicaid members' rights for each scenario, particularly in the areas of behavioral health, substance abuse, HIV/AIDS, reproductive care, and for minors. The three options for each scenario are as follows:

- Option 1**:** Align NYS law with federal HIPAA protocol. Because NYS must already abide by HIPAA, this option provides a less restrictive and more updated alternative to many potential data privacy issues while maintaining a baseline privacy and security protocol; however, a broad alignment may not take into account various NYS specific policies regarding patient confidentiality.

- Option 2**:** Create specific exceptions to the NYS laws in an effort to accommodate the shift from a fee-for-service system to VBP. This option would help mold NYS law to accommodate VBP, but the layering of exceptions may become cumbersome to address all relevant privacy and confidentiality laws.

[1] The five scenarios are not meant to be exhaustive. Even with consensus for these scenarios, there will likely be specific data privacy questions and uncertainties that arise in which interpretation of consents, opt outs, and state laws and regulations will be necessary.

- Option 3: Replace/rewrite existing NYS privacy laws and regulations in an effort to accommodate the shift from a fee-for-service system to VBP. This option would generally require the greatest degree of legal work; however, it may provide a balanced solution that maintains NYS policy concerns, takes into consideration the existing federal law, and accommodates VBP.

In considering these options, the Subcommittee should also recommend the degree of State involvement required and related considerations and regulatory impacts associated with each option. Further, the Subcommittee should consider whether a data privacy and security workgroup should be developed to follow up on the recommendations and future data and privacy issues that arise over the course of VBP implementation.

Introduction

The Subcommittee will focus on developing policy recommendations related to HIPAA and NYS privacy and security. These issues will require coordination between both the New York State Department of Health (DOH) and the New York State Education Department (NYSED) as well as other NYS stakeholders.

This brief will provide an overview of the regulatory framework that governs federal HIPAA an NYS privacy laws and regulations. The brief will then present policy options for the Subcommittee's consideration. The policy options included in the brief are not exhaustive, and the Subcommittee is encouraged to consider alternatives outside of the options listed herein.

HIPAA and State Privacy

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 HIPAA and NYS patient confidentiality laws and regulations contain restrictions on the sharing of PHI; however, NYS 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 cost savings.

The success of VBP may be hindered due to current NYS law being more restrictive and affording less flexibility for providers compared to HIPAA. For each of the issues described below, the Subcommittee should decide whether to 1) Align NYS law with federal HIPAA protocol; 2) Create exceptions to the NYS laws to accommodate VBP; or 3) Replace existing NYS law in an effort to accommodate VBP. Some processes are already in place, such as the DSRIP Opt Out process, but these processes are limited in scope.

Below are five scenarios in which current NYS laws and regulations present challenges to VBP. While these scenarios provide five strong examples of potential data sharing issues under VBP, they do not encompass every potential issue.

Scenario 1 – DSRIP Opt Out and DEAA Processes:

The DSRIP Opt Out and DEAA processes are limited to NYS provided data. The DEAA process only applies to downstream transactions and does not apply to non-state provided data. There is currently uncertainty on upstream sharing of data and 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 per PPS or provider or requiring additional consents for each transaction would be burdensome and may cause delays in review processes and timing of payments.

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

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. There is also a lot of confusion about the appropriate sharing of information with and by care management agencies (including health homes) which leads to burdensome and unnecessarily complex consent processes that are not clearly communicated to consumers. If care management facilities such as Health Homes are one of the potential points of attribution in a VBP environment, these issues need to be clarified and addressed.

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. The consent process may delay, or in some cases deny, the care management entity's access to patient information.

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

Scenario 3 – RHIO and SHIN-NY Data:

The RHIO and SHIN-NY data may be incomplete due to NYS patient confidentiality laws (e.g., Public Health Law §2782) which limit provider-to-provider data access. If data access is 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/AIDS; mental health; and maternity and reproductive health confidentiality laws which are more restrictive than 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	**Notes**
1. Align NYS Law With HIPAA	Allow data sharing consistent with HIPAA (e.g., health care operations).	Does not fully solve the issue. Certain state restrictions (e.g., minor consent laws) are important to the State's policy interests. HIPAA does not account for minor confidentiality, maternity, HIV/AIDS, and related NYS policy considerations.
2. Create Exceptions to NYS Law	Create exceptions to allow for providers to disclose and access PHI through the RHIOs and SHIN-NY to accommodate VBP.	Exceptions can be made to all or some of the following restrictions to: minor consent, HIV, mental health, and maternity confidentiality laws. This requires analysis and evaluation including an update on how the RHIOs are functioning and what protections are currently in place. This requires further discussion and a deeper understanding of the RHIO and SHIN-NY networks and scope of data access.
3. Replace existing NYS law	Replace existing NYS law to allow for providers to disclose and access PHI through the RHIOs and SHIN-NY to accommodate VBP.	This approach will require a great deal of legal work and time. However, replacing existing, pre-HIPAA law would provide the State with an opportunity to customize laws and regulations to accommodate VBP while maintaining critical policy interests.

Scenario 4 – Scope and Medicaid Consent:

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

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 (there are limited exceptions for non-Medicaid members).

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	**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 mom-baby 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.

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 on a case by case basis.