NASTAD

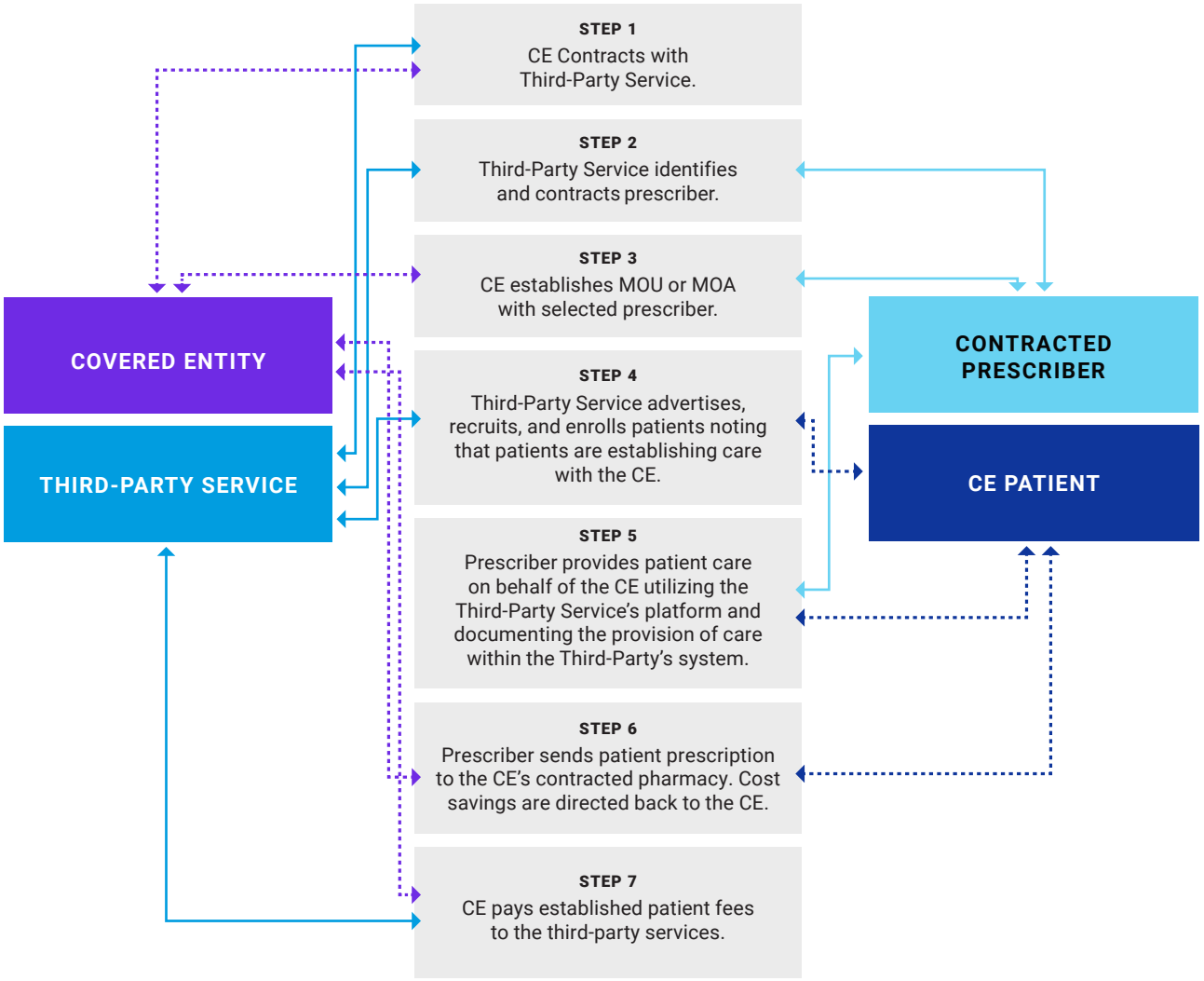
Partnering with a Third-Party TelePrEP Program:

Patient Record Retention Compliance Strategies

Introduction and Background:

Organizations registered as covered entities (CE) under the HRSA 340B Drug Pricing Program are partnering (or considering partnering) with third-party telePrEP services in an effort to extend pre-exposure prophylaxis (PrEP) care for HIV prevention to more individuals within their service areas. These third-party programs typically identify and contract with licensed prescribers within the jurisdictions they are operating, and facilitate memorandums of agreement or understanding (MOAs or MOUs) between the prescriber and the CE whereby the prescriber agrees to provide specific services on behalf of the CE.

The third-party service providers, who generally facilitate these arrangements and maintain responsibility for overseeing the activities of the prescribers, provide client recruitment/marketing services, conduct client enrollments, provide access to the telehealth platform being utilized to provide patient services, and maintain patient records with access granted to the originating CE. In return for this set of services, the CE agrees to pay a per patient fee to the service provider to cover the costs of the services. The ability of CEs to cover these costs relies on patient medication cost savings derived from the 340B Drug Pricing Program. This process is outlined in the graph below.



“The burden of compliance for our organization was not clear when we entered into our agreement (with a third-party provider). While it may have been included in our contract language, we did not fully understand our compliance responsibilities as it related to 340B. The actual storage of the requirement documentation was not explicitly stated.”

Problem Statement:

CEs participating in third-party telePrEP service agreements are obligated to ensure compliance with all standards and requirements of the 340B Drug Pricing Program consistent with their registration as a CE. This obligation includes ensuring patients who are provided medications through the 340B Drug Pricing Program meet the definition of a CE patient.

HRSA DEFINITION OF COVERED ENTITY PATIENT[1]

1. The CE has established a relationship with an individual, such that the CE maintains records of the individual’s health care,
2. The individual receives health care services from a health care professional who is either employed by or provides care under a contractual or other arrangement such that responsibility for care remains with the CE, and
3. For CEs who qualify for 340B eligibility, through the receipt of a federal grant, the individual receives health care from the CE which is consistent with the scope of services of its grant funding.

Based on the third-party service provider model outlined above, CEs would appear to be in compliance with 340B Drug Pricing Program standards for points two and three of the patient definition. **However, in situations where patient records are primarily maintained in external databases, not managed or regulated by the CE directly, CEs may be vulnerable to non-compliance with requirement one**.

There are multiple reasons why a patient record could fail to meet program requirements when maintained solely by an external partner, including:

- Archiving of patient records when discontinuing from the program, and/or
- Archiving of patient records when lost to follow up.

Loss of records, which causes concerns for 340B program compliance, also poses a threat to continuity of care which would prevent the CE’s ability to provide reengagement, adherence, or persistence support to patients who may benefit from additional intervention.

It is ultimately the obligation of the CE, and not the third-party service provider, to ensure compliance with 340B Drug Pricing Program requirements. As such, CEs who are engaged in these types of arrangements should take action related to patient record retention to ensure they are compliant with program standards.

[1] https://www.govinfo.gov/content/pkg/FR-1996-10-24/pdf/FR-1996-10-24.pdf#page=85

Recommended Actions

Disclosures to Clients/Patients:

CEs should work with third-party telePrEP programs to ensure that individuals registering to become patients are informed of how their data will be collected and shared. These disclosures should plainly state that the patient is registering as a patient of the CE and receiving services from the third-party telePrEP program on behalf of the CE. The patient should also be provided contact information for the CE and directed to that contact should they have questions or concerns related to the services provided or the handling of their medical record data.

Patient Record Retention, Storage, and Forwarding:

CEs should negotiate contract terms with third-party telePrEP programs to ensure that patient records are appropriately handled and routinely forwarded to the CE and/or exported into the CE's medical record system. Contract terms should explicitly clarify each party's responsibility for data collection and documentation practices as well as define policies for the storage, retention, and sharing of patient records.

When negotiating auto-forwarding requirements for patient records, CEs should establish defined intervals for uploads of client records to the CE record keeping system. Greater frequency of these intervals (e.g., weekly) will minimize the risk of record loss, though it is not recommended that interval frequency be greater than monthly.

In cases where auto-forwarding of records is not possible, CEs should explore options to routinely extract patient records from the third-party telePrEP program's system and store extracted records in the CE's medical record system. This may be done by working with developers who can write code to automate record extraction or may be done manually by CE staff in instances where patient volume is not prohibitive.

When auto-forwarding or manually extracting client records for storage and retention, CEs should adhere to agency-established file security, storage, and retention policies. In the absence of established policies (for those who do not have electronic medical record systems), CEs should discuss best practices and program requirements with funders and/or other local regulators who oversee grant and program compliance.

Regardless of the method used to receive patient records CEs should ensure that complete patient records are documented within their systems, including all of the following variables related to the provision of care:

- Patient Name,
- Patient Address,
- Patient Phone Number,
- Patient Date of Birth,
- Visit Date(s),
- Test Records and Results,
- Treatment Records;
- Prescription Records, and
- Provider Notes.

System Interoperability:

For CEs that utilize electronic medical records (EMR) systems, it may be beneficial to ensure that the CE and the contracted third-party telePrEP program(s) are compliant with current EMR best practices and standards, Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) to ensure interoperability across EMR systems. CEs can also consult The Trusted Exchange Framework and Common Agreement (TEFCA℠) guidelines developed by the Office of the National Coordinator for Health IT.

Image credit: Building Healthy Online Communities

> *"Our third-party telePrEP program does not provide follow up with reactive tests or provide supports related to medication adherence, persistence, discontinuation, or enrolled patients otherwise falling out of care. Our navigators do not have direct access to the contracted providers and instead must route inquiries through the third-party program's support platform."*

Patient Retention and Persistence Support Strategies:

In addition to ensuring compliance as a CE, timely and accurate data forwarding can play a vital role in supporting patient retention and persistence strategies.

Third-party telePrEP programs generally operate to prescribe and manage oral PrEP therapies exclusively, and do not typically provide comprehensive care or support for associated conditions. This reality leaves the CE responsible for providing follow-up care, arranging timely and appropriate treatment for identified sexually transmitted infections, coordinating care for those found to be living with hepatitis B, as well as providing ancillary supports related to PrEP retention and persistence. **Timely receipt and review of patient records originating from third-party service providers addresses more than compliance by allowing CEs to provide timely and responsive care to patients who are enrolled in these services through their organizations**. For these reasons, CEs that plan to engage with these services should consider strategies for integrating record reviews into existing navigation and patient support workflows.