

Providing Services Globally: The Experience of an Internet Pharmacy



COMMENTARY

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ABSTRACT

Globalization of hospital-based medical services represents another step in the globalization of healthcare. The rise of transnational pharmaceutical firms represents an early example of the globalization of healthcare, which on the whole has provided many benefits. Medical discoveries made in one country are rapidly and seamlessly made available to patients in other parts of the world. Clinical research methodology has become much more sophisticated, and both the size and the scope of clinical studies have increased. Regulatory practices have developed to meet the highest national requirements and thus have served to improve standards worldwide. Globalization of hospital-based medical services may similarly serve as a catalyst to new methodologies and improve standards of service worldwide.

Before such benefits can be realized, however, there are a number of regulatory and economic obstacles to overcome. An insight to some of these obstacles can be gleaned from the experiences of the Internet pharmacies. Provision of pharmacy services via the Internet has raised a number of regulatory and human resources issues. The revenue model is also instructive and has implications for the expectations of globalization as a source of revenue for hospitals. This paper will report on the development of one Internet pharmacy and the initiatives of other Internet pharmacies to overcome provincial and federal regulations limiting the provisions of services across borders. Some of these issues will also be problems for the provision of global medical services by hospitals as presented in the lead paper.

OUR PHARMACY WAS set up to provide compounding services to meet the needs of patients not served by the pharmaceutical industry. The pharmaceutical manufacturer is selective about the markets entered and, within these markets, restricts itself to standardized high-volume products. We felt that there was an opportunity to provide products directed at the needs of individual patients for whom the ideal product is not available from among the standardized offerings of the industry. Finding patients who could benefit from our specialized services in a market dominated by standardized products delivered through retail pharmacy presented a substantial problem. The catchment area of retail pharmacy is very small. To find enough patients to sustain a business, we would have to draw from a very large population. We registered the Web name "pharmacy.ca" and developed a website explaining our services. Our primary target was the Greater Toronto Area and our secondary target the remainder of the province of Ontario. It came as a very pleasant surprise when we received inquiries from the United States, Hong Kong, Korea, South Africa, Australia, New Zealand, United Kingdom, Italy and Spain. It was even more satisfying to receive repeat business from patients in these countries. We could never have generated this demand if we had been restricted to a catchment area typical of a retail pharmacy in Ontario. The patients benefited because they had access to a product not otherwise available. Clearly, this was a real-life demonstration of the power of the World Wide Web.

The requests from across the globe were certainly satisfying, but they raised for us many regulatory hurdles. The

University Health Network will need to deal with similar issues if the hospital wishes to provide services beyond the boundaries of Ontario. At the time of Confederation, the regulation of hospitals, pharmacies, physicians and pharmacists was considered a matter of property and civil rights or a matter of a local nature, and under the British North America Act, regulation became the jurisdiction of the provinces. Reaching beyond provincial boundaries is not a simple matter. The scenario outlined in the lead paper, where Dr. Shiran advises in the treatment of Maria Contreras, is very different from the situation where surgeons at the Hospital for Sick Children treated Herbie, the patient who led to the establishment of the Herbie Fund (www.sickkids.on.ca). When Herbie was treated at the Hospital for Sick Children, the medical act was carried out in Ontario in a hospital accredited in Ontario and by a surgeon licensed in Ontario. There was no question of jurisdiction and licensing requirements. But where is Dr. Shiran practising when she treats Maria Contreras?

Limitations Imposed by the Ontario College of Pharmacists

Pharmacists in Ontario are restricted from filling prescriptions written by a medical practitioner who is not licensed in Ontario. Other provinces permit their pharmacists to fill prescriptions written by any prescriber licensed in a province or territory in Canada. Federal regulations restrict the sale (filling of prescriptions) of products containing substances listed in Schedule F to the regulations to the Food and Drugs Act. A sale can be made only if the pharmacist receives an order from a

licensed practitioner who is licensed in a province or territory in Canada. It is clear that a pharmacy in Canada cannot fill a prescription written by a medical practitioner licensed in the United Kingdom or a state of the United States. Similar rules apply in most other countries (i.e., a pharmacist in the United Kingdom cannot fill a prescription written by a practitioner not licensed in that country). This is frustrating for patients who have found what they need but can't obtain it because of rules based on geography. These rules have placed major limitations on our ability to provide services outside of Ontario and Canada.

Limitations Imposed by the College of Physicians and Surgeons

Some enterprising Internet pharmacies have recruited Canadian physicians to review and rewrite the prescription written by a foreign physician so that the patient can present the pharmacist with a legal prescription. This practice is not new. Since the 1950s immigrant Canadians have brought prescriptions to their physicians seeking help in obtaining medication for their relatives behind the Iron Curtain. The physician would translate and rewrite the prescription so that a Canadian pharmacy could be presented with a legal prescription. The medication so obtained was sent to the relative behind the Iron Curtain. It was considered a humanitarian act even if it wasn't 100% legitimate. As is usually the case with the Internet, it is not that the service wasn't available before, it is just that the scale is of a different magnitude. The College of Physicians and Surgeons of Ontario now condemns this practice. Policy #8-00

approved by Council on November 2000 reads in part: "It is incumbent upon the physician to obtain an adequate history and perform an appropriate physical examination to reach a diagnosis that will ensure that the requested medications are appropriate." Presumably the requirement for a physical examination is a standard applicable to all medical treatments and not just a medication.

The policy in Saskatchewan is similar. Under bylaw 51, *Bylaws Defining Unbecoming, Improper, Unprofessional or Discreditable Conduct*, section (1)(h) reads:

"Prescribing to a patient without establishing an appropriate physician-patient relationship" includes any situation in which a physician issues a prescription, via electronic or other means, unless the physician has obtained a history and has performed an appropriate physical evaluation of the patient adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided.

"Prescribing to a patient without establishing an appropriate physician-patient relationship" does not include a situation where the prescription is issued:

- (i) In an emergency situation to protect the health or well-being of the patient;
- (ii) In consultation with another Saskatchewan physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including use of any prescribed medications.

Section (1)(h)(ii) contemplates the type of relationship that exists between Dr. Gomez, Dr. Shiran and Maria Contreras and would generally be considered appropriate. Unfortunately, the restrictions in section (1)(h)(ii) require a Saskatchewan physician to have an ongoing relationship with the patient. Dr. Gomez is presumably not licensed in Saskatchewan, and thus the consultation described would not be appropriate if Dr. Shiran was practising in Saskatchewan.

Limitations of Prescribing Medications

What if the patient needs a drug that is not available in Colombia but only in Canada? Dr. Shiran could write the prescription and a pharmacist could fill it legally. Unfortunately, Dr. Shiran would not be able to do a physical examination and thus would not be meeting an appropriate standard of practice as outlined above. Similarly, the pharmacist may not be in a position to meet the Ontario College of Pharmacists standard of practice because the pharmacist may not be able to counsel the patient. Problems of accessibility and of language are the most obvious reasons. The problem is more complex if the best available medication is not “approved” in Canada but is approved in, say, the United States or Britain. After all, Dr. Shiran is being consulted because of her expertise, and she is expected to bring the best available medical science to bear. Now Dr. Shiran runs into more problems with the College of Physicians and Surgeons of Ontario. College Policy #8-01 reads: “The College recommends that physicians not prescribe to their patients drugs that have not been approved for use in Canada...” This policy

totally ignores the current and historical role of pharmacy and views the pharmaceutical industry as the only and omniscient source of medications to treat the ills of human kind. One hopes that Dr. Shiran will select the best available treatment, from whatever source, for her patient.

Defining the Extent and Limitations of Services

Some Internet pharmacy operators have dealt with the above regulatory limitations imposed by the colleges of pharmacy and medicine by carefully defining the service to be provided by the physician and the pharmacy. In its “Authorization and Consent Customer Agreement Form,” Canadian Meds USA requires patients to agree to the following: “I hereby appoint CanadianMedsUSA and its partnered Canadian Pharmacy as my agent and attorney for the purposes of obtaining a prescription from a Medical Doctor in Canada (the ‘Canada MD’) which corresponds to the prescription included in this order, which may include directly contacting my prescribing physician, and purchasing and arranging delivery of the medications prescribed in the Canadian prescription, substantially on the terms set forth below, all to the same extent I could if I personally took such steps” (www.canadianmedsusa.com/powerofattorney.htm). It is not yet clear whether this will appease any or all of the provincial colleges regulating medicine and pharmacy. Various challenges are underway. In Dr. Shiran’s case, it may be possible to enter into such an arrangement with the patient provided it is not against public policy in either Colombia or Canada.

A Role for the Federal Government

Although healthcare is a provincial matter in Canada, the federal government could take a leadership position in the provision of global pharmacy services. Schedule F to the regulations to the Food and Drugs Act makes it illegal to sell a substance contained in the schedule except when a prescription is written by a healthcare professional licensed in a jurisdiction in Canada. An order-in-council changing this regulation to read "a healthcare professional licensed in any jurisdiction in Canada, the United States or Mexico" would make the filling of prescriptions written by out-of-country practitioners legal. The regulation could, of course, be written to include any other jurisdiction in the world.

Why should Canada bother to change the rules? There are a number of reasons why Canada should take such a leadership position. The purchase of medications over the Internet is a growth industry that is not confined just to prescription products. Governments' ability to control the movement of small packages is limited, especially in light of more pressing security issues. Encouraging the development of an open industry with the legitimate players clearly identified is the consumer's best protection. For example, Ontario licensed pharmacies with an Internet presence must carry the logo of the Ontario College of Pharmacists. A click on the logo places the patient in contact with the College. Opening up the rules is consistent with the North American Free Trade Agreement. Chapter 12 deals with the cross-border trade in services by service providers of another party. In the table on Medical/Allied Professionals, pharmacists and physicians are listed.

And, finally, Canada should get involved so that Canada can be instrumental in the development of a vibrant new industry with spinoff benefits for domestic pharmacy services in its own underserved regions.

Human Resources Mobility Takes a Quantum Leap

The growth of Internet pharmacies has resulted in expressions of concern about pharmacist shortages (see David Square, "Online Rx Debate Rages," *Pharmacy Post* October 2002). Pharmacists have been under enormous pressure in the last three years because of an increase in the number of store openings especially in the food sector, the length of business hours, and migration to the United States. The number of pharmacists absorbed by the Internet pharmacy is small. Fundamental to the shortage of pharmacists in clinical practice is poor working conditions and remuneration. The same dynamics will apply in clinical medicine. Canada has a shortage of physicians and is also affected by migration to south of the border. Do we have the human resources to "export" more medical professionals by absorbing their time in the provision of services to the rest of the world? Closing one's practice and moving one's family is a substantial barrier to migration of physicians out of Canada. Imagine a situation in which physicians could move out of Canada without relocating themselves or their family. Given the improvements in communication technologies, a radiologist could read X-rays, MRI scans and so on or an internist could read ECGs for a U.S. HMO at a lower cost than a U.S. service provider. However, the Canadian clinician could be paid more for these services than

the provincial government is willing to pay for the same services. This process could also be used to escape fee caps imposed by various provincial medical plans. Clearly, evolving ICTs will increase the ability of clinicians to adopt practices that better fit their needs. As with all human resources shortages, attention to working conditions and remuneration are important inputs in an environment of almost unlimited choice.

Here, too, the federal government can play a pivotal role. The provinces are responsible under our Constitution for setting standards and licensing healthcare professionals. However, in the international arena the federal government has primacy and can enter into international treaties. The federal government could use the Medical Council of Canada in an expanded role to develop national licensing standards for healthcare professionals and to negotiate bilateral agreements with other states. Although we have become accustomed to healthcare professionals leaving Canada, this need not be the case if we as a country had a much wider pool to draw on. Clearing up the ambiguities associated with the provision of cross-border services in healthcare would encourage Canadian healthcare professionals to work in a global context.

Is There a Workable Revenue Model?

One of the motivations for hospitals to provide global services is the generation of alternative sources of revenue. Generally, professional fees are lower in Canada than in the United States. However, fees in Canada are higher than in many other countries of the world. The lessons from Internet pharmacies are clear. There

are only two reasons patients go to the Internet for pharmacy services: medications are much less expensive, and the medication is not available in the local market. Canada is not a low-cost service provider relative to the rest of the world. This, then, leaves only one alternative available to the Canadian institution: the provision of services not available in a given local market. Identifying and marketing of such services will be a major hurdle for an institution geared to operating through government grants.

Providing hospital services globally has a number of regulatory hurdles engendered by a regulatory scheme set up during an era when communications were primitive. Evolving information and communications technologies have made this regulatory model obsolete. The limitations encountered by Internet pharmacies are discouraging; however, it is important to remember that the faxing of prescriptions and mail-order pharmacies are very recent innovations. It is encouraging to see a major institution such as the University Health Network take a proactive stance in the utilization of the latest communications technologies to extend the reach of the best in Canadian medical care. An institution with the stature of the UHN is in the ideal position to remove regulatory hurdles to globalization.

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