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POLICY BRIEF

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WHY POLICY MATTERS: Regulatory Barriers to Better Primary Care in Africa – Two Private Sector Examples

POLICY, REGULATION, AND PRIVATE HEALTH SECTOR

The private health sector plays a critical role in the provision of health care in sub-Saharan Africa. On average 49 percent of expenditures on health are private, primarily out-of-pocket expenses by individuals (World Health Organization Statistical Information Systems [WHO SIS] 2004). When it comes to specific reproductive health and family planning (RH/FP) services, Demographic and Health Surveys show that in many African countries a large number (over 40 percent) of current users are going to the private sector for their RH/FP needs.

It is not only the wealthy who use private health care in sub-Saharan Africa. Africans of all socioeconomic backgrounds turn to the private sector for their health care needs. Why do so many people go to the private health sector and pay out-of-pocket when free government services are available? There are a variety of reasons, including convenience, perceived quality, confidentiality, or because nothing else is accessible.

Meeting RH/FP and other health care needs in sub-Saharan Africa is an enormous challenge for ministries of health (MOHs) that are coping with limited public health budgets. The private health sector – which in sub-Saharan Africa includes traditional healers, pharmacies, and shopkeepers who sell health care products to non-profit, faith-based, and for-profit clinics and hospitals – is an untapped resource, bringing financing, infrastructure, capacity, and expertise to public health. Considering the limitations on African countries' public health budgets and the reality of out-of-pocket spending, it is time to engage the private sector in the struggle to provide quality health services.

Cumbersome or misdirected laws, regulations, and policies, however, can hamper the development of the private health sector, raising the cost of care, compromising quality, and limiting its accessibility. Policies that increase the cost, and therefore affect the feasibility, of establishing and maintaining a business include the qualifications for practice, the scope of practice, requirements to open a private practice, and the monitoring of services (Ravenholt et al. 2006). The challenge for the public sector, therefore, is to balance regulations aimed at quality control while simultaneously creating market conditions conducive to private sector participation in the delivery of RH/FP and other services.

> The sustainability of delivering RH/FP and other services in the private sector depends on their profitability. What the public sector sustains through tax revenues, the private sector must sustain through profits.

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PRIVATE SECTOR PARTNERSHIPS FOR BETTER HEALTH

In the following pages, this paper examines recent experiences in Zambia, and Ethiopia that illustrate why policy matters for developing the private health sector and underscoring the need for rational regulatory policies and practices. In Zambia, barriers exist to extending the availability of primary care through the private sector by nurses, midwives, and clinical officers. In Ethiopia, clinics run and funded by major employers have until recently been barred from disseminating antiretroviral (ARV) therapy.

ZAMBIA: WHY NURSES AND MIDWIVES DON'T DO WHAT THEY ARE TRAINED TO DO

Multiple factors threaten the fragile health system in Zambia. The MOH is experiencing shortages in health professionals, particularly among doctors (there are only 12 doctors[1] and 156 nurses per 100,000 people) (WHO SIS 2004). This scarcity is exacerbated by the migration of many qualified health professionals to other countries. High rates of AIDS-related mortality in nurses and clinical officers further undermine the health workforce.[2]

A health worker speaks to women about family planning in a clinic waiting room in Zambia

The government of Zambia (GOZ) is considering innovative strategies to address the crisis in human resources for health, including stimulating the private health sector to take a greater role in the provision of primary health care services, but current regulations and legislation hamper the GOZ's ability to grow the private health sector.

The Problem

Under existing laws and regulations, the scope of practice for public sector nurses, midwives and clinical officers has been liberalized. Their enhanced scope of work reflects their central role in public health facilities where they provide most of the primary care due to the shortage of physicians. While these health cadres operate with substantial independence in public clinics, the higher requirements for the private sector discourage them from opening their own practices in the private sector, which could improve access to health and stem the brain drain.

- **Medical Council Guidelines**. All private clinics and consulting rooms require a license from the Medical Council of Zambia; to get a license, a registered physician must directly supervise these facilities. As nurses, midwives, and clinical officers are also subject to the Medical Council guidelines, they are not allowed to own or run a clinic unless a physician supervises it. The dearth of physicians and additional costs of hiring a physician prevent these health professionals from opening or operating their own private primary care clinics.
- **General Nursing Guidelines**. The General Nursing Council of Zambia issued guidelines for nursing homes and nursing agencies but does not specify whether a nurse or midwife can operate an independent primary care clinic. Because the guidelines are silent about this issue, there are no nurse clinics licensed under these regulations.

[1] WHO recommends a minimum of 20 physicians per 100,000 people.

[2] A 2004 study showed annual mortality of 3.5 percent among nurses and 2.8 percent among clinical officers at University Hospital/Lusaka and two Zambian health districts (Feeley et al. 2004).

- **Pharmacy Guidelines.** Pharmacy regulations appear to bar pharmacists from filling prescriptions written by private sector nurses and clinical officers.[3] In public facilities, nurses and clinical officers are authorized to prescribe a set of essential primary care drugs that are then dispensed at the treating facility and/or private pharmacies. A licensed pharmacy, however, could not legally fill the same prescription by private sector nurses and clinical officers, creating an additional barrier to private practice.

Impact on Private Sector

The cumulative effect of these laws and regulations combined with more stringent standards for the private sector create enormous disincentives for many health care professionals to enter into private practice. This policy stance contrasts dramatically with other developing countries, such as Indonesia, Kenya, and Uganda, where nurses, midwives, and clinical officers legally run private practices (see text box).

Private Sector Nurse and Midwives

Many countries in Africa and Asia have liberalized their health norms to give private sector nurses and midwives the autonomy to establish private practices. Examples in Africa include Ethiopia, Namibia, Nigeria, and Uganda. In Indonesia, the government not only changed the health norms but also provided training and seed funds for nurses and midwives to establish private practices. This policy resulted in a dramatic increase in the private sector provision of RH/FP and other essential primary health care services by this cadre.

Reforms to Address the Barriers

In 2004 the MOH issued regulations that expanded the scope of practice for nurses, including the conditions they can treat and the drugs they can prescribe to treat these conditions (General Nursing Council of Zambia 2004). Moreover, in that year the Nursing Council revised the nursing regulatory system, permitting nurses to own and operate nursing homes, a category of facility that was recognized in the revised nursing law. Although the laws have been modified to address barriers to private practice, there has been limited ability of nurses to establish nursing homes, which would offer midwife-assisted deliveries. Nurses are unable to access the capital needed to establish a nursing home – a facility requiring more capital than clinics and consulting rooms – illustrating the fact that policy reforms, at times, are not sufficient to increase private sector growth.

The Private Sector Partnerships-*One* project helped the Medical Council draft a new health professions licensing bill (Berg et al. 2006). This process included representatives of different medical professions, the Nursing Council, teaching hospitals, dentists, pharmacies, and other health professionals. The law was delayed by the 2006 presidential election, but it should be introduced to Parliament in late 2007. If passed, the law would overcome many of the barriers to routine private practice by

- recognizing the right of a nurse or midwife to run a clinic within the scope of his/her practice without obtaining a Medical Council clinic license, thereby eliminating the need for physician supervision
- granting the new Health Professions Council the right to codify the scope of practice for each professional group it registers, including clinical officers, possibly paving the way for a special category of clinic or consulting room for clinical officers
- establishing authority to accredit specific services within licensed facilities; initially, this would be used to implement the planned certification[4] of highly active antiretroviral therapy (HAART) services

[3] Section 42.6 of the Pharmaceutical Act of 2004 defines an "authorized prescriber" as a medical practitioner, dental surgeon, or veterinary surgeon, but leaves open the opportunity for the minister of health to designate others as authorized prescribers on the advice of the Pharmaceutical Authority. Some informational materials, however, indicate that pharmacists cannot dispense prescription drugs on the authorization of a nurse or clinical officer (Government of the Republic of Zambia 2004).

[4] "Accreditation" is used and defined in the legislation to indicate the imposition of additional requirements for a particular specialized service within a licensed institution. Others may refer to this concept as "focused accreditation" or "service certification." The goal is to set higher and enforceable standards for certain critical services without imposing unnecessarily costly standards on the whole class of facilities.

- leveling the playing field by including a statement that both public and private facilities must obtain required licenses under the act

ETHIOPIA: WHY CAN'T COMPANY CLINICS TREAT THEIR EMPLOYEES WITH AIDS?

The health system in Ethiopia is beset with many of the same problems as those in Zambia. It is challenged by poverty, underfunding (per capita health spending is only $21; overall it is about 5.3 percent of the gross domestic product), vast geographical distances, poor infrastructure, and a shortage of health professionals – WHO reports only three physicians and 20 nurses per 100,000 Ethiopians (WHO SIS 2004). The number of AIDS-related patients further stresses the beleaguered health system. Possibly in response to the troubled public health system, many Ethiopians use their own resources to seek health care in the private sector. It is estimated that 48.5 percent of funding for health care is private – almost entirely out of pocket (WHO SIS 2004).

Because of its history of socialism under the Mengistu regime, the public health system in Ethiopia is even more dominant than in other African countries. There are a few private hospitals in the major cities, however, and the government now recognizes the right to private practice. According to the MOH, which runs the licensing system, there were 1,299 licensed private clinics in 2003 for an estimated population of 71 million people (WHO Health Action in Crises 2005).

Also as a result of Ethiopia's socialist past, the government still owns many of the large industries. These large employers traditionally have operated on-site clinics for their employees. The licensed clinics that larger employers run typically employ at least one physician and one or more nurses on staff.

The Problem

Employer-run clinics are an important source of HIV/AIDS services in Ethiopia. To address the growing AIDS epidemic, many large employers established a range of programs including AIDS education, HIV testing, and referrals for voluntary counseling and testing. In addition many company physicians and nurses treat common opportunistic infections caused by AIDS; some company clinics even have begun treating tuberculosis on site. Yet, prior to late 2005, the MOH did not authorize any company clinics to offer HAART on site, including those that held medium or higher clinic licenses.

There were multiple barriers to company clinics providing HAART. First, the national AIDS protocol, which governs AIDS care in public and private facilities, required more than one trained physician on staff, so someone is present at all times to cover ARV treatment services.

A second barrier was that free or subsidized government ARV drugs could not be distributed to private clinics: Initially a few large employers in Addis Ababa paid for HAART in private facilities. As HAART became available in the public sector, company clinics referred their employees to government AIDS clinics, because of the restrictions barring them from providing HAART and because the repeal of user fees in the public

A health worker counsels a female client at a Maternal Child Health Clinic in Chongwe, Zambia

sector removed their incentive to pay for their workers in the private sector (Van der Borght et al. 2006). As a result, the Ethiopian government and international donors cover the full cost of care.

Impact on the Private Sector

Employer-based clinics in the private sector are an underutilized resource for delivering HAART. In general the employee clinics that large companies operate appear to be some of the few health resources in Ethiopia with excess capacity. They have doctors and nurses on staff and report fewer daily visits than is typical for a public facility of similar size. These facilities could provide on-site treatment for AIDS, facilitating adherence and reducing missed work time, with no incremental cost to the public health system. The requirement for two trained doctors on staff, however, prevented company clinics from providing a full range of AIDS-related services including ARV therapy.

Reforms to Address Barriers

Until recently, the Ethiopian MOH's attitude toward the provision of ARV treatment in licensed private clinics was more restrictive that of other African governments. Ghana, Kenya, Uganda, Namibia and South Africa have all liberalized their policies in order to mobilize private sector resources, such as company-owned clinics, in the struggle to roll out ARV therapy to all those who need it (see text box).

Successful Employer Programs Providing HAART

Employer-run clinics can be an important source of quality care for AIDS. Since 2001 Heineken has been providing HAART for employees and dependents at its African breweries, reporting impressive results in testing and treatment. In South Africa, Anglo Gold and other large employers were treating their employees with ARV drugs before the government rolled out a public treatment program (Venter 2005).

The situation began to change in late 2005 when the Wonji Sugar Works received approval to provide HAART to its patients, with the government providing the drugs at no cost. By April 2006, the Wonji Sugar Works' clinic was treating 70 ARV patients. A second plantation health clinic also was approved to provide HAART in 2006. The MOH further loosened its restrictions on the provision of HAART when it was forced to revise the protocol and staffing guidelines for its public clinics to expand the rollout of publicly provided ARV care. This change in policy opened the door for the expansion of the number of company clinics to provide ARV drugs, although this policy decision apparently has not been codified.

Although the principal barrier to provide HAART has been removed, other barriers remain for company clinics to realize their full potential in AIDS care and treatment. With this reform, private – including company – clinics can provide HAART only if they receive comparable training as MOH health care providers. However, accessing training in HAART and obtaining copies of clinical guidelines and protocols is difficult for private providers because they are not included in MOH or donor work plans. The government will also have to make available donor-funded or low cost drugs to the private sector to offer to those patients who can not afford treatment. The Wonji Sugar Works program demonstrates the positive impact – more patients on treatment at no additional cost for the government – when the MOH offers free ARVs to qualified company clinics. Creating favorable conditions for private sector entities such as company clinics to offer ARV therapy to their workers benefits both the employer and the government.

THE NEED TO PAY ATTENTION TO OUTDATED AND INEFFECTIVE REGULATIONS

As the two examples demonstrate, the legal and regulatory environment can have a profound effect on the private sector provision of essential services, such as RH/FP and HIV/AIDS. In the

absence of a supportive policy framework, the private sector will either provide fewer services than its potential or operate outside of the existing regulatory framework.

In many developing countries, new and revised policies and regulations are needed that recognize current private sector practices and that stimulate increased provision of primary health care services where private sector has latent capacity. Improving the policy environment will encourage greater private sector participation in the delivery of essential services and increase the accountability and quality in the private health sector.

Removing or modifying policies and regulations, however, may not prevent or resolve other constraints to greater private sector participation in primary health care services. Indeed, some of the greatest barriers to private sector provision of RH/FP and HIV/AIDS programs arise from factors not based in law. In Zambia nurses and midwives need access to capital to help them establish a private practice. In Ethiopia physicians need access to MOH training and guidelines as well as to donated and/or subsidized ARV drugs so they can treat their AIDS patients at a reasonable cost. Other factors limiting the private sector's role include concerns for profitability, market disincentives, MOH biases toward the private health sector, and political priorities. And societal factors, such as religious beliefs, cultural mores, and provider biases also constrain private providers' ability to provide RH/FP and HIV/AIDS services.

Despite the importance of the legal, regulatory, and policy environment *as well as* non-policy factors such as market conditions and socio-political factors, many program planners and policymakers overlook these areas when designing health policies and programs. An assessment of existing laws and regulations and the wider policy environment should be part of the design of all private sector RH/FP and HIV/AIDS programs (for a guide to assess the policy environment, see ***Navigating Uncharted Waters: A Guide the Legal and Regulatory Environment for Family Planning Services in the Private Sector*** at http://www.psp-one.com/content/resource/detail/3178/). Ignoring policy factors may deny developing country governments and MOHs the opportunity to mobilize additional resources and partners through the private health sector to address some the long-standing challenges in delivering much needed primary health services.

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About PSP-*One*

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Banyan Global

Dillon, Allman and Partners, LLC

Family Health International

Forum One Communications

IntraHealth International

O'Hanlon Health Consulting

Population Services International

Tulane University School of Public Health and Tropical Medicine

For more information about PSP-*One* or current publications (available for download) please contact:

Private Sector Partnerships *One*
Abt Associates
4800 Montgomery Lane, Suite 600
Bethesda, MD 20814 USA

Tel: (301) 913-0500
Fax: (301) 347-5610
E-mail: info@psp-one.com
http://www.psp-one.com