

Partnering with a Third-Party TelePrEP Program: Protective Contracting Best Practices: Operational Considerations

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Introduction

As the demand for telePrEP services escalates, driven by the accessibility benefits of virtual HIV prevention services and opportunities to leverage the 340B Drug Pricing Program, healthcare organizations find themselves navigating a complex vendor landscape. This resource delves into protective contracting—a critical strategy to safeguard interests and ensure sustainable program operations.

TelePrEP vendors generally provide a virtual care delivery platform that enables organizations to leverage the power of telehealth to engage a wider audience in PrEP care, in a more accessible manner. Beyond the scope of virtual care, however, is a variety of service considerations that can dramatically impact the overall expected performance of a 340B PrEP program, such as insourcing versus outsourcing, vendor selection, data management, etc. This resource identifies both operational and legal considerations for organizations to utilize when contracting with external telePrEP providers. Information shared in this document are examples of items to look out for when engaging in contractual relationships with third-party telePrEP providers, and includes an introduction to contracting, language to flag, and recommendations for addressing challenges.

The goal of this resource is to raise awareness of these contracting considerations while also working to help prevent unfair contracts between third-party telePrEP providers and organizations looking to expand PrEP access through these platforms.

Disclaimer: The information in this paper is for information purposes only and should not be considered client operational, finance, or legal advice. Any information specific to your program should be consulted with your own program experts and/or health department resources.

Contractual Framework and Negotiation Tactics

Protective Contracting Importance

Organizations registered, or considering registration, as 340B covered entities (CE) are partnering (or considering partnering) with third-party telePrEP services in an effort to extend PrEP service delivery 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 contracts 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.

The rapid growth in telePrEP services has introduced risks related to unfair contracts that may include restrictive services, unrecognized fees, and unfavorable terms. Organizations entering into a relationship with a third-party program providing telePrEP services must therefore prioritize protective contracting to prevent these pitfalls and maintain mutually beneficial relationships with third-party providers.

Master Services Agreement (MSA)

A cornerstone of effective contracting, the MSA covers crucial aspects such as roles, responsibilities, privacy, fees, and termination terms. Clear definitions and responsibilities outlined in the MSA ensure all parties have aligned expectations and obligations, minimizing potential disputes. A breakdown of MSA sections is below.

MSA Sections

Section	Definition
Definitions and Interpretations	This section clarifies the terminology used throughout the agreement to ensure mutual understanding and prevent ambiguities.
Scope of Service	Details the specific services that the pharmacy will provide, including but not limited to the dispensing of PrEP medications, patient counseling, adherence support, and any telehealth services involved.
Roles and Responsibilities	Outlines the obligations of each party, ensuring that each knows their duties regarding service delivery, patient care, and other operational tasks.
Compliance and Regulatory Adherence	Stipulates the requirement for compliance with healthcare regulations, including pharmacy practice standards, patient privacy laws (e.g., HIPAA in the U.S.), and 340B program requirements.
Payment Terms	Specifies the compensation structure, including payment schedules, invoicing procedures, and details regarding any performance-based payments or reimbursements.
Data Management and Privacy	Details the protocols for handling patient data, ensuring privacy and security in compliance with applicable laws, and outlines the rights and responsibilities related to data ownership and transfer.
Performance Standards	Defines the quality and performance metrics that the service provider must meet, and may include service level agreements (SLAs) to ensure high-quality patient care.

Term and Termination	Establishes the duration of the agreement and the conditions under which either party may terminate the agreement, including notice periods and obligations upon termination.
Dispute Resolution	Outlines the methods for addressing any disagreements or disputes between the parties, which may include mediation or arbitration procedures before resorting to litigation.
Confidentiality	Protects sensitive information shared between parties during the course of the agreement's execution from being disclosed to unauthorized third parties.
Liabilities and Indemnities	Clarifies the liabilities of each party and includes indemnity provisions to protect against losses due to breaches of the agreement or negligence.
Amendments and Notices	Specifies how changes to the agreement should be made and the manner in which formal communications related to the agreement should be sent.

Setting Contract Expectations

Establishing clear and measurable contract expectations is paramount. Organizations should define performance metrics, operational responsibilities, and regular communication protocols. Such clarity not only fosters accountability but also enhances the partnership's overall efficacy and longevity.

Operational Best Practices and Team Roles

Operations Role in Contracting

Operational teams, particularly those involving care navigators, are instrumental in managing day-to-day contract adherence and service level agreements. Their hands-on experience ensures that the operational realities align with contractual stipulations. To optimize the contracting process, organizations should engage in practices like establishing minimum bids and leveraging local testimonials. Inter-departmental collaboration ensures that contractual terms meet the comprehensive needs of diverse organizational facets, from pharmacy services to clinical operations.

Operational Team Roles

Team Member	Operational Significance
Pharmacy	The Pharmacy department ensures that contract terms support the seamless integration of pharmacy services and adherence to medication management protocols, which are critical for the effectiveness of PrEP treatments.
Clinical Services	Clinical Services reviews the contracts to verify that the clinical aspects of PrEP delivery, including patient care standards and provider qualifications, align with healthcare regulations and best practices.
Patient Navigation	This department assesses how the contract addresses the support and resources available to patients, ensuring that navigation services effectively facilitate access to PrEP and continuity of care.
Compliance	Compliance is crucial in reviewing contracts to ensure that all stipulations adhere to health care regulations, including those specific to the 340B program, protecting the organization against legal and financial penalties.

Finance	The Finance department evaluates the financial implications of the contract, including cost-effectiveness and budget alignment, ensuring that the terms do not impose undue financial strain on the organization.
Executive Leadership	Executive Leadership takes part in reviewing contracts to align the strategic vision and broader organizational goals with the services provided by the telePrEP provider, ensuring long-term sustainability and effectiveness.

Legal Considerations and Compliance

No Regulatory Caps or Protections

In the absence of predefined regulatory standards in the 340B telePrEP space, organizations must diligently craft contracts that preemptively address potential issues and compliance pitfalls. Engaging with experienced legal teams ensures that contracts are not only fair but also tailored to the specific regulatory landscape.

The Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs, which oversees the 340B program, has no predefined regulatory considerations in relation to fees to contractors or standards in scopes of services.¹ This means there are no minimum requirements or standardized credentialing systems that can ensure the quality of care specific to 340B telePrEP delivery. It is important that 340B covered entity providers use all resources available to help prevent and flag instances before they take effect.

Collaboration with Legal Teams

Legal expertise is crucial in navigating the complex contractual landscape of telePrEP services. Legal professionals ensure that agreements are enforceable, reflective of all parties' interests, and compliant with applicable laws and regulations.

The intersection between operational and legal expertise is most critical during the contract development phase. The most important consideration for an operations team member is to know when to raise issues with legal. Below are a few scenarios where direct legal guidance could be considered. It's important to note that each lawyer is different in scope and expertise and not all lawyers may be contract experts.

Scenarios

Example		Description
Extended Terms/Evergreen Clause	Terms and Termination	<i>This language is intended to lock the organization into multi-year terms with an auto-renewal trigger to the agreement in perpetuity.</i>
Monthly Minimum Fee	Fees and Payments	<i>This language is intended to allow the provider to impose a minimum fee if certain terms are not met.</i>
Marketing as a Service	Vendor Responsibilities	<i>This language is intended to provide additional fees associated with the marketing and outreach to initiate the launch of the telePrEP program.</i>

¹ <https://www.klgates.com/340b-update-hrsa-indicates-it-lacks-authority-to-enforce-340b-program-guidance-7-21-2020>

Exclusivity Language	General Provisions	<i>This language is intended to prevent the organization from working with other partners to expand outside the existing relationship.</i>
Hidden Fees	Fees and Payments	<i>This language is intended to implement additional "pass-through" or service fees that fall outside the scope of the normal service offered.</i>
Early Termination Fees	Fees and Payments	<i>This language is intended to implement a fee to be assessed if the organization terminates the agreement prior to the end of the term.</i>
Patient Cancellation Fee	Patient Responsibilities	<i>This language is intended to provide additional fees directly to the patient if a service is returned, not completed, or discontinued.</i>

In many cases, the PrEP program may not have access to legal resources for daily questions, therefore it is important to know what questions to ask when meeting with the legal team. It is highly recommended to meet with the legal team prior to signing the contract.

Strategic Planning and Program Development

Flexibility to Develop an Internal TelePrEP Program

Contracts with third-party telePrEP programs should allow for flexibility, enabling organizations to adapt and evolve their internal processes as program needs change. This adaptability is crucial for long-term sustainability and effectiveness in delivering telePrEP services.

Developing an internal telePrEP program not only enhances control over service quality and patient care but also provides significant financial and compliance benefits. Financially, retaining services in-house can reduce costs associated with third-party fees and allow for more direct allocation of funds according to changing program needs, increasing overall cost-efficiency. From a compliance perspective, managing a telePrEP program internally ensures that all aspects of the program strictly adhere to 340B program requirements and other regulatory standards. This internal oversight minimizes the risk of compliance breaches that could result from misunderstandings or misalignments with external providers, thus safeguarding the organization against potential fines and enhancing its reputation for stringent compliance and patient care standards.

Ease of Termination and Offboarding

Smooth transitions in the event of contract termination are essential to maintaining patient service continuity and operational integrity. Contracts should clearly outline processes for offboarding and transferring patient documentation and care responsibilities.

Allowing health departments the ease of terminating contracts through clear language is crucial to ensuring they can swiftly adapt to emerging needs or address service deficiencies. Contracts should ideally include clauses that specify acceptable grounds for termination, such as non-compliance with service levels or regulatory requirements, along with detailed descriptions of the termination process. For instance, the contract might stipulate a notice

period that is reasonable yet sufficiently prompt (e.g., 30-60 days) to prevent prolonged service disruption. Additionally, it should outline the exact procedures for offboarding, including timelines for transferring patient records and other critical information, to maintain continuity of care. This flexibility not only empowers organizations to manage resources effectively but also reinforces their capacity to uphold high standards of patient care and compliance in a dynamic healthcare landscape.

Ownership of Patient² Records

Ensuring that contracts clearly define the ownership, storage, and transfer of patient records is critical to 340B compliance and continuity of care. This clarity prevents disruptions and ensures that patient care is not compromised during transitions or terminations. In the event of a HRSA sectioned 340B audit, the covered entity must be able to access and demonstrate ownership of the patient records in order to validate 340B patient eligibility for the auditors.

Owning the storage of medical records within the health center is pivotal for maintaining rigorous compliance with health data regulations such as HIPAA in the U.S., and similar standards globally. By centralizing record storage, health centers can directly manage and secure patient data, reducing the risk of breaches and unauthorized access that could occur with third-party storage solutions. This direct control facilitates more robust data protection practices and enables health centers to promptly respond to compliance audits, data requests, and patient access rights under privacy laws. Ultimately, in-house record management supports the health center's accountability and strengthens trust with patients by ensuring their sensitive information is handled with the highest standards of care and security. An additional NASTAD resource on [patient record retention strategies can be accessed here](#).

Conclusion

NASTAD developed this "Protective Contracting" document to help healthcare organizations better understand the components of telePrEP provider agreements. Whether a program has already contracted with a third-party provider or are considering contracting with one, there is valuable information to help inform contracting processes or later contract changes. The below is a summary of steps identified as key items in the contracting process:

1. Review state regulatory policies to see if any requirements currently exist
2. Develop an internal contracting committee composed of team members across all the relevant program departments
3. Review the agreement and flag any information for follow up
4. Assign the operations team to review the Team Responsibilities and confirm that the team has the internal capability to complete responsibilities listed
5. Assign the compliance team to review the operational processes within the contract and confirm the compliance integrity of the contracting processes

² Due to the compliance nature of this document, PrEP users are referred to as "patients" throughout this resource.

6. Develop questions for legal or document the legal team's response to internal questions
7. Assign the Contract Committee the task of confirming the contract meets the minimum requirements described in this document
8. Assign the legal team a final review of the contract to ensure all the legal components are met
9. Complete the signature process by both parties

Protective contracting is not merely a defensive strategy—it is a proactive approach to fostering robust, transparent, and equitable relationships with third-party telePrEP providers. By integrating operational insights with legal acumen and strategic foresight, organizations can protect their financial and operational interests while expanding access to critical PrEP services.

It is essential to ensure that contracting is inter-departmental and involves input from both operations and legal departments. Additionally, to foster a competitive and robust process, multiple third-party telePrEP providers should be considered. Protecting your financial and operational interests through effective contracting also requires maintaining flexibility and autonomy as your 340B capabilities change and evolve. By working with legal professionals and other impacted departments, your 340B programs can create clear, enforceable contracts that reflect their unique needs and objectives. Investing in effective protective contracting processes can help prevent disputes, missed opportunities, and even litigation down the line, ultimately leading to greater success for your 340B program.