Legal and Regulatory Assessment of Private Sector Provision of HIV Services in Cambodia

HP+ POLICY *Brief*

January 2020

Background

Cambodia is successfully controlling and managing its HIV epidemic through active case-finding strategies, increasing coverage of antiretroviral therapy (ART), and achieving a high rate of viral load suppression. It is globally recognized as one of the few countries to reach UNAIDS' "90-90-90" targets, achieved through strong commitment and implementation by the Royal Government of Cambodia, development partners, and civil society organizations. Between 2010 and 2018, ART coverage for all ages increased from 54 to 81 percent (UNAIDS, 2018).

While these achievements are attributable to the public sector, Cambodia's private sector remains a significant provider of healthcare services, serving as the first point of contact with the health system for most Cambodians—constituting 67–78 percent in urban areas and 65 percent in rural areas (WHO, 2015). According to the 2014 Cambodian Demographic and Health Survey, only 21.9 percent of ill or injured patients initially sought care in the public sector, while 67.1 percent sought care in the private sector; the latter includes both medically trained professionals and traditional healers (National Institute of Statistics et al., 2015). In regard to HIV service delivery, there are private ART clinics that provide comprehensive HIV services to those who choose to pay for HIV care through the private sector. In turn, these private clinics refer patients to private laboratories and pharmacies for their diagnostic and drug needs.

There is a need to better understand the legal and regulatory landscape that governs the private sector's provision of HIV services in Cambodia. The current policy and regulatory environment is more oriented toward the public sector, leaving the private health sector insufficiently regulated despite a majority of the Cambodian population seeking health care from these facilities (HP+, 2019). To better understand the legal status of private sector providers within the larger context of healthcare provision in Cambodia, the National AIDS Authority, with support from the Health Policy Plus project, conducted a comprehensive legal and regulatory assessment. This work was funded by the U.S. President's Emergency Fund for AIDS Relief's Sustainable Financing Initiative for HIV/AIDS at the U.S. Agency for International Development. This assessment focuses on private providers that deliver HIV services, with an objective of clarifying the legal and regulatory framework that governs their provision of HIV services. The assessment builds on a prior broader legal and regulatory assessment of private healthcare provision in Cambodia that focused on private providers' perceptions of licensing and accreditation processes and requirements.

Methods

This assessment was conducted through a document review, key informant interviews, and a consultative workshop. The document review focused on relevant laws, regulations, and policy documents related to HIV and the private sector. Informants who participated in the interviews included judges, members of the Council of Jurists at the Office of the Council of Ministers, and lawyers in the national bar association; officials from the Ministry of Health, the National AIDS Authority, the National Center for HIV/AIDS, Dermatology, and STDs (NCHADS), and the Institut Pasteur du

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Cambodge; and development partners, nongovernmental organizations, a private ART clinic, and a private insurance company. Interviews were followed by a consultative workshop wherein partner agencies, donors, and provider organizations convened to discuss next steps to better engage the private sector in HIV service provision in Cambodia.

Key Findings

Provision of HIV services by private providers is not restricted but also not specified in current laws ("Royal Kram") and ministerial regulations ("Prakas").

Strategic plans, standard operational procedures, and HIV guidelines in Cambodia focus on public sector provision and implementation. The only HIV-specific law is Royal Kram 0702, a royal code known as the Law on Prevention and Control of HIV/AIDS, released almost 18 years ago in July 2002. The objective of the law is to put forth measures for the prevention and control of the spread of HIV in Cambodia. It contains provisions related to education and information dissemination, safe practices and procedures, testing and counseling, health and support services, monitoring, confidentiality, discrimination acts and polices, penalties, and the establishment of the National AIDS Authority. According to the law, "the State shall ensure that all persons with HIV/AIDS shall receive primary healthcare services for free of charge from public health networks and **encourage participation from the private sector**" (Article 26, page 6). Therefore, while the private sector is not restricted from participating in the provision of HIV services, the law does not specify the types of private providers that can provide services, which services can be provided, nor how these services align with specific guidelines and regulations. The law also does not specify provider eligibility criteria, required personnel qualifications, or a mechanism of reporting to the national HIV surveillance system. Clear guidance is needed for the private health sector to provide comprehensive HIV services that are appropriately managed and adhere to regulations.

Several general laws and regulations (i.e., non-HIV specific) pertain to management and licensure of general health services and practitioners in Cambodia, including private providers that operate in the health sector (Table 1). These provide overarching guidance on the legal and regulatory landscape governing the provision of HIV services by private providers but do not specify requirements regarding HIV service provision. The existing regulations do not detail which private sector actors can deliver HIV services, how they should do so, what standards they are required to meet, or how they will be held accountable for compliance with relevant guidelines and reporting standards.

Table 1. Relevant Laws Regulating Private Sector Healthcare Providers and Services

Category	Relevant Law	Requirement for Private Sector Service Providers
HIV-specific	Law on The Prevention and Control of HIV/AIDS (Kingdom of Cambodia, NS/RKM/0702/015, July 26, 2002)	For all persons living with HIV, the state must encourage participation from the private sector in primary healthcare service delivery. Healthcare providers in the private sector have a duty to educate and disseminate information on HIV/AIDS. Denial of private healthcare service based on a person's perceived or suspected HIV/AIDS status is prohibited.

Category	Relevant Law	Requirement for Private Sector Service Providers
General licensing	On the Modification of Procedures and Technical Conditions of the Request to Open or Close, Transform, or Relocate Private Medical, Paramedical, and Medical Aide Services (Ministry of Health, Prakas 034 ABS/AP, July 4, 2011)	Specifies who is eligible to operate a private health facility, licensing application processes, and guidelines for opening, closing, renewing, or transferring ownership of a private health facility. Includes nine defined categories of private providers (medical, dental, and prenatal consultation, kinesitherapy, ophthalmology, aesthetic surgery, medical laboratory, obstetrics and gynecology, and clinic or policlinic) that must be managed by health professionals and authorized by the Ministry of Health to operate. Licensed services must report patient treatment to the ministry on a quarterly basis. Failure to comply with reporting requirements permits the ministry to refuse renewal of the private provider's license to deliver those services.
General licensing	Inter-Ministerial Prakas on Agreement on Health Service Consumption and Provision for Health Care between the National Social Security Fund and Health Facility (Ministry of Health and Ministry of Labour and Vocational Training, Prakas No. 291 LV/PrK, 2016)	Private health facilities participating in the National Social Security Fund provider contract network must be licensed by the Ministry of Health.
General licensing	Law on Regulation of Health Practitioners (Kingdom of Cambodia, NS/RKM/1116/014, November 19, 2016)	Health professionals, including pharmacists, must register with their respective health profession councils, obtain licenses, comply with professional codes of conduct and standards/norms, and adhere to scopes of practice.
Pharmaceuticals	Law on Compulsory Licensing for Public Health (Kingdom of Cambodia, CS/RKM/0418/006, April 27, 2018)	Applicant entities—public and private as well as local, international, and foreign nongovernmental organizations recognized by the Ministry of Health—are permitted to produce, import, export, and/or distribute pharmaceuticals.
General management	Royal Kram on Health Care Services Management (forthcoming)	Details are forthcoming. The law is designed to ensure and promote the quality of health services provided by both public and private health facilities.

There are varying degrees of compliance with requirements and standards among private health facilities and laboratories.

Currently, a diverse set of private health facilities and laboratories provide HIV services, with varying degrees of compliance with training requirements, clinical guidelines, and reporting standards. Twenty-seven private providers of HIV services in Cambodia participated in a 2018 assessment conducted by FHI 360's LINKAGES project (LINKAGES, 2018). Of these, 18 facilities were able to provide complete information on the range of HIV services offered, including ART, treatment and adherence counseling, post-exposure prophylaxis, and pre-exposure prophylaxis. The assessment found that private practitioners sent patients' blood samples to private laboratories for HIV testing. Additional HIV services provided by private laboratories included confirmation testing, counseling, viral load testing, and CD4 testing.

All 18 facilities claimed to follow opportunistic infection and ART clinical management guidelines. Two of the facilities reported that their private practitioners did not receive the required training on opportunistic infections or ART clinical management from NCHADS. In addition, several staff from private laboratories claimed that they had not received the required training from NCHADS. The assessment also found that none of the private providers reported their HIV patients to NCHADS—private practitioners were generally reluctant to report on their patients and claimed that they were never requested by NCHADS to do so.

The Ministry of Health has a mandate to oversee private provider licensing and renewal.

This mandate presents an opportunity to the Ministry of Health to clarify existing, or develop new, licensure standards to govern private sector provision of HIV services. According to the Law on the Establishment of the Ministry of Health (Kingdom of Cambodia, NS/RK/0196/06, January 24, 1996), the Cambodian Ministry of Health has a mandate to (a) determine health policies based on government programs aimed at promoting the health and well-being of Cambodian citizens, (b) develop strategies for the health sector, (c) develop laws and regulations to ensure the maximum quality of public and private health services, (d) manage the production and distribution of drugs and medical and paramedical equipment to all public and private units, and (e) monitor compliance and evaluate the technical and administrative performance of health units. Most regulations that would be relevant to clarifying the eligibility criteria and guidelines for private sector provision of HIV services are ministerial regulations related to private provider and practitioner licensure. Therefore, it is well within the Ministry of Health's scope to clarify the requirements for private sector providers to deliver HIV services, including licensing standards and compliance enforcement mechanisms within licensing laws and procedures. In addition, the ministry could leverage its mandate to manage supply chain and medical equipment across public and private providers to incentivize compliance with standards and reporting requirements.

Private sector providers require clear guidance to deliver comprehensive HIV services that are appropriately managed and adhere to regulations, guidelines, and reporting requirements.

Legal experts, government officials, development partners, and provider associations agree that private sector providers should provide comprehensive HIV services to complement public sector provision and expand choice and access for patients, as long as they are managed

by qualified health professionals who are properly trained and licensed, and who comply with relevant regulations, guidelines, and reporting requirements. Although key informants had different views on what constituted "primary healthcare services" for HIV, they agreed that any HIV service available in public health facilities should also be permitted to be delivered by private health providers. Informants concurred that private sector providers, whether for-profit or non-profit, must be licensed by the Ministry of Health and receive proper training from NCHADS to ensure appropriate provision of quality HIV services. Key informants also agreed that compliance with (a) the Law on Prevention and Control of HIV/AIDS, (b) operational and clinical guidelines from NCHADS and the Ministry of Health, (c) reporting requirements to NCHADS, the National AIDS Authority, and the Ministry of Health, (d) broader laws and regulations for the health sector, and (e) codes of conduct for health professions should be firm requirements for private sector provision of HIV services.

Public-private partnerships could reduce out-of-pocket costs and expand access.

For-profit private sector providers typically require uninsured patients to pay out of pocket for services. However, if a patient has private or National Social Security Fund-administered health insurance, private providers can obtain reimbursements from those schemes. The Health Equity Fund, which covers the lowest social-economic quintile, only contracts with public sector facilities, so beneficiaries would typically pay out of pocket to access care through private providers. To promote more equitable access to HIV services through private providers, key informants suggested the development of public-private partnerships with for-profit private facilities. In this scenario, patients would pay for medical consultation services out of pocket but receive free antiretroviral medication procured by the public sector. Incentives, including professional development, tax exemption, and national recognition could be used to encourage private provider participation in HIV service provision. These public-private partnerships could have varying degrees of formality, ranging from simple agreements to more complex arrangements.

There is a critical gap in understanding the full extent of the HIV response due to a lack of reporting from private providers to NCHADS.

The lack of routine reporting on HIV service provision from private providers to NCHADS results in a critical gap in understanding of the HIV response, and requires a mix of education, efficiency, and enforcement to promote compliance. Addressing private providers' concerns about patient confidentiality through sensitization on the confidentiality protocols in place will help to ensure compliance with the requirement to report to NCHADS' databases. Ensuring that the reporting process is streamlined and efficient, and sharing with providers how data is utilized, will promote timely, accurate, and complete reporting practices.

Policy Recommendations

1. ***The Ministry of Health should amend existing, or develop new, guidelines to explicitly regulate HIV service provision in the private sector.*** These revised or new regulations should include clear definitions of what types of private providers can deliver HIV services, and requirements for (a) licensing and renewal for private HIV service providers, (b) training, qualifications, and licensing of personnel delivering HIV services, (c) guidelines, protocols, and regimens for the treatment and management of HIV patients, and (d) reporting to the national HIV databases managed by NCHADS.

2. ***NCHADS should align policy and regulation development and review processes across public and private providers of HIV services. Aligning these processes ensures that guidelines and standard operating procedures are consistent regardless of which type of provider is delivering HIV services***. Steps should be incorporated into the regulatory process so that the private sector is explicitly considered during the development of new and revised guidelines and procedures, and that new guidelines are effectively disseminated to the private sector. This may require distinct requirements for private providers to ensure that they are delivering HIV care that is aligned with national guidelines. NCHADS may also need to pay special attention to creating accreditation standards and processes that include proper training to ensure that private providers develop competency in testing, treating, managing, and reporting HIV patients who seek their services.

3. ***NCHADS should ensure that guidelines and standard operating procedures that govern private health providers' delivery of HIV services are enforced through a standardized process to periodically and comprehensively monitor compliance with policies and regulations.*** Current ambiguity within regulations and guidelines have allowed private providers to essentially self-govern the HIV services that they deliver. Once regulations are clarified and explicitly reference private provision, they will require consistent monitoring and enforcement to ensure adherence. Compliance should be promoted through well-disseminated, integrated policies, and a standardized process should be clearly communicated to providers.

4. ***The government should consider whether separate legislation is required to define reporting obligations and a clear mechanism for private providers to share public health data with the national HIV surveillance system.*** This law could define (a) the list of HIV services for which reporting is compulsory, regardless of provider type, (b) what HIV surveillance information to report, (c) the frequency and process of reporting required surveillance information to NCHADS, and (d) the obligations of all institutions and personnel involved in reporting to protect patient privacy and ensure confidentiality in the sharing and management of patient health information. The reporting process should be intuitive and streamlined with existing reporting requirements to minimize administrative burden on providers and improve the accuracy, timeliness, and completeness of reporting. Streamlining reporting from private providers would also require appropriate systems to be in place, along with training for staff to ensure quality reporting and ongoing supportive supervision. Reporting regulations should specify the sanctions associated with non-compliance. NCHADS should periodically verify providers' adherence to reporting requirements as part of the compliance monitoring described above.

Conclusion

Cambodia's success in managing its HIV epidemic and reaching "90-90-90" targets has occurred without consideration of the private sector's contribution to the HIV response. Current laws and regulations related to HIV service provision in Cambodia have not been well implemented and enforced with the private sector. In addition, it is unclear how private providers are expected to deliver HIV services and comply with relevant policies and regulations. Nevertheless, a wide range of private providers are providing HIV services in Cambodia, with varying degrees of compliance with general health sector regulations. This limitation of regulation and oversight may negatively impact the HIV response with private facilities potentially providing variable quality of HIV care, which may lead to

increased drug resistance, transmission, and ultimately morbidity and mortality.

Cambodia's government should prioritize policy and regulation development, implementation, and enforcement initiatives aligned with the four policy recommendations outlined in this brief. This will ensure that the private health sector's contribution to the HIV response is aligned with national policies and regulations and is captured and effectively overseen by NCHADS, ultimately leading to a more effective, expansive, and sustainable HIV response in Cambodia.

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Health Policy Plus (HP+) is a five-year cooperative agreement funded by the U.S. Agency for International Development under Agreement No. AID-OAA-A-15-00051, beginning August 28, 2015. The project's HIV activities are supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). HP+ is implemented by Palladium, in collaboration with Avenir Health, Futures Group Global Outreach, Plan International USA, Population Reference Bureau, RTI International, ThinkWell, and the White Ribbon Alliance for Safe Motherhood.