Journal of Pharmacy Practice and Community Medicine.2016, 2(3):60-64 • http://dx.doi.org/10.5530/jppcm.2016.3.1 e-ISSN: 2455-3255

REVIEW ARTICLE

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Dispensing Practices in India and United States

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Received: 19 February 2016;

Accepted: 30 March 2016

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Abstract

Physician dispensing refers to the legal practice where physicians directly supply their patients with medication bypassing the need for patients to use a community pharmacy to fill their prescription. This practice is common in India where 80% of all physicians are legally allowed to dispense medications. Problems persists because patients are required to purchase any medication deemed necessary by the physician; therefore, conflicts of interest can arise due to financial incentives based on the number of medications the physicians dispense to the patient. Physician dispensing has negatively impacted community pharmacy relationships by taking away their business and forcing them to close. Similar to the United States, dispensing physicians are regulated by the board of pharmacy and are required to be compliant with the same regulations as pharmacies, however inspections are not nearly as often or as strict. Loopholes in the laws allow physicians to find ways around regulations and be noncompliant without sustaining consequences. Regulations, such as those in United States, that prohibit physicians from receiving profits based on the number of medications they dispense should be created in India to reduce conflicts of interest and prevent community pharmacies from going out of business.

Key words: Dispensing, Schedule K, Pharmacist, Physician, India.

INTRODUCTION

A dispensing physician is defined as a registered medical practitioner who is permitted to sell and dispense a drug to his or her patients, either as an exemption to the general legislation governing the provision of pharmaceutical services, or as part of the overall provision of medical services.[1] Physician dispensing has increased in many countries,[1] such as South Africa,[2] the United Kingdom[3] and the United States,[4] where at least 10% of all general practitioners are licensed to dispense medication to their patients. In Asian countries, physicians have historically been the healthcare professional who dispenses medications to patients, but pharmacists have started take on more business and are now playing a larger role in patient care.[1,5] In Scandinavia[1] and India[6]

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physicians are not allowed to prescribe medications and dispense them concurrently.

Schedule K of the Drugs and Cosmetics Act and Rules in India regulates certain conditions regarding dispensing by physicians. Schedule K states "A Registered Medical Practitioner (RMP) can supply drugs to their own patients or any drug specified in Schedule C at the request of another practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the RMP is not: a) keeping an open shop or b) selling across the counter c) engaged in the importation, manufacture, distribution, or sale of drugs in India to a degree, which renders him liable to the provisions of Chapter IV of the Act and the rules there under."[6,7]

Drugs that are dispensed by physicians must be purchased only from a wholesaler or a manufacturer licensed under Schedule K regulations, and records of such purchases showing the names and quantities of the drugs, together with their batch numbers, and names and addresses of the manufacturer must be maintained. These records must be available in the pharmacy for inspection by an inspector appointed under the act who may, if necessary, make enquiries about purchases of the drugs and may also perform drug testing. Unfortunately, Schedule K is not without ambiguity. It does not specify whether the physician can sell medications or the amount to be charged for dispensed medications. In addition, it does not clarify whether medications are taxable or not.

Unfortunately, in actual practice, physicians do not abide by the rules under Schedule K. Instead, they stock drugs according to their wish without complying with other regulatory conditions and continue doing so without any legal ramifications. Physicians use the provisions in the law as a profiteering tool, and not as a service to the public. The law, when it was framed in 1948, intended to make medications readily available to patients. Six decades ago, there were very few pharmacies in the country. Today, there is an explosion of pharmacies with around four lakh pharmacies throughout the country. While it would be reasonable and moral for a physician to dispense medications due to unavailability of a pharmacy within a 5 km radius, it is unethical for a physician to dispense or sell medications if one or more pharmacies are present within the 5 km radius.[6,7]

Physicians often dispense bulk pack products to their patients. Bulk pack products force the patient to take the medications dispensed by the physician. Because each product is not in its original packaging, its name and other details are unknown. This means that the product may be of dubious or questionable quality. Both the physicians and the patients handle medications while counting and packing, which renders them unhygienic. Loose tablets and capsules may be packaged in one bag without identification and may not contain other details. Medications may also be exposed to air leading to faster degradation.

OBJECTIONS OF PHARMACIES

In India, patients are unable to refuse medications dispensed by physicians, therefore decreasing sales and profits of retail pharmacies. Existing independent pharmacies are now losing business due to an increased number of dispensing physicians. Also, some physicians dispense only high-profit medications and prescribe low profit medications for patients to fill at pharmacies. Physicians also dispense specialty medications that pharmacies do not generally stock, and patients upon needing refills for the same medications go back to the physician rather than the pharmacy.[8,9] This is an unregulated trade, which is largely cutting into the sales and profits of pharmacies.

There have been some instances where deliveries to physicians from the medication wholesaler are much larger than those delivered to the pharmacies in the same neighborhood. Such acts continue to drive down pharmacy sales leading pharmacists to devise other means to generate revenue. Some pharmacies have resorted to undercutting medications, selling medications without prescriptions, or selling counterfeit medications. All of these can potentially hurt the consumer i.e. the patient, since pharmacists are left with little choice to compete with dispensing physicians.

Pharmacies are required to have a drug license, appoint a pharmacist, maintain detailed records of purchase and sales of all scheduled drugs, keep receipts for every sale, keep all purchase bills in serial order, maintain bill books for two years, store drugs in hygienic conditions, maintain clean shelves, and be open to inspection by drug inspectors. On the contrary, dispensing physicians stock and sell drugs but do not abide by all of the above regulations. Drug inspectors do not often visit physician offices to enforce the rules and regulations, so the physicians do not feel they need to follow the dispensing laws.

In addition to not abiding by the same laws as pharmacies, dispensing physicians fail to pay sales tax. Since physicians who dispense medications receive medications directly from the pharmaceutical companies, they do not pay local taxes, though they charge sales tax on the medications that they sell to their patients. Physicians may also receive medications

from medical representatives, which may be bought from out of the state without any guarantee that they are not spurious or counterfeit. The medical representatives carry the products with them in their travels where adequate storage conditions cannot be maintained. Physicians will often take these medications and sell them to their patients even though they cannot be sure that the drug has met the necessary storage conditions set by the manufacturer.

The Indian FDA should take upon itself the task of revamping the Drugs and Cosmetics Act, including Schedule K. Some recommendations to aid the process would be:

(a) Requiring physicians to dispense drugs if a patient has serious difficulties in obtaining the medicine supplied by a pharmacy, or drugs that are needed in an emergency. Authorities should set standards that regulate dispensing, and medicine management related to pharmacy practice and physician dispensing.

(b) Prohibiting physicians to be licensed to dispense if a pharmacy is within 5 km of his or her practice.

(c) Requiring physicians to surrender their dispensing licensure if a pharmacy opens within 5 km of his or her practice.

(d) Specifying minimum standards for setting up a dispensing physician's facility in the Drugs and Cosmetics Act.

(e) Requiring any physician seeking to dispense drugs to be licensed with the FDA to stock drugs other than those permitted for emergency use. The government should create an emergency drug list and specify which drugs should be listed as such. The doctors will then have permission to stock only these emergency drugs provided they maintain proper conditions for storage.

(f) Requiring all physicians, dispensing and non-dispensing, to be open to inspection by drug inspectors, however, details (as under Schedule K) must be maintained stating whether the doctor stocks emergency or non-emergency drugs for dispensing.

(g) Prohibiting physicians from selling medications to persons who are not on his or her patients. Physicians should only dispense medically necessary medications to their patients.

(h) Requiring drugs to be dispensed in person by the physician and not a nurse or their assistant. Alternatively, a pharmacist may be hired to dispense medications for the physician.

(i) Requiring physicians to keep detailed records indicating batch number, expiration date, name of company, name of drug, and price charged to the patient for each medication that is dispensed.

(j) Creating a mechanism that traces all medications to their manufacturer. Records of medications that are dispensed from the physician's practice should be kept in their office for a minimum of two years.

PHYSICIAN DISPENSING IN THE UNITED STATES

In the United States, physician dispensing is legal in 44 of the 50 states. Midlevel practitioners such as nurse practitioners and physician assistants are allowed to dispense in 38 states. In 6 states, non-pharmacist dispensing is generally prohibited, except for 3 states that allow physicians to dispense in rural areas that are geographically isolated from a pharmacy.[10] Some states do not require physicians to obtain a dispensing license, whereas other states require a dispensing license. Depending on the state, physicians may be allowed to dispense only 72-h emergency medications or they may also be allowed to dispense other non-emergency medications depending on the practice settings. Physicians are also allowed to dispense controlled substances, however, it depends on the state of practice and their regulations.[11]

The incidence of physician dispensing is relatively low, however it is growing. The board of medicine in each state is the regulatory body that sets the rules for dispensing physicians in their respective state. Compliance with pharmacy regulations is required for physician dispensing in 26 states. Examples of compliance include labeling information, controlled inventory, and other record keeping requirements that are dependent on the state of practice. There are five states that require physicians to follow the same dispensing requirements as a pharmacist (Table 1).[10]

Among the states, there are five regulatory requirements that govern dispensing physicians: 1) permit dispensing only in limited situations, 2) enable state agencies to identify dispensing physicians, 3) limit profits on drugs dispensed by physicians, 4) protect freedom of choice for consumers, and 5) impose procedural controls such as labeling and record keeping.[12]

Table 1: Physician Dispensing in the United States[11]

	No of states	Names of states
States that allow physician dispensing	44	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming
States that allow dispensing by midlevel practitioners such as nurse practitioners and physician assistants	38	Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Washington, West Virginia, Wisconsin, Wyoming
States where non-pharmacist dispensing is prohibited	6	Massachusetts, Montana, New Jersey, New York, Texas Utah
States that allow physicians to dispense in rural areas that are geographically isolated*	3	Montana, Utah, and Texas
States that require compliance with pharmacy regulations for dispensing	26	Alabama, Arizona, Arkansas, California, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Tennessee, Virginia,
States that require physicians to follow the same dispensing requirements as a pharmacist	5	Florida, Georgia, North Carolina, North Dakota, Virginia

*Physician dispensing in prohibited in these states, but provisions have been made for physicians to dispense in rural areas where access to medications is not widely available

PHYSICIAN DISPENSING SAFETY

Patient safety is of high concern with physician dispensing due to the lack of oversight for the medications received by the patients. Prescriptions do not go through drug use reviews and depending on the physician, drug interactions may be overlooked.[14] In the United States, pharmacists are the only health professionals with extensive training and knowledge on medication therapies. Pharmacists should always be involved in a patient's medication therapy regimen as they are drug experts and can prevent unwanted adverse reactions. Pharmacists can also provide vital information on drug therapies in patients who have multiple co morbid disease states. These patients are on multiple drugs that encompass multiple medication drug classes, which increase the risk of drug interactions in them. Drug interactions can range from mild to severe; if a drug interaction is missed because the physician did not conduct a drug use review, it can result in severe consequences to the patient, which could have been prevented if a pharmacist was involved in the medication therapy.[13]

PHYSICIAN DISPENSING COST IN THE UNITED STATES

In most states, physicians are not allowed to dispense medications to patients for profit. Profit is defined as any amount that exceeds the acquisition amount in which the physician purchased the drug from the wholesaler.[14] However, in some states (See Table 1), this is not as tightly regulated which can allow the physician to mark up the price of the medications with less, if any, consequences. In states where profit dispensing is not tightly regulated, physician dispensing can result in conflicts of interest in the patient-provider relationship. In Florida, $3.3 million dollars was spent in political contributions in order to beat out laws that prevented physician dispensing and mark ups on the medication.[13]

Regulations that prevent physicians from monetarily benefiting from dispensing medications to patients should be in place in India. Dispensing physicians gain huge profit margins from patients who choose to receive their medications from them as opposed to going to a nearby pharmacy. Because of the monetary gains, patient care can be compromised as the physician becomes wrapped up in the profits that he receives from his patients causing him to dispense medications that are not medically necessary.

CONCLUSION

If the trend of dispensing doctors continues, retail pharmacies will inevitably be forced to close. Pharmacies

only depend on sales from medicines to pay rent, salaries and other expenses. If the doctor does most of the sales, the pharmacy will no longer serve a purpose and will not be able to stay in business. If the functions of prescribing and dispensing cannot be separated, it is reasonable to advocate that the doctor shouldn't profit from drug sales. A fixed dispensing fee without markup on the drugs should be decided. There will presumably always be a need for medicines to be prescribed and dispensed by the same person in certain situations (emergencies), but on a daily basis, a conflict of interest between the prescriber and the patient should be avoided by ensuring that the dispensing is not-for-profit service for the prescriber. Physicians and pharmacies should be allowed to generate income by treating sick people; however, the process should be regulated and ethically acceptable, without exploiting patients who place their trust in their healthcare providers.

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Cite this article as: Darekar A, Patel I, Clemons M, Tan X, Rana R, Bhatia D, Chang J. Dispensing Practices in India and United States. J Pharm Pract Community Med. 2016;2(3):60-64.