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Guidance Documentation: Privacy and Data Sharing within DSRIP (June 5, 2017)

This document outlines strategies to facilitate protected health information (PHI) data sharing within the Delivery System Reform Incentive Payment (DSRIP) program. This document seeks to define the functions of the NYS Medicaid program, the DSRIP Performing Provider Systems (PPSs) and managed care organizations (MCOs) that provide services to the Medicaid population, to facilitate sharing of clinical and claims data for Medicaid beneficiaries between PPSs and MCOs.

This guidance is for information purposes only and is not intended as legal advice. Specific questions regarding compliance with federal and state laws should be referred to legal counsel.

Introduction

What is a DSRIP Performing Provider System (PPS)?

A PPS is a coalition of providers in a community (PPS Partners) led by an entity (PPS Lead Organization) that has been approved by DOH to operate select projects outlined within the DSRIP program, as governed by the New York State 1115 Medicaid Redesign Team (MRT) Waiver Amendment. A PPS Lead Organization may be a hospital, a limited liability corporation or a not-for-profit corporation. To date, the Department has approved twenty-five (25) PPSs. Each of the 25 PPS Lead Organizations and their PPS Partners are enrolled in the NYS Medicaid program.

Each PPS was approved either because its PPS Lead Organization is a safety net hospital, or the PPS Lead Organization and one or more of its PPS Partners form a coalition of safety net providers. The DSRIP accountability and funds must be controlled through the reserve powers of the safety net entity approved by DOH and Centers for Medicare & Medicaid Services (CMS).

What is the scope and function of the PPS?

PPSs are assigned Medicaid lives by DOH based on service area and the Medicaid member utilization of the providers in the PPS. PPSs have specific projects and organizational requirements that contribute to building integrated delivery systems and enhancing provider performance, to meet the State's goal of reducing avoidable hospital admissions and improving efficiency and effectiveness. DOH pays PPSs for performance based on achievement of project milestones and population-based metrics, as agreed to with CMS and defined in the 1115 MRT Waiver Amendment.

Each PPS performs a range of functions to support its network of providers, including but not limited to population health management, provider and clinical performance measurement, HIT support, continuous performance improvement, care coordination/management, practice transformation, workforce training, data analysis and value based payment support. In addition, the PPS may fund or directly provide services to patients in care management and coordination, outreach to Medicaid eligible members, patient education and other direct services.

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Data Sharing Guidance for PHI Data

Covered entities under the federal regulations established by the Health Insurance Portability and Accountability Act (HIPAA) include health plans and health care providers. The Medicaid program and managed care organizations are health plans, and Medicaid providers that provide health care treatment to Medicaid beneficiaries are health care providers. A contractor of a HIPAA-covered entity that creates, receives, maintains or transmits protected health information (PHI) on behalf of the HIPAA-covered entity is a HIPAA Business Associate of that covered entity, and is also regulated by HIPAA. Each of the PPS Lead Organizations has entered into a data exchange agreement with the NYS Medicaid program that complies with HIPAA's requirements for Business Associate Agreements (BAAs). For data sharing of state provided data between PPS Partners, other than the Lead PPS, the PPS Partner can establish appropriate BAAs that cover the direction of the data sharing similar to Health Homes ("lead to lead"/ "sub to sub"). The PPS Partner that wishes to share specific information may also request that the PPS Lead share that specific information with the other PPS Partner. Finally, a PPS Partner may share data with other PPS Partners with affirmative member consent to share the data.

When a member has opted out of DSRIP data sharing, the PPS Lead needs to ensure that any Medicaid data related to the member in current data sets, and moving forward, will no longer be utilized by the PPS or shared. The PPS does not have to redact data from previously developed data sets containing commingled data. If a member has previously opted out of DSRIP data sharing and then opts back in, the PPS cannot resurrect member information that was previously suppressed at the point of opt-out but must utilize the new information on the member as shared by NYS in current and future copies of NYS Medicaid data sets.

Data from State Medicaid Sources

The PPS must adhere to the requirement that state provided Medicaid data shared with the PPS according to a Data Exchange Application and Agreement (DEAA) must only be used for Medicaid purposes, related to the administration of the Medicaid program, even when that data has been commingled with other PPS generated data. PPS Leads may commingle state data with other data generated by PPS Partners or MCOs. A commingled data set is defined as any data set utilized or generated by the PPS that maintains fields found originally with NYS Medicaid claims/encounters data other than member name and member client identification number (CIN). Commingled data may only be used for the administration of the Medicaid program and all state and federal regulations related to privacy of PHI must be followed.

If a PPS uses a NYS issued data set and creates a data set that does not include any information other than name and CIN number this data set is not governed by DOH data sharing, security and privacy regulations. If PHI is contained in this new data set, however, the State cannot provide a legal opinion on the methodologies of PPSs to address data sharing of PHI generated within the PPS and the PPS should seek their own legal counsel to ensure they are compliant with all state and federal privacy laws.

Possible Methods for Data Sharing within the PPS



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Possible methods for data sharing within the PPS could be that the PPS Lead and PPS Partner are both part of the same Organized Health Care Arrangement (OHCA) under HIPAA, and the PPS Provider's Notice of Privacy Practices indicates that this data may be shared with the PPS Lead. See 45 CFR §164.506(c)(5). Another possible route would be to make the PPS Lead a HIPAA Business Associate of the PPS Partner. For example, the PPS Lead is, on behalf of the PPS Partner, creating, receiving, maintaining or transmitting clinical data for a function or activity regulated by HIPAA. See 45 CFR §160.103 (Business Associate). The disclosure is for treatment and/or payment and/or health care operations because the disclosure is, among other things, for delivery system reform incentive payments and quality management. Thus, the PPS Partner is disclosing clinical data to the PPS Lead the same way that a PPS Partner, as a QE Participant, shares information with the QE (the QE is the Business Associate of the QE Participant). The BAA in this scenario needs to clearly allow for the direction of data flow, whether it is one direction only or both directions (upstream and downstream/bidirectional). The QE may perform this task on behalf of the PPS Partner. For example, each PPS Partner has an agreement to share its information available in a QE with a PPS Lead. By having 100 agreements with its 100 PPS Partners the PPS Lead may access data from those 100 PPS Partners. However, the PPS Lead would not have access to data elsewhere on the network from other providers who did not a sign a similar agreement with the PPS Lead. This process is different from a "community wide consent" where a PPS Lead would have access to all of an individual patient's data available in the QE.

Again, the PPS Lead will need to seek legal counsel on which of these two scenarios or other potential scenarios meet its need for data sharing and is consistent with state and federal laws. This document cannot be relied on as legal advice.

PHI Generated within the PPS

PHI generated within the PPS also includes information generated or obtained by health care providers and may be included in the record of the patient's evaluation and treatment ("clinical data"). Clinical data is also referred to as clinical records, medical records or patient information. Such clinical data may be generated by: (1) general health care providers (see Public Health Law (PHL) §18); (2) mental health providers (see Mental Hygiene Law (MHL) §33.13); or (3) substance use disorder (SUD) treatment providers (see 42 CFR Part 2). PHI generated by any of these providers may include confidential HIV-related information (see PHL Article 27-F).

Clinical data generated within the PPS may be shared with the adequate and appropriate consent of the patient. PHI maintained by general health care providers, including confidential HIV-related information, may also be shared under the terms of a contract with a contractor that creates, receives, maintains or transmits PHI on behalf of the covered entity who generated the PHI, if the contract complies with the HIPAA requirements for BAAs. With the exception of SUD treatment data, PHI generated within the PPS may also be shared without additional consent (beyond what is already contained in the Medicaid application, DOH-4220), with third-party reimbursers or their agents, to the extent necessary to reimburse health care providers for health services.

Accordingly, health care providers may share the clinical data described above with a PPS Lead Organization for the purpose of reimbursement in the form of DSRIP payments for achievement of project milestones and population-based metrics, as agreed to with CMS and defined in the MRT Waiver Amendment. Consent to disclose PHI to agents who execute BAAs is not required



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under HIPAA or State law. Under State law, health care providers need consent to disclose clinical data to third parties who are not contractors under the basic ethical rule of provider-patient confidentiality that is codified in State law. See, e.g., Education Law §6530(23), 8 NYCRR §29.1(b)(8).

Where applicable, disclosures of mental health data must be permitted under MHL §33.13.

In the case of SUD treatment clinical data maintained by a Part 2 provider, the data may be shared with a consent from the patient that meets the requirements of 42 CFR Part 2, or under a contract with a Qualified Service Organization (QSO) that meets the requirements of 42 CFR Part 2 for Qualified Service Organization agreements (QSOAs). A PPS Lead Organization could be both a HIPAA Business Associate and a 42 CFR Part 2 QSO of its PPS Partners, such that PPS Partners could share PHI generated within the PPS with the PPS Lead Organization, under the terms of a contract that meets the requirements for a HIPAA BAA and those of a 42 CFR Part 2 QSOA.

PHI Generated by Managed Care Organizations (MCO)

NYS DOH and MCOs share data based upon the model contract. It is agreed that PHI data that is provided to the MCO on PPS' attributed members can be shared with the PPS Lead based on the language of the "opt out" letter as long as the member has not opted out of this data sharing.

However, other PHI data that the MCO may wish to share are not covered by the "opt out" letter. If the MCO is providing additional data to the PPS, then it is up to the MCO and its attorneys to determine how that information can or should be transmitted and what governs this data sharing.

It is noted that the PPS Lead is not a contracting agency at this time.

PHI Managed by QEs

PHI can be managed by QEs acting in one of two different roles: a) a contractor for a PPS Lead or b) health information exchange organization to facilitate the exchange of data among QE Participants. A PPS Lead may wish to contract with a QE to provide analytic services. In this case, the QE is acting as a contractor for the PPS Lead. The PPS Lead and QE would execute a contract that contains the appropriate BAA that would allow data sharing with the QE for performance of analytic services on behalf of the PPS. The BAA would have to reflect the source of the data, whether from NYS DOH and/or generated within the PPS.

As a heath information exchange organization, the QE could execute a DEAA with the NYS DOH and receive a data stream of demographic information and claims/encounters that it can hold. However, release of that data to any provider would require explicit affirmative consent by the member as any data sharing within the QE requires. The QE could also execute a contract with a BAA with the PPS Lead and receive state provided data from the PPS Lead. However, again, release of that data to a provider require an explicit affirmative consent to that provider signed by the member.

Additional Information



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PPS Partners may wish to obtain a written authorization from patients to disclose PHI, using a form such as the DOH-5032, which is approved by DOH, OMH and OASAS and is available on DOH's website at: https://www.health.ny.gov/forms/doh-5032.pdf.

For additional information related to security needs or questions, please contact the Security and Privacy Bureau at doh.sm.Medicaid.Data.Exchange@health.ny.gov.

References

- 1. Disclosure of clinical data by health care providers:
 - a. HIPAA allows disclosure by health care providers for "treatment, payment, or health care operations" without a HIPAA authorization. 45 CFR §164.502(a)(1)(ii). This would include disclosures for DSRIP, a program that results in payment from the Medicaid program to PPS Partners. See 45 CFR §164.501(Payment). Disclosures that are not for treatment, however, may only be the "minimum necessary" amount of health information to accomplish the purpose of the disclosure (e.g., determining DSRIP payments to the provider). 45 CFR §164.502(b)(1). PPS Lead Organizations have agreements with PPS Partners that establish how DSRIP payments will be distributed. These agreements should specify what disclosures of health information each PPS Partner is required to make in order to receive DSRIP payments.
 - b. PHL Article 27-F allows disclosures of confidential HIV-related information by health care providers for payment without consent. The disclosure must be to third-party reimbursers or their agents and must be only to the extent necessary to reimburse health care providers for health services. PHL §2782(1)(i). Each PPS Lead Organization has agreements with its PPS Partners that establish how DSRIP payments will be distributed. These agreements should specify what disclosures of health information each PPS Partner is required to make to the PPS Lead Organization and its agents in order to receive DSRIP payments.
 - c. MHL Article 33 allows disclosure by facilities, as defined in 33.13(a), for payment without consent pursuant to MHL §33.13(c)(9)(i) and to entities authorized by the Office of Mental Health or DOH to provide, arrange for, or coordinate health care services for care coordination purposes pursuant to MHL §33.13(d). DSRIP projects may require such facilities to share identifiable clinical information and/or clinical records with PPS Lead Organizations to enable such entities to monitor network and project-specific performance. Facilities under the jurisdiction of the Office of Mental Health may disclose identifiable clinical information and/or clinical records to the PPS Lead Organization of the PPS to which the individual is attributed to aid the PPS Lead Organization in overseeing the projects in which the facility participates pursuant to Section 33.13(d) of the Mental Hygiene Law as amended by Part M of Chapter 59 of the Laws of 2016. A facility may also share limited identifiable clinical information with the PPS Lead Organization for purposes of determining the facility's eligibility for Medicaid-funded incentive payments pursuant to Section 33.13(c)(9)(i) of the Mental Hygiene Law. Even



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though such disclosures are authorized by the Mental Hygiene Law, the following restrictions continue to apply:

- i. The disclosing facility shall limit the information disclosed to that information necessary and required in light of the reason for disclosure, pursuant to the "minimum necessary rule," codified at MHL §33.13(f).
- ii. Once a PPS Lead Organization has obtained identifiable clinical information and/or clinical records, such information shall remain confidential pursuant to the Section 33.13(f) of the Mental Hygiene Law and shall not be re-disclosed except as permitted by the Mental Hygiene Law. This means that the PPS Lead Organization cannot re-disclose identifiable information in the form of a referral to a care manager or other provider with whom the PPS Lead Organization has contracted unless the patient has provided consent to this disclosure. However, the PPS Lead Organization may share information with other mental health providers who currently provide services to the patient, or their Health Home care coordinator or their managed care plan pursuant to MHL §33.13(d).

The PPS Lead Organization has an agreement with its PPS Partners that sets out how DSRIP payments will be distributed to the PPS Partners. This agreement should specify what disclosures of MHL clinical data each PPS Partner is required to make to the PPS Lead Organization. The PPS Partner (1) may disclose to the PPS Lead Organization limited identifiable clinical information to aid the PPS Lead Organization in overseeing the projects in which the facility participates and/or for purposes of determining the PPS Partner's eligibility for Medicaid-funded incentive payments; and (2) must limit the information disclosed to that information necessary and required in light of the reason for disclosure.

d. SUD treatment programs governed by 42 CFR Part 2 must obtain patient consent to disclose information to PPS Lead Organizations, and PPS Lead Organizations may not re-disclose such information without patient consent if no Qualified Service Organization agreement (QSOA) exists. 42 CFR Part 2 allows disclosure by a federally-funded SUD treatment facility for audits and evaluations on behalf of a third party payer without a 42 CFR Part 2 consent. 42 CFR §2.11(Third party payer), 42 CFR §2.53(b)(2)(ii). Unlike HIPAA, which generally permits the disclosure of PHI without patient consent or authorization for the purposes of treatment, payment, or health care operations, Part 2, with limited exceptions (e.g., audits and evaluations), requires patient consent for such disclosures. 42 CFR §§2.3, 2.12, 2.13, 2.31(a)(4)(iii)(A). Consent must include the name of the individual or entity to which disclosure is to be made; or, a general designation of individuals or entities who are participants in one of the health information organizations (known as "qualified entities") that are part of New York's Statewide Health Information for New York (SHIN-NY) and have a treating provider relationship with the patient. See 42 CFR §2.31(a)(4)(iii)(B).

Some types of exchange, however, may take place without patient consent when a QSOA exists. A Qualified Service Organization (QSO) means an individual or



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entity that provides services to a Part 2 program. Where a Part 2 program has entered into a QSOA with an entity, patient consent is not required. 42 CFR §§2.11(Qualified service organization), 2.12(c)(4).

The PPS Lead Organization has an agreement with its PPS Partners that sets out how DSRIP payments will be distributed to the PPS Partners. In the case of a PPS Partner that is a Part 2 health care provider, one possibility is that the PPS Lead Organization is both the HIPAA Business Associate and the Part 2 QSO of the PPS Partner. As a Business Associate and QSO, the PPS Lead Organization is, on behalf of the PPS Partner, receiving and using patient information to fulfill the requirements of the DSRIP program so that the Part 2 PPS Partner will be able to receive the DSRIP incentive payments. See 82 Fed. Reg. 6052-6127 (January 18, 2017).

2. Disclosure of claims data by health plans, including managed care organizations:

- a. HIPAA allows disclosure by health plans for "payment" without a HIPAA authorization. 45 CFR §164.502(a)(1)(ii). This would include disclosures by the Medicaid program and MCOs for DSRIP, a program that results in payment from the Medicaid program to PPS Partners. See 45 CFR §164.501(Payment).
- b. The Medicaid program is a health plan under HIPAA. Medicaid law allows disclosure by the Medicaid program for purposes directly connected with administration of the State Plan for Medicaid (including waiver amendments). 42 USC §1396a(a)(7), 42 CFR Part 431, Subpart F.
- c. PHL §4410 and Insurance Regulation 169 allows health plans, including PHL Article 44 managed care organizations qua health plans, to disclose claims data as permitted by HIPAA. 11 NYCRR §§420.3(p) and 420.17(b). HIPAA permits a health plan to disclose PHI to another HIPAA-covered entity (or the Business Associate of a covered entity) for the recipient's health care operations if both covered entities have or had a relationship with the subject of the records to be disclosed, the records pertain to that relationship, and the recipient uses the records for purposes of evaluating a provider's or supplier's performance, conducting quality assessment and improvement activities and conducting population-based activities relating to improved health. See 45 CFR §164.506(c)(4). This would apply where the PPS Lead Organizations are receiving PHI as a covered entity or as a Business Associate of their PPS Partners. Compare 76 Fed Reg 19556-19560 (discussing disclosures for health care operations under Medicare shared savings accountable care organization ("ACO") program.
- d. PHL Article 27-F does not restrict disclosures by health plans. PHL §2784. PHL Article 27-F does, however, regulate re-disclosure of confidential HIV-related information disclosed to a health plan by a health care provider. PHL §2782(5).
- e. Health plans are permitted to re-disclose identifiable information received from facilities governed by MHL § 33.13, including claims data, for payment purposes pursuant to MHL §33.13(c)(9)(i) or care coordination purposes pursuant to MHL §33.13(d). MHL Article 33



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also regulates the re-disclosure of MHL clinical records by a PPS Lead Organization. MHL §33.13(f).

f. 42 CFR Part 2 does not directly apply to disclosures by health plans, because health plans are not Part 2 programs. 42 CFR §2.11(Program). 42 CFR Part 2 does, however, regulate re-disclosure of SUD treatment information disclosed to a health plan by a Part 2 program. 42 CFR §2.32.

3. Requirement for health care providers to make patients aware of disclosures to third parties:

- a. The basic ethical rule of provider-patient confidentiality, as codified in Education Law §6530(23) and 8 NYCRR §29.1(b)(8), requires some form of consent to reveal personally identifiable information to a third party. At a minimum, the patient must have knowledge that the patient's chosen health care provider is making the disclosure.
- b. PHL §18(6) requires health care providers to make a notation of disclosures of patient information to third persons in the patient's clinical record. Likewise, facilities under the jurisdiction of the Office of Mental Health must also make a notation of disclosures in a patient's clinical record, with the exception of disclosures made to the Mental Hygiene Legal Service, disclosures made for compliance reviews, or disclosures made for payment purposes. Patients must be informed of all such disclosures on request. (See Mental Hygiene Law §33.13(f)).
- c. HIPAA requires the Notice of Privacy Practices of a health care provider or health plan to give examples of disclosures for treatment, payment and health care operations. 45 CFR §164.520(b)(1)(ii)(A). Mere receipt of a Notice of Privacy Practices, however, does not constitute consent to the provisions in the Notice of Privacy Practices.
- d. Under 42 CFR Part 2, patients who have consented to disclose their patient identifying information using a general designation pursuant to §2.31(a)(4)(iii)(B) must be provided a list of entities to which their information has been disclosed.

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