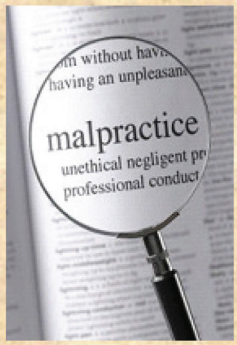
DERMAPRACTICE

The Dermatology Practioner's Guide

Brought to you by Practice Management Cell, IADVL

APRIL 2015 VOL 1; ISSUE 1



My Two Cents of Worth:

"MY DOCTOR IS NICE; EVERYTIME I SEE HIM, I'M ASHAMED OF WHAT I THINK OF DOCTORS IN GENERAL....."

Mignon McLaughlin

Well, times are changing friends. The medical profession no longer commands the respect as in the era of our forefathers and the science and art of medicine have become marred with scepticism of patients and their relatives. Doctors are no longer "DemiGods"; they are better approached as "people with license to kill"!

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Guest Editor – DERMAPRACTICE

Dr Sidharth Sonthalia

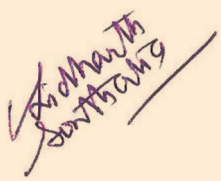
The premonition about this evolutionary phase in medical practice has been unsettling our Hon'ble President Dr Mysore for the past many months. Sir, finally barefaced his concerns to all of us, and the sheer brilliance and need of the idea took no time to bring in a consort of people who shared this concern and wanted to contribute to turn this dream into a reality.

The Practice Management Cell (PMC) was born and zealous participation with plethora of ideas started pouring in. We realized that when faced with a practice-related issue, our colleagues end up wrangling the unending array of information or rather misinformation on the net and from other unreliable sources. They had no other option, but to rely on what was 'told' and 'advised'. The time had come! Time to empower our fraternity, so that we know the difference between 'ethical and correct' practice and 'malpractice! Yes, the vision of engaging, educating, and helping practicing dermatologists to know the principles of ideal practice, the potholes therein, and the strategies to circumvent them had to be realized!

With the unrelenting efforts of Dr Mysore leading our team, and with the guidance of dynamic leaders like Dr Patwardhan and Dr Gokhale, and literary contributions from our authors with unparalleled research and writing skills; this cogitation finally alchemized into DERMAPRACTICE, a periodical extraordinaire!

It was indeed an honour for me to have been invited to be the guest editor of the maiden issue of DERMAPRACTICE. We have made an attempt to keep the first issue concise and crisp and provide IADVLites a food for thought; evoke the need for going beyond their comfort zones of sitting and treating patients comfortably in their clinics, and know what dangers and other practical issues are there in the real world for us! Future issues shall deal with many more issues; with the endeavour to share fool-proof, time-tested and evidence-based knowledge about issues that stare in the face of a practicing dermatologist in India.. And don't worry; we shall ensure that the format of the bulletin will keep you caffeinated and engaged.

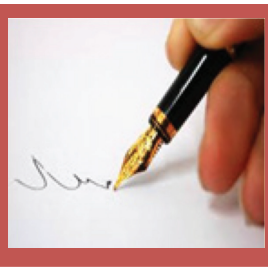
Indulge.....



SIDHARTH SONTHALIA

IN THIS ISSUE

FROM THE PRESIDENT'S DESK



Practice management cell (PMC) was proposed by me to deal with issues of relevance for the practicing dermatologists, who constitute a majority of our fraternity. In some ways this is a counter part to IADVL academy which deals with academic issues.

Dermatological practice has evolved greatly and today's practitioner deals with a wide range of issues including taxes, investments, softwares, communications, human resources, medicolegal issues etc. Often our members run more than one clinics. Issues of rural practice are different from urban issues. Like-wise, the range of practice varies from general clinical dermatology to aesthetic and surgical dermatology. Clinic regulations and governmental requirements are other issues that are faced by the practitioner. A beginner faces challenges that are different from those of an established practitioner. And we have so little guidance available for these challenges- the training is on the job and hence learning curve becomes longer. Mentorship and leadership will be an important goal of PMC. I conducted a leadership session in DERMACON and hope there will be more of these in future congresses.

Our profession faces challenges from not only each other, but from corporate clinics, spas, beauty clinics, alternative medicine practioners- who often advertise heavily and resort to unethical practices. PMC needs to face this challenge head on.

Last year, under the convenership of Dr Niteen Dhepe, a vision statement for PMC was prepared. I am happy that this year, under the leadership of Dr Narendra Patwardhan and Dr Narendra Gokhale, we have made a strong beginning. This bulletin **DERMAPRACTICE** is the first of the bulletins to be published as a part of the series. And I am sure it will go on to greater things from here.....

We also hope to organize multiple meetings on skill development and practice management this year, and decide on a clinic software for use by members. Need for ethical practice and comradiere amongst our members has never been felt more! I do hope that the PMC serves all these aspirations.....

I convey my best wishes to all members of PMC and complement all the authors who have contributed for the bulletin. I also urge all members to make use of this forum to air their views, learn from each other, and serve our patients better.

Best wishes

DR VENKATARAM MYSORE

President

IADVL 2015-16

HONORARY SECRETARY'S MESSAGE

Dear IADVL Members,

It is a matter of great pride for us that **IADVL Practice Management Cell (PMC)** is coming up with **DERMAPRACTICE**, its maiden newsletter. This publication will be a great source of information on these very important but neglected topics in Dermatology. It is indeed the need of the hour, as we require more update on clinic management, taxes, finances, legal issues, and so on. The Practice Mangement Cell is a flagship project of our President Dr Venkataram Mysore. I congratulate the Chair, Dr Narendra Patwardhan, the Convener, Dr Narendra Gokhale , and all the honorable members, and especially Dr Sidharth Sonthalia for energetically giving a beautiful and engaging shape and color to the vision of our President. I wish that the PMC group keeps up this good work.

For the rest,

"Enjoy & Enrich from this useful edition!"

Best wishes

Rashmi Sarkar

DR RASHMI SARKAR

Honorary General Secretary

IADVL 2014-16

MESSAGE FROM THE PMC CHAIRPERSON

Dear IADVL colleagues,

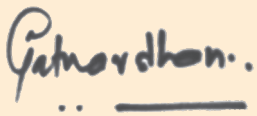
It gives me immense pleasure to interact with you on such a different but vital aspect of clinical practice, through the first edition of **DERMAPRACTICE**, the PMC bulletin of IADVL.

Gone are the days when doctors were considered as 'GODS' on earth, and gone are the days when a dermatologist used to sit in his room with gigantic number of OPD patients; ethically prescribing steroids and antibiotics to his patients, with not even an iota of skepticism in his/her patients' minds.

With the advent of computers, the internet and other forms of digital technology and media have become available to the patients; and we need to implement the same in our practice. With this great initiative by our president Dr Mysore, we are here to implement management tips to our esteemed IADVLites. It will cover topics ranging from setting up of a dermatology clinic, medical malpractice and negligence-related issues, maintenance of records and patient photos, necessity and modes of a dermatologist's knowledge upgradation, and very importantly, an in-depth knowledge of often-ignored monetary issues like service tax and income tax, and the government regulations and legalities that oversee these issues.....

The rising competition within our own fraternity needs no overemphasis. With dermatosugery and cosmetology making deep inroads into every practicing dermatologist's work profile, advertizing and marketing oneself has become a necessary evil. Ethical marketing can increase awareness in community and it's the best cost effective way to increase revenue. But do we all really know what marketing is ethical and what is not!

With PMC, we shall try to ponder over, argue and generate valuable, evidence-based solutions to these unanswered questions and wrong presumptions. I am honored to Chair this brilliant and dedicated team of PMC members, with Dr Narendra Gokhale as the Convenor of the group. Friends, so flip the pages, find your solutions and kindly contribute your ideas and queries with us; to take this cell to greater heights.



Dr NARENDRA PATWARDHAN

Chairperson

Practice Management Cell 2015

WHO IS AFRAID OF MEDICAL NEGLIGENCE LAWS! OPTIONS TO THE PATIENTS AND YARDSTICKS USED BY THE COURTS

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"If a physician operates and cures the disease or saves the eye, he shall receive ten shekels in money. If a physician, while operating, kills a man, or cuts out the eye, his hands shall be cut off"

THE CODE OF HAMMURABI, MESOPOTAMIA, 1754 B.C.

This was the fate of our colleagues 3800 years back. Thankfully we are in a more civilised society with more civilised laws. Aren't we?

Landmark Judgement by the Hon'ble Supreme Court of India

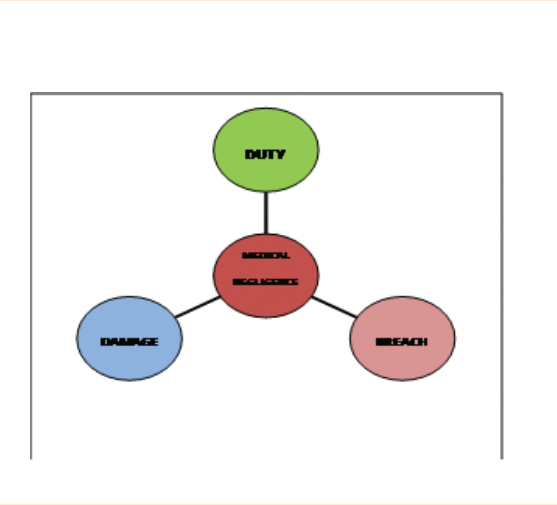
October 24, 2013

"Therefore, a total amount of rupees six crores and eight lakhs along with 6% interest per annum from the date of application till the date of payment is the compensation awarded in this appeal.....right to health of a citizen is a fundamental right guaranteed under Article 21 of the Constitution of India. The doctors, Hospitals, the Nursing Homes and other connected establishments are to be dealt with strictly if they are found to be negligent with the patients who come to them pawning all their money with the hope to live a better life with dignity. .... We, therefore, hope and trust that this decision acts as a deterrent and a reminder to those doctors, Hospitals, the Nursing Homes and other connected establishments who do not take their responsibility seriously"

This was the much needed wakeup call to the Indian medical system. Now, many Indian doctors are debating whether the code of Hammurabi was more severe or this judgement by the Supreme Court of India. On this background, it has become essential for Indian doctors to know, where they stand with respect to the current medical negligence laws of India. The doctors should know about the options their patients have when a medical negligence is alleged. They also need to know how a court comes to a decision in medical negligence cases. A working knowledge of these facts, go a long way in alleviating the fear of the unknown that is experienced by the medical community in India today.

HOW DO THE COURTS DECIDE MEDICAL NEGLIGENCE CASES!

If an injury or damage or death is caused during treatment, it does not automatically lead to the punishment of the doctor or the hospital involved, simply based on the damage suffered by the patient; many other facts are taken into account. There's no straight jacket approach applicable to every medical negligence case. Each case is assessed differently, based on that particular case's facts and merits. But there are certain fundamental principles which apply to each and every case of medical negligence.



What constitutes Medical Negligence!

Negligence is the breach of a duty caused by the omission to do something which a reasonable man would do, or doing something which a prudent and reasonable man would not do. There are three components of medical negligence. When all three components are proved, it leads to the court to decide that the doctor is negligent. Absence of even one may lead to the dismissal of the case.

Duty to take care

The first thing that must be established in a medical negligence case is that the doctor owed a legal duty to the patient. To establish this, the patient must be able to demonstrate that a doctor-patient relationship existed at the time of the alleged medical negligence. For this the patient may need to submit medical records showing the complete course of treatment. A patient may not be able to support a claim that the doctor owed a duty to the patient if the doctor is able to show that the doctor-patient relationship was terminated prior to the date on which the alleged medical negligence is said to have occurred.

To implicate a doctor, the patient must be able to prove that:

1. The doctor owed a **duty** to take care,
2. The doctor **breached** this duty, and
3. The patient suffered a **damage** as a direct consequence of this breach of duty.

Exceptions to this clause are medical emergencies when there is an impending danger to the life of a person. In such situations, every doctor, government hospital or elsewhere has a professional obligation to provide his services with due expertise for protecting life. In such situations, no doctor can claim that there was no patient doctor relationship.

Breach of Duty

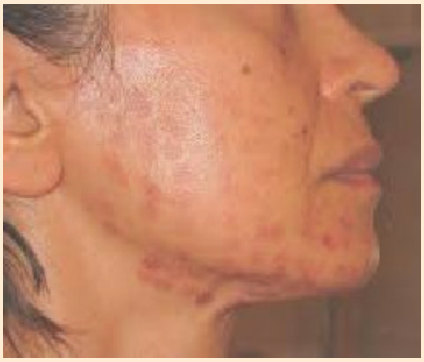
The first and foremost question asked by the courts under this heading is about the qualification of the doctor – is he **skilled enough** to undertake the procedure under question. The patient's lawyers always try to raise a doubt that the doctor is not skilled or qualified to take up the procedure under question. Therefore, it is best advised for doctors to regularly update their skills and also to keep all their relevant certifications at hand.

A doctor owes the patient certain duties, viz., a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give and a duty of care in the administration of that treatment. A breach of any of these duties gives a right of action for negligence to the patient. The doctor no doubt has discretion in choosing treatment which he proposes to give to the patient as well as the method of administration of the selected treatment. But there always comes the question of the doctor exercising a reasonable degree of skill and care.

The practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. The law expects and requires neither the very highest nor a very low degree of care and competence judged in the light of the particular circumstances of each case. The doctor needs to demonstrate that his approach is similar to that of an ordinary competent member of his speciality in the circumstance in question.

Damage to the patient

If there is no damage, there can be no compensation, even if it proved that the doctor has breached his duty of care. When there is minimal or negligible damage, the compensation would be nominal.



When there is indeed a damage, it must be proved that the damage was caused as a direct result of the breach of duty of care by the doctor. The questions that the doctor and his lawyers should be asking the court are:

1. But for the doctor's negligence, would the patient have sustained these injuries?'; and

2. Whether the chain of causation was broken by an intervening act or event!

Where another cause has also contributed to the patient's injuries, depends on the court's discretion.

THE DIFFERENCE BETWEEN CIVIL AND CRIMINAL NEGLIGENCE

The 3 components discussed above, duty-breach-damage, are all that are needed to establish a civil liability. To establish criminal liability, the courts go beyond these three components and ask for certain additional requirements.

The courts will apply 3 additional principles for incriminating the doctors under criminal law.

They are: **Gross negligence, Recklessness**, and ***Mens rea***.

1. **Gross negligence**: Under criminal law, it is defined as '*the doctor did something or failed to do something which in the given facts and circumstances no medical professional in his ordinary senses and prudence would have done or failed to do*.' The hazard taken by the accused doctor should be of such a nature that the injury which resulted was most likely imminent'

2. **Recklessness:** Risk taking behaviour, a latent disregard for the possible consequences, failure to take proper safety precautions and a thrill-seeking behaviour – all these are seen by courts as reckless acts of doctors

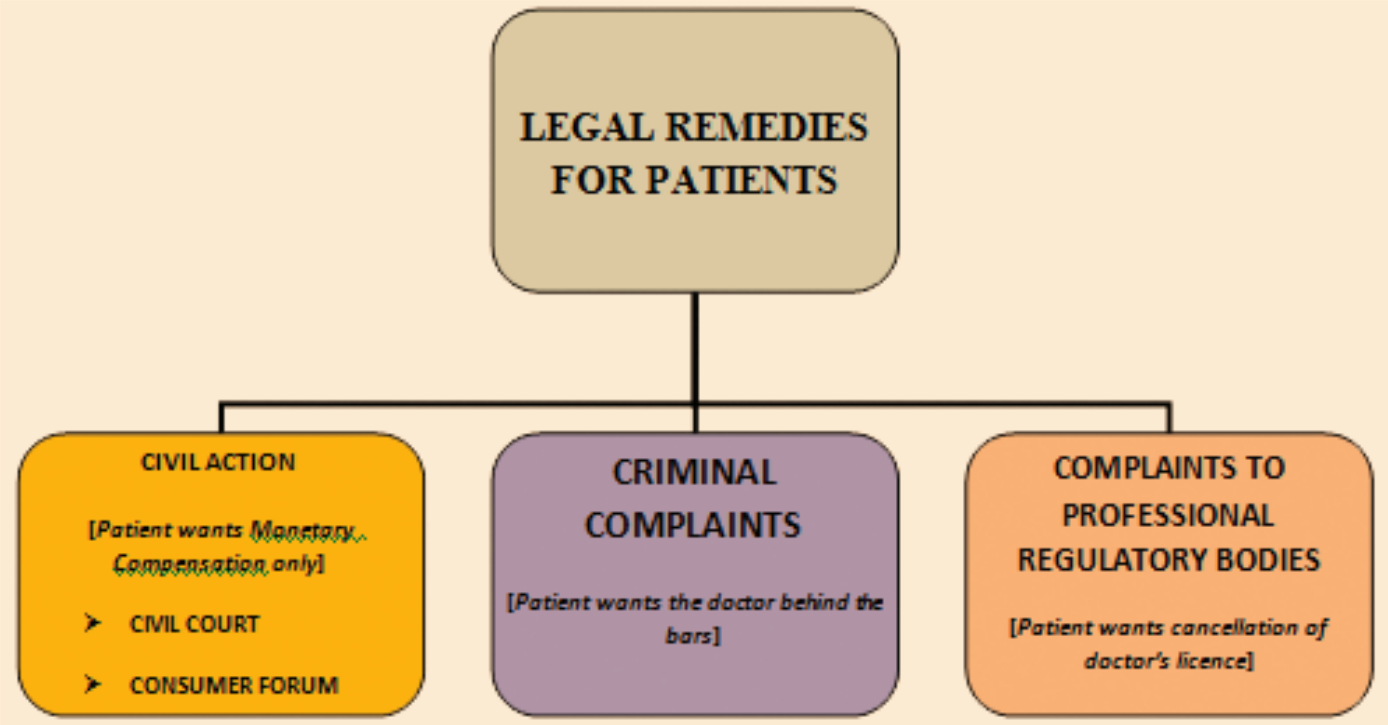
3. ***Mens rea***: It refers to 'a guilty mind' or 'an evil intention'. It is essential to prove that the doctor had a guilty mind and was negligent intentionally to inflict upon the damage to the patient.

Options available to patients to proceed against the doctors & hospitals when medical negligence is alleged

"Ubi Jus, ibi Remedium"

LEGAL MAXIM MEANING ***"WHERE THERE IS A RIGHT, THERE IS A REMEDY"***

Our patients have a multitude of rights. They also have multiple options to proceed against a doctor and a medical establishment in case they suspect they are the victims of medical negligence. The remedies available to the patients when medical negligence is alleged can be broadly divided into 3 groups. This classification is based on the type of justice the patient intends to seek.



These are the actions which can be initiated by the patient when he is seeking ***monetary compensation*** from the doctors and the hospital. He can proceed under various civil laws like Tort laws, Contract laws and the Consumer laws. Here the patient can choose between two judicial platforms. He may either approach the civil court or he may approach the consumer forum.

A) **Civil lawsuit in a civil court** is time consuming, complicated and expensive. Therefore the patients generally do not prefer them. They approach the civil court in certain instances where they are not entitled to approach consumer forum.

B) **Consumer forum:** This is a relatively simple procedure. A complaint can be lodged on a plain white paper, with a nominal fee. Lack of need of a lawyer, quicker proceedings and the forum's apparent favour skewed towards the consumer make it the preferred forum when the patient seeks monetary compensation for medical negligence.

Which hospitals come under consumer act and which hospitals do not!

It is a myth that government hospitals are not covered under the consumer protection act.

In its landmark judgement in the Indian medical association v/s *V P Shantha case*, the Supreme Court of India has clearly defined which medical establishments come under the consumer act and which establishments do not.

FREE MEDICAL SERVICE PROVIDERS: When medical negligence is alleged against medical establishments wherein every patient is provided free medical service, such medical establishments and doctors and paramedical staff working in them cannot be proceeded against in the consumer forum. In such cases, patients who allege medical negligence, have to approach a civil court and file a **civil suit**. Examples for such establishments include both private and government hospitals which provide free treatment for all patients. Collection of a nominal registration fee will not be counted as a payment for services.

CHARGING ESTABLISHMENTS: Medical establishments which collect charges for their services from all categories of patients and the doctors and paramedical staff working in such medical establishments are included under consumer protection act (CPA). Therefore a complaint demanding monetary compensation can be filed against these medical establishments and their staff in the **consumer forum**.

SEMI-CHARGEABLE (MIXED) ESTABLISHMENTS: Hospitals (government/private), which treat some categories of patients free but collect charges from other categories of patients; come under consumer protection act unlike the hospitals which treat all categories of patients free of charge. The patient can approach the **consumer forum or civil court** against **both charging and mixed** establishments, government/ private, if negligence is alleged. But he cannot file the same complaint simultaneously in both these courts.

CRIMINAL PROCEEDINGS

- When the intention of the patient is not to get monetary compensation, but to punish the hospital and the doctor, he can file a criminal complaint at the police station. The police may register an FIR and initiate criminal proceedings against the doctor.
- The sections of IPC that are commonly used by the police against doctors in medical negligence are **Section 304-A** which deals with "causing death by negligence" and **Sections 319-338**, which deal with "causing simple hurt and grievous hurt."

Harassment of doctors by the police based on patient's complaints

The Supreme Court of India has given a warning to police officials not to arrest or harass doctors unless the facts clearly come within the parameters laid down in the *Jacob Mathew's case*. Police must take expert opinion about the facts of the complaint lodged by the patient, preferably by government doctors of the same speciality before registering a criminal case against a doctor. Even then an arrest should be made only in exceptional circumstances. The policemen are warned that if they do not follow these guidelines, they themselves are liable for legal action.

COMPLAINT TO PROFESSIONAL REGULATORY AUTHORITIES

A patient can complain against a doctor alleging professional misconduct to the Medical Council of India (MCI) or the state medical councils. They are empowered to take disciplinary actions against registered medical practitioners for misconduct and remove their names from the medical register if they are found guilty of professional misconduct.

Section 20 of Indian Medical Council Act prescribes standards of professional conduct and etiquette and a code of ethics for medical practitioners. These regulations are called the ***Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations***. This document is freely available online and all doctors are advised to be thorough in these regulations. http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx.

For a given instance of medical negligence, the same patient, against the same hospital and doctor, has the right to seek all three remedies (the civil, criminal and professional) simultaneously.

If a complaint is filed, it does not mean that the doctor is wrong and negligent and must pay compensation or face punishment. For a legal action against the doctor, the patient has to prove that medical negligence has happened.

If the doctors adhere to basic standards and maintain good records, there is nothing to be feared of!

SIMPLE TIPS TO SAFEGUARD YOURSELF

✓ **General measures** like following the established protocols and guidelines in case management, regular skill updation, keeping all certificates readily accessible and getting a good indemnity insurance.

✓ **Universal precautions** like good communication, proper counselling, complete documentation, pre and post treatment photographs, consent forms and staying within your limitations.

✓ **When you get a legal notice,** do not panic, immediately inform your insurer, contact a lawyer, check your documents, actively involve yourself in the legal proceedings and search for similar court cases decided in the past.

TAKE HOME MESSAGES

- Every practicing dermatologist should be aware about the concept of medical negligence: its definition, implications, patients' rights and self-defence mechanisms.
- A doctor can be implicated to have been negligent with absolute certainty only if the three pillars of medical negligence are proven, i.e. the doctor failed his ***duty*** to take care of the patient, the doctor ***breached*** this duty, and the patient suffered a ***damage*** as a direct consequence of this breach of duty. The courts apply 3 additional principles, namely gross negligence, recklessness, and *Mens rea*.
- To prove medical negligence in court, a lack of doctor's skill to take up the procedure under question needs to be proved. Thus, doctors should regularly update their skills and also keep all their relevant certifications at hand.
- A patient can recourse to three legal remedies for redemption against damage caused to him by the doctor: civil action, criminal complaint and criminal complaint to professional regulatory bodies.
- **Civil actions** are initiated for seeking ***monetary compensation*** from the doctors and the hospital. **Of the two options available under this ambit, compared to consumer forum, a civil lawsuit in a civil court** is time consuming, complicated and expensive.
- It is a myth that government hospitals are not covered under the consumer protection act.
- The patient's option of **Civil action** depends on the type of establishment. Simple rule of thumb:
    - Free establishments – Civil Suit
    - Charging establishments – Consumer forum
    - Semi-charging (Mixed) establishments – Civil Suit OR Consumer forum (but not both)
- **Criminal complaints** are filed as an FIR with the police station, when the intent of the patient is non-monetary compensation, but to punish the hospital and the doctor. IPC **Section 304-A** which deals with "causing death by negligence" and **Sections 319-338**, which deal with "causing simple hurt and grievous hurt." apply here.
- **Criminal complaint to professional regulatory bodies**, like MCI and state medical councils may entail removal of the doctor's name from the medical register if found guilty of professional misconduct. **Section 20** of Indian Medical Council Act deals with this issue.
- When a case of medical negligence is filed against a doctor, it does not simply lead to punishment based on the damage suffered by the patient; each case is assessed differently, based on that particular case's facts and merits.
- As per the Hon'ble Supreme Court of India, a police official cannot arrest or harass a doctor charged with medical negligence, without taking an expert opinion from another (preferably government) doctor.
- There is nothing to be afraid of, if the doctor's skill has been used as per protocols, skill updating is done regularly, certifications are stored, a good doctor-patient communication with proper counselling is maintained, documentation including consent forms, and pre- and post-treatment photographs are maintained.
- **Do not panic** if a law suit is filed against you. Bring in your imdemnity insurer and lawyer in the picture immediately, check your documents and present your case well.

For the Dermatological Entrepreneur: Regulations for starting a skin clinic in India

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Dermatology is primarily a non-emergency, out–patient based speciality. Except for some government and institutional doctors who are not allowed to have a private practice, most Indian dermatologists own private clinics. With the advent of procedural dermatology, skin clinics in particular have been expanding their services in size as well as staff. With this, several new practice management issues are faced by dermatologists. ***A skin clinic, akin to any medical clinic, is regarded as a business or a trade enterprise by government authorities and as a service provider under Consumer Protection Act 1986.***

Traditionally, doctors have little knowledge or training in business/hospital management. These issues are neither taught in medical curriculum nor are they addressed in any conferences. This article addresses this need and reviews various regulatory requirements to be followed by our doctors. It is further clarified that the regulations discussed here are of a general nature and these may vary from one state to another state. The authors are familiar with regulations and their requirements in Karnataka and hence refer to such protocols. It is further advised that members need to consult their local agencies for precise local regulations.

Licences

To initiate the setting up a clinic, of foremost importance is a working knowledge of the licences and related permissions that need to be obtained **(Table 1).** This table enumerates most of the licenses required; however, the requirement of a particular license may vary from the format of the clinic.

TABLE 1: LICENCES NEEDED FOR SKIN CLINIC

- ❖ Registration under clinical establishments act
- ❖ Trade licence from local corporation
- ❖ Agreement / MOU with bio- medical waste disposal agency
- ❖ State pollution control board exemption
- ❖ Professional tax registration
- ❖ Service tax registration (if cosmetic surgeries are done)
- ❖ Medical indemnity insurance
- ❖ Pharmacy licence (if a full-fledged pharmacy is attached)

REGISTRATION UNDER CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT 2010 OF GOVERNMENT OF INDIA

This is done at the office of the **District health officer**, which has a cell for registering clinical establishments. In the state of Karnataka, **Form B** for registration of new medical establishment and **Form A** for old medical establishment are issued. State of Haryana requires **Form F**, in addition.

Skin clinic comes under the category of **Allopathic consultation centre** (Uni-speciality).

The documents to be attached with the application for obtaining a clinic registration are shown in **Table 2.**

TABLE 2: DOCUMENTS NEEDED FOR REGISTERING CLINIC[1]

A) Covering letter to district health officer from doctor/ manager of clinic

B) Two passport size photos of proprietor/ doctor

C) State medical council registration certificate- photocopy

D) Degree certificate of medical degree/diploma- photocopy

E) Copy of agreement /MOU with local bio-medical waste disposal agency

F) Pollution control board authorization

G) **Price list of services provided**: It must mention consultation fees and the list of procedures. The minimum or a range of price of surgery may be mentioned. Dermatologist may add that the precise fee for surgery depends on time taken and complexity of surgery.

H) The **amount of fee** charged is entirely at the discretion of dermatologist. Though there are some reports of efforts being made to regulate this through a possible central legislation, no limit has been placed on the fees as yet.

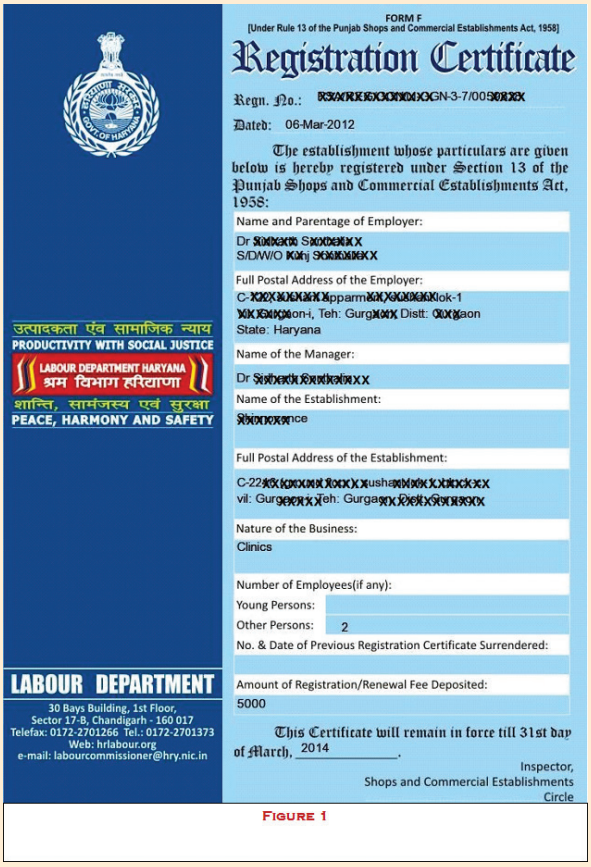
I) **Paramedical staff certificates**: Pharmacist, nurse/ laboratory technician etc. Often in dermatological clinics, nurses/technicians perform procedures such as laser hair removal, phototherapy, which are not taught formally in nursing schools. It is advised in such cases, that a proficiency training issued by the manufacturer / distributor or a senior trained technical person in another clinic be obtained

J) Doctor's consent letter for running the clinic in his name, with photo and self attested State medical council certificate

K) Ownership documents of the building if it is owned by the doctor or Rental agreement with landlord.

L) Declaration from dermatologist stating that he/she is aware of clinical establishments act and will comply with its rules.

Inspection



उत्पादकता एवं सामाजिक न्याय
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e-mail: labourcommissioner@hry.nic.in

FORM F
[Under Rule 13 of the Punjab Shops and Commercial Establishments Act, 1958]

Registration Certificate

Regn. No.: [redacted]GN-3-7/005[redacted]

Dated: 06-Mar-2012

The establishment whose particulars are given below is hereby registered under Section 13 of the Punjab Shops and Commercial Establishments Act, 1958:

Name and Parentage of Employer:
Dr [redacted]
S/DW/O [redacted]

Full Postal Address of the Employer:
C-[redacted]
[redacted]
State: Haryana

Name of the Manager:
Dr [redacted]

Name of the Establishment:
[redacted]

Full Postal Address of the Establishment:
C-22[redacted]
vil: Gurg[redacted]

Nature of the Business:
Clinics

Number of Employees(if any):
Young Persons:
Other Persons: 2

No. & Date of Previous Registration Certificate Surrendered:

Amount of Registration/Renewal Fee Deposited:
5000

This Certificate will remain in force till 31st day of March, 2014.

Inspector,
Shops and Commercial Establishments
Circle

FIGURE 1

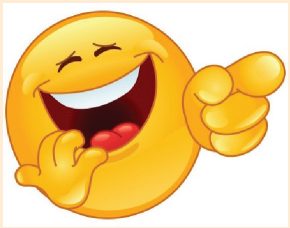
An inspection committee is supposed to inspect the clinic after giving a notice and then give registration. Generally, the team of inspection is composed of three government and local IMA office bearers. Dermatologist will have to be ready with a photocopy of above documents.

Several short comings have been recognized in this act and medical fraternity is fighting to remove them. There is a category titled "Traditional healers". So, a variety of quacks can apply for registration under this category and get the certificate too. Earlier, health authorities would insist on availability of separate toilets for male and female in clinics. Such structural requirements are difficult to enforce in rented premises.

The authorities must be informed about change of address or even closure of skin clinic. The certificate issued will have a photograph of proprietor/dermatologist, a registration number for clinic and a **validity of 2-5 years.** As an example, just check out **Figure 1**, a clinic registration certificate of a dermatologist (details stashed), who obtained it from the Department of Labour in Haryana.

TRADE LICENSE

Local municipality or corporation issue the trade licence for traders and businessmen. ***Whether medical profession comes under the category of "trade", is a hotly debated topic.*** Some city corporations have made it mandatory (e.g. Bengaluru).



The trade licence is common to all trades including bars, restaurants, barber shops etc. and this has lead to a hilarious situation in Bengaluru. ***The trade licence clearly specifies that patients with infection and communicable diseases should not be allowed inside the premises.*** Certainly, this is an untenable situation for patients and clinics!

This issue has been dealt with in several court cases such as:

IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CRIMINAL APPELLATE JURISDICTION
CRIMINAL WRIT PETITION NO.1731 OF 2002
JUNE 12, 2014

ISSUE: Clinics and hospitals are not establishments, so no need to register under Shop act

Dr (Smt.) Shubhada Motwani (Petitioner)
Versus
The State of Maharashtra (Respondent)

The honorable judges in the above case clearly held that "*In our view, therefore the amendment within the definition of commercial establishment will have to be held ultra virus and is accordingly struck down*". However, despite the above judgement, local corporation officers assert that they follow bye-laws of the corporation /municipality and insist that the doctors register and obtain a trade license during their visits to the clinics**. *Hence the issue continues to be debated*.....**

However, it has to be conceded that obtaining a Trade Licence has its advantages:

- It gives a certain validity to the clinic
- It also helps when obtaining and raising bank loans. The banks insist on two separate forms of registration for the clinic prior to sanctioning the loan. Trade license comes in handy in such situations.

Generally, the trade licence application is available on the corporation website or zonal office. The needed documents in Karnataka for obtaining a trade license are shown in **Table 3.**

TABLE 3: DOCUMENTS NEEDED FOR TRADE LICENCE

✓	A notarized affidavit from dermatologist stating that he will run the clinic as per rules of corporation and not inconvenience the public, has to be submitted.
✓	A notarized affidavit from owner of building (in case of rented clinic) stating that he permits the dermatologist to run the skin clinic at his premises.
✓	Photocopy of rental agreement
✓	Latest property tax paid receipt
✓	Photograph of clinic name board. Some states including Karnataka insist that the name must also be prominently in the local language.
✓	The fees depend on the floor area of the clinic and is generally a reasonable amount

Trade licence may be procured for **1 year or 5 years.** Local health inspector will come for a visit at the time of issue. Subsequently, the trade licence has to be renewed by February every year. There will not be any inspections for renewals.

BIO-MEDICAL WASTE DISPOSAL[2-4]

- Clinics generate bio-medical waste, both solid and liquid and hence this is absolutely mandatory. ***Not having a system for waste disposal is an offence and can lead to cancellation of license, penalty or even imprisonment.***
- Pollution control rules mandate that clinics enter into an agreement/MOU with local bio-medical waste disposal agency and also keep a copy of it at the clinic.
- It is the responsibility of dermatologist to segregate waste at source and place in color-coded bags.
- The clinic then has to hire an approved agency to collect the waste. It is the responsibility of disposal agency to collect the waste from the clinic on a regular/daily basis and dispose it in a scientific manner at a common treatment plant.
- It is also crucial to keep the receipts of payment made to the bio-medical waste disposal agency. This proves the dermatologist's compliance with pollution control laws. In many smaller cities and taluks, the disposal agency may not visit all clinics on a daily basis. They may come once or twice a week.
- Disposal agency will not collect and dispose liquid waste generated at clinic. Pollution laws state that it must be treated in 1% sodium hypochlorite (bleaching powder) for 1 hour, before letting out into the sewage.
- Plumbing alterations can be done to comply with this law too. In the operating theatre wash basins, a plastic can with tap may be connected below the sink. Such cans are generally used to store 25 litres of mineral water. Bleaching powder may be added from the top end and the treated water may be let out

through the tap, after 1 hour or even overnight.

Figure 2 shows a wash basin connected to a 25 litre mineral water can below. Bleaching powder is added through the wash basin. After 1 hour or overnight immersion the tap of the can may be opened to release the effluent to the drain. Wash basins of 2 or more procedure rooms may be connected and drain to a plastic tank. Bleaching powder may be added to the plastic tank. After 1 hour or overnight immersion, effluent may be released to the drain. Such alterations are easy to do for a plumber. Moreover, dermatologist can demonstrate these to any visiting pollution control board official.

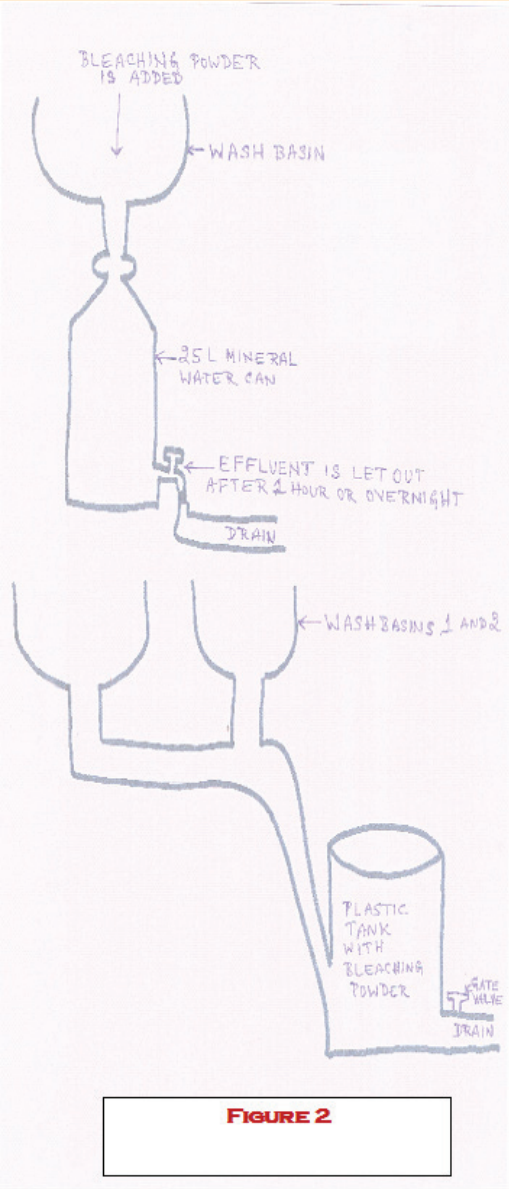


FIGURE 2

LICENCE/ EXEMPTION FROM STATE POLLUTION CONTROL BOARD[2]

State pollution board aims to enlist all health care centres in its jurisdiction. So, the dermatologist must submit duly filled form to the state pollution control board. **Table 4** shows documents to be submitted for licence from pollution board

TABLE 4: DOCUMENTS NEEDED FOR STATE POLLUTION CONTROL BOARD EXEMPTION[3]

1.	Agreement / MOU with local bio-medical waste disposal agency
2.	Notarized affidavit in prescribed format stating that the clinic is handling less than 1000 patients a month
3.	Trade licence from local corporation
4.	Duly filled in form for registering the clinic under state pollution control board (available at their office or website)

The exemption certificate is to be kept at the clinic premises - in case pollution control board officials come for an inspection. Generally, pollution board targets bigger hospitals which generate huge amount of bio- medical waste (aborted fetus, excised body parts etc.).

Having an Incinerator at Skin clinic is an option. But, State pollution board expects the clinic to apply for a licence and submit quarterly reports about the emission of the Incinerator. Bio- medical waste is diverse in nature- bloody dressings, plastic syringes and excised body parts. So, bio-medical waste incinerator must be rigorous enough to incinerate this waste in an eco- friendly manner. With advancements in technology, this may be possible in the future.

MAINTENANCE OF PATIENT RECORDS

- Details of patients treated and procedures done, have to be maintained in an organized manner – ***preferably computerized***. An out-patient register and a ***carbon–copy*** type of prescription pad is a minimum requirement. The dermatologist can retain the carbon copy of the prescription and the notes in the Out-patient register. For medico-legal purpose, the records have to be preserved for ***3 years.***

- Not having even a carbon copy of the prescription can land the dermatologist in trouble- if a medico-legal case is filed by the patient. Patient will have the prescription, while the dermatologist may not have any record.
- Installing **Clinic Management Software (Figure 3)** with imaging facility is a good option- right from the beginning of the clinic. Storage of pre-operative and post-operative digital photographs are also strongly recommended.
- Income tax act mandates that records must be maintained in **Form 3C format (Figure 4)** given below. Patient's name and nature of professional services rendered (consultation, surgery/procedure) must be mentioned. Fees received must be entered in a separate column. Date of receipt of fees must be clearly mentioned- since there are different deadlines for Income tax and Service tax returns. The clinic management software will usually have an option of maintaining records in the above format. Form 3 C can be downloaded from www.incometaxindia.gov.in[5]

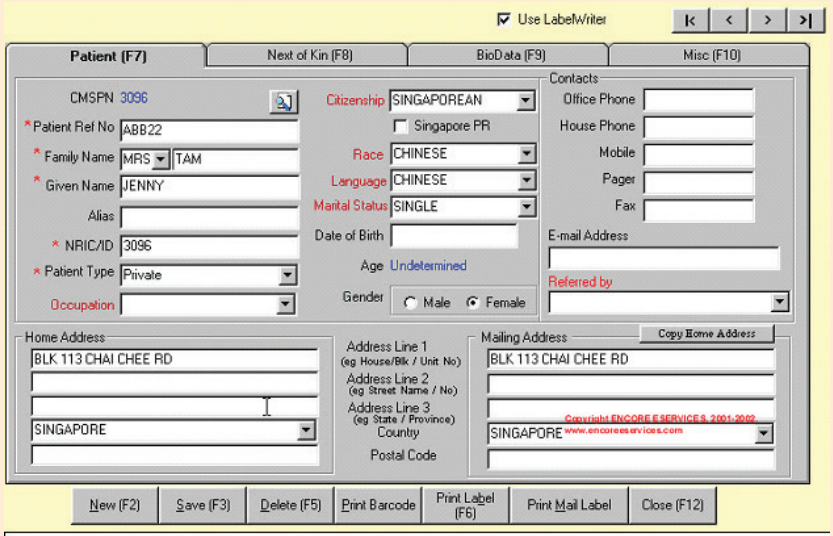


FIGURE 3

FORM NO. 3C
[*See* rule 6F(3)]
Form of daily case register

[TO BE MAINTAINED BY PRACTITIONERS OF ANY SYSTEM OF MEDICINE, I.E., PHYSICIANS, SURGEONS, DENTISTS, PATHOLOGISTS, RADIOLOGISTS, VAIDS, HAKIMS, ETC.]

Date	*Sl. No.*	*Patient's name*	*Nature of professional services rendered, i.e., general consultation, surgery, injection, visit, etc.*	*Fees received*	*Date of receipt*
(1)	(2)	(3)	(4)	(5)	(6)

FIGURE 4

INCOME TAX ACT AND DERMATOLOGIST'S RESPONSIBILITY

Dermatologist' s income is treated as Professional Income, with permissible deductions in **TABLE 5.**

TABLE 5: DEDUCTIONS ALLOWED UNDER INCOME TAX ACT

1. Rent for clinic
2. Utility charges- power, water,
3. Staff salaries
4. Repair and maintenance of clinic and its equipment
5. Interest on loans taken for clinic construction or equipment purchase
6. Car maintenance
7. Depreciation on assets including equipment in the clinic. That is why it is very important to get bills for equipment purchased and NOT to undervalue the equipment.
8. Books and journals for improving professional knowledge are 100 % exempt.
9. Similarly, conference registration, travel and accommodation expenses can also be claimed

- **Disallowance** is done if ***more than Rs. 20,000/- has been paid in cash***. It is supposed to be paid by cheque, demand draft or online bank transfer. When turnover of clinic or professional income exceeds Rs. 25 lakhs, a Tax audit by a Chartered accountant is mandatory.

- **Books of accounts:** They have to be maintained on Financial Year basis from 1st of April to 31st of March. Cash book showing daily cash flow, journal and receipt book must be maintained. Original bills for various expenses of clinic, such as stationery, equipment purchase and consumables must be preserved. This has to be mandatorily done when annual income exceeds Rs. 1.2 lakhs per annum. Practising doctors must maintain daily case register in Form no. 3 C (**Figure 4**), as per Income tax act. [5]

- Failure to maintain these books attracts a **fine of Rs. 25,000/- per year** under Section 271 A of Income tax act. Then, the assessing officer may estimate the income as per his discretion and levy tax accordingly. All these books or computerized records are supposed to be kept at the clinic.

- This is a very large issue and cannot be dealt with in the space of this article- the dermatologist needs to seek the advice of an auditor for further details.

INCOME FROM PHARMACY

This is treated as business income. Accounting has to be done separately. Inventory register has to be maintained. When turnover from pharmacy exceeds ***Rs. 2 lakhs per annum, state VAT tax is applicable.***

DEADLINE FOR FILING INCOME TAX RETURNS

- It is **July 31st** for Individuals and professionals like doctors, E filing is done. By filing returns before July 31st, the assessee or tax payer has the right to file revised returns at a later date- if any error or omission is noted. Also, loss from profession can be carried forward- if returns are filed before July 31st.

- Filing after July 31st attracts interest of 1 % per month till March 31st of subsequent year. If returns are not filed even by March 31st of the subsequent year, the assessing officer will issue a notice to the tax payer. It is upto the assessing officer to accept the reasons for not filing returns.

- Latest amendment to Income tax act has made it mandatory to register mobile number and e mail ID of assessee for better communication.

CONCEPT OF ADVANCE TAX: When tax liability is more than Rs. 10,000/- per annum, the tax payer must pay advance tax in 3 instalments by Sept 15th, Dec 15th and March 15th.

STANDARD DEDUCTION: Latest Income tax act amendments have raised Standard deduction limit from Rs. 2 lakhs per annum to ***Rs 2. 5 lakhs/annum***. Thus, there is a tax saving of Rs. 5,000/ - per annum. For 60 to 80 years age group, Standard deduction is increased from Rs. 2.5 lakhs to Rs. 3 lakhs. For 80 years above, Standard deduction is Rs. 5 lakhs per annum.

SECTION 80 C EXEMPTIONS: These include Public Provident fund savings, health insurance premium, tuition fees of children, interest on housing loan. Together, they are eligible for exemption of ***Rs. 1.5 lakhs***, as per latest amendment.

PROFESSIONAL TAX PAYMENT[5]: As professionals, doctors are expected to register themselves with local Professional tax officer and pay tax annually as per the slab and location. It can be done online. For Karnataka state, the professional tax website is: www.pt.kar.nic.in. [6]

SERVICE TAX AND DERMATOLOGIST'S RESPONSIBILITY[7]

- Health care services provided by doctors including dermatologist for treatment or cure of a MEDICAL CONDITION do not attract service tax. They are included in the negative list of services.

- However, for a service that enhances beauty or looks ***cosmetic procedures***- a client falls under the purview of Service tax. ***When the income from such cosmetic procedures crosses Rs. 10 lakhs per annum, Service tax applies***.

- If dermatologist provides the taxable services under a brand name or trade name (whether the same is registered or not) owned by some other person, he/she does not get the benefit of the threshold exemption and will have to pay service tax on the value of the taxable service right from Re.1 of the service rendered. But if the dermatologist provides service under his/her own brand name, he/she can claim the exemption of Rs. 10 lakhs per annum.

- **Special Procedures** like Hair transplantation, lasers, aesthetic treatments such as botulinum toxin, and cosmetic surgery will attract Service Tax. If reconstructive surgery is performed as a part of treatment of a disease, it is not leviable to Service Tax.

- In a particular year, when dermatologist's turnover **crosses Rs. 9 lakhs**, he/she must apply for the Service tax registration within 30 days of such crossing of the turnover. The application is to be made in the prescribed form to the Superintendent of Central Excise having jurisdiction in the area where the clinic is run. A registration number which is known as **Service Tax Code (STC)** is given.

- Invoices must be issued after obtaining the registration and should be serially numbered. The invoice must mention

  (i) Dermatologist's name, address and STC number
  (ii) Name and address of the receiver of the service
  (iii) Description and value of taxable service provided
  (iv) Service Tax collected from the client and payable to the government.

- The applicable rate of Service Tax including the Educational & Secondary Higher Education cess is ***12.36%.***
- Once dermatologist obtains the STC and turnover of taxable services crosses Rs. 10 lakhs, Service Tax has to be collected from clients and paid to the government on a quarterly basis, by 6th day of the following quarter.
- Service tax records have to be preserved for ***5 subsequent years***.
- Returns are to be filed on a ***half-yearly basis*** i.e. one return for the period from 1st April to 30th September must be filed by ***25th October.*** Then the other returns for the period from 1st October to 31st March must be filed by ***25th April***.

What happens when turnover of taxable services falls below Rs. 10 lakhs after a few years of collecting and paying the service tax?

First of all, dermatologist will know this fact only AFTER that year is over. Hence, he/she will continue to collect and pay the service tax in that year - because turnover in the preceding

year was more than Rs. 10 lakhs. In the subsequent year, he/she is NOT LIABLE to collect and pay any service tax, since the taxable turnover in the preceding year is less than the threshold limit.

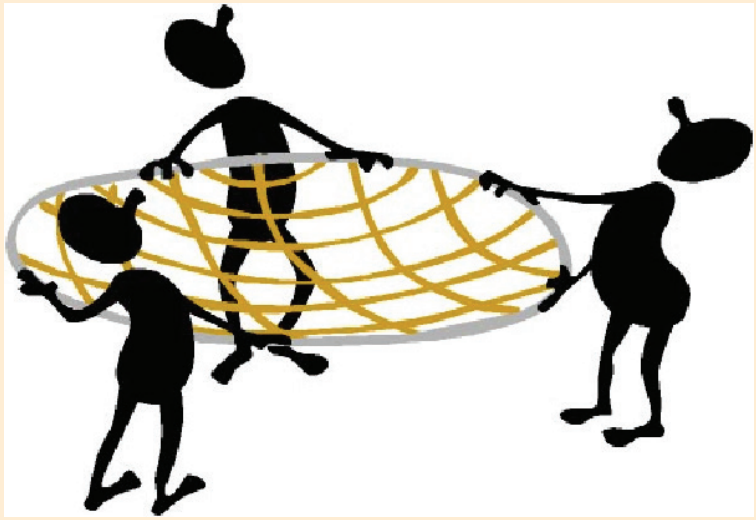
What if dermatologist stops practice of Cosmetology altogether?

He/she is free to surrender registration and have it cancelled.

PROFESSIONAL INDEMNITY INSURANCE

In the current era of medical consumerism, it is extremely important for the practicing doctor to have some form of monetary insurance cover against any medicolegal litigation filed against him/her. To this effect, the PROFESSIONAL INDEMNITY INSURANCE cover for doctors and medical establishments became available, w.e.f. December 1991.

- Insurance companies like *Allianz, Doctor Shield* provide such indemnity, which means reimbursement (to compensate). These insurances are designed to provide the insured doctor against financial consequences of legal liability. If the insured is legally liable to pay monetary damages to others, the policy will indemnify him/her, subject to the terms, conditions and limitations of the contract.
- Indemnity is also available in respect of legal costs awarded against the insured as well as legal costs and expenses incurred by the insured with the written consent of the insurers in the defence of settlement claims.
- Not only is professional indemnity important for a doctor's own safety, it has become mandatory for doctors to have a minimum recommended level of this insurance if they wish to join a corporate hospital as a consultant.
- The amount and annual premium cost of insurance is similar in many ways to other forms of insurances, with coverages ranging from INR 5 lakhs to 25 lakhs or even higher, depending on: (a) doctor's specialty (surgeon's need a higher coverage plan); (b) requirement of the hospital; and (c) individual preference for self-safety.



MANDATORY HOLIDAYS FOR CLINIC STAFF

- Under Labour rules, mandatory holidays have to be declared on 15th August, 26th January, 1st May and 2nd October. States may declare the State formation day as a mandatory holiday (for example, November 1st in Karnataka).
- If the clinic staff is made to work on these days, they must be paid double the wages for the day. Alternatively, an additional day off must be given within a week's time.

MINIMUM STANDARDS OF DERMATOLOGY (CLINIC) AS PER GOVERNMENT OF INDIA GUIDELINES

- Recently GOI has tried to formulate such guidelines and proposed some guidelines -these can be accessed on www.clinicalestablishments.nic.in[1] under the subheading of speciality clinics.

- According to these proposals, a clinic offering laser and cosmetology services must have a dermatologist who has certified ***laser training of 6 months duration***. Standards for equipment maintenance and patient record keeping are also listed. These guidelines are being reviewed by Ministry of Health and will be finalized after feedback from all parties concerned. IADVL has already recommended modifications to these on the ground that these guidelines are too strict and need modification. However, it is important that all members obtain proper hands on certificates for training and keep updating their knowledge as well as skills w.r.t. these and evolving procedures.

MINIMUM STANDARD GUIDELINES FOR OPERATION THEATRE AND LASER ROOM

These have been enumerated in IADVL approved standard guidelines of care and readers are referred to the relevant articles.[10,11] .

"NO, NO! How many times do I have to tell you, nurse? The appendix is a small pink thing about this big ..."

TAKE HOME MESSAGES

- A skin clinic, akin to any medical clinic, is regarded as a business or a trade enterprise by government authorities and as a service provider under Consumer Protection Act 1986.

- To initiate the setting up a clinic, is a working knowledge of various licences and related permissions that need to be obtained, is a must and should be done as soon as possible with the authorities.

- Clinic registration is typically done at the office of the District health officer, which has a cell for registering clinical establishments.

- The certificate is issued after verification by an inspection team; and bears a photograph of proprietor/ dermatologist, a registration number for clinic and stays valid for 2-5 years

- Whether medical profession comes under the category of "trade", is a hotly debated topic. Although in a landmark case, the court gave the verdict in favour of the doctor (i.e. trade license is not required by her as a practitioner), the debate continues. However, obtaining a trade license has its own merits for the doctor himself/herself.

- Proper bio-medical waste disposal (solid as well as liquid) is absolutely mandatory. Not having a system for waste disposal is an offence and can lead to cancellation of license, penalty or even imprisonment.

- Maintenance of patient records is essential. Details of patients treated and procedures done, have to be maintained in an organized manner – preferably computerized. An out-patient register and a carbon–copy type of prescription pad is a minimum requirement, and these records should be maintained for at least 3 years.

- Installing Clinic Management Software with imaging facility is a good option- right from the beginning of the clinic. Storage of pre-operative and post-operative digital photographs are also strongly recommended.

- A Dermatologist' s income is treated as Professional Income and is taxable. Legal and legitimate deductions are allowed as detailed above.

- A book of accounts has to be maintained on Financial Year basis from 1st of April to 31st of March. Cash book showing daily cash flow, journal and receipt book must be maintained. Original bills for various expenses of clinic, such as stationery, equipment purchase and consumables must be preserved. This has to be mandatorily done when annual income exceeds Rs. 1.2 lakhs per annum. Practising doctors must maintain daily case register in Form no. 3 C as per Income tax act, failure to do so may invite penalty.

- Income from pharmacy will also be treated as business income. Accounting has to be done separately. Inventory register has to be maintained. When turnover from pharmacy exceeds Rs. 2 lakhs per annum, state VAT tax is applicable.

- As for any other trade, income tax returns must be filed on or before 31st July of that financial year.

- Service tax issue: Health care services provided by doctors including dermatologist for treatment or cure of a MEDICAL CONDITION do not attract service tax. However, for a service that enhances beauty or looks cosmetic procedures- a client falls under the purview of Service tax. When the income from such cosmetic

procedures crosses Rs. 10 lakhs per annum, Service tax applies. Special Procedures like Hair transplantation, lasers, aesthetic treatments such as botulinum toxin, and cosmetic surgery will attract Service Tax. However, if reconstructive surgery is performed as a part of treatment of a disease, it is not leviable to Service Tax.

- The applicable rate of Service Tax including the Educational & Secondary Higher Education cess is 12.36%.
- Service Tax Returns are to be filed on a half-yearly basis i.e. one return for the period from 1st April to 30th September and the other for the period from 1st October to 31st March.
- It is extremely important for the practicing doctor to have some form of monetary insurance cover against any medicolegal litigation filed against him/her. If the insured is legally liable to pay monetary damages to others, the policy will indemnify him/her, and also reimburse the insured doctor's legal expenses incurred; subject to the terms, conditions and limitations of the contract.
- Having a minimum amount of professional indemnity has become mandatory for joining a corporate hospital as a consultant.
- Mandatory holidays have to be declared for clinic staff, on 15th August, 26th January, 1st May and 2nd October. If the clinic staff is made to work on these days, they must be paid double the wages for the day. Alternatively, an additional day off must be given within a week's time.
- A clinic offering laser and cosmetology services must have a dermatologist who has certified laser training of 6 months duration.
- For other details of minimum standard guidelines for a skin clinic, Dermatosurgery operation theatre and laser room, refer to the sources mentioned in the REFERENCE section.

REFERENCES:

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10. Rajendran SC, Omprakash HM. Standard guidelines for setting up a dermatosurgery theatres. Ind J Dermatol Venereol Leprol 2009;75:76-82.

11. Dhepe Niteen. Minimum standard guidelines of care on requirement for setting up a laser room Ind J Dermatol Venereol Leprol 2009;75:101-10.

Code of ethical conduct for doctors

Dr Ankur Talwar[1], Dr Kshama Talwar, Dr Sidharth Sonthalia
[1]Consultant Dermatologist, Talwar Skin Centre, Lucknow, Uttar Pradesh
[1]docankurtalwar@gmail.com

Most of the doctors in today's world are so busy with their professional life that they often do not pay attention to the nitty-gritties of their profession. Recently we have seen a spate of actions taken against various doctors, either by the MCI or the judiciary, for irregularities which were hitherto unknown to many of us. Most of the doctors are too busy to follow the latest amendments in MCI guidelines. This article is an endeavor to educate our fraternity about the various unpleasant situations they are likely to encounter, and also to remind them of their responsibility towards the patient and the society.

ARE CLINICS COMMERCIAL ESTABLISHMENTS!

"The word 'profession' used to be confined to the three learned professions: the Church, Medicine and Law"

HON'BLE DELHI HIGH COURT (2004)

To understand this concept with a little depth, we need to know the basics of the 'commercial' nature of an establishment; as envisaged and interpreted in our legal system. The Bombay Shops and Establishments Act (BSEA) of 1948, forms the basis of defining an establishment and the legal necessities for its maintenance.

The Bombay Shops and Establishments Act (1948)

Section 2 (4) of the original act defines a commercial establishment as "an establishment which carries on, any business, trade or profession or any work in connection with, or incidental or ancillary to, any business, trade or profession (and includes establishment of any legal practitioner, medical practitioner, architect, engineer, accountant, tax consultant or any other technical or professional consultant and also includes) a society registered under the Societies Registration Act, 1866 (XXI of 1860), and charitable or other trust, whether registered or not, which carries on (whether for purposes of gain or not) any business, trade or profession or work in connection with or incidental or ancillary thereto but does not include a factory, shop, residential hotel, restaurant, eating house, theatre or other place of public amusement or entertainment".

Section 2 (7) deals with the 'Registration of establishments". These acts have on multiple occasions in the past been slapped against medical practitioners to convict them under the premise of exploiting their clinics as 'commercial establishments' without adhering to the norms required for the same.

Thankfully, one of the landmark judgments of the Hon'ble Supreme Court of India in the case of **Dr Devendra M. Surti VS The State of Gujarat** (where the doctor had been convicted by the Gujarat High Court), in 1968 clearly established that "***A Private Doctor's Clinic is not a commercial establishment***" A **1977 amendment** in the act further excluded medical practitioner's establishments from the ambit of 'commercial establishments'. Despite this, cases have been filed by local authorities like municipal corporations in different states to harass doctors, for opening a clinic in his residential premises. They direct you to pay house tax at commercial rates. However there are important judgments which ***allow you to open a clinic at your residence***. Some of the important ones are mentioned in **TABLE 1**.

TABLE 1: SOME LANDMARK JUDGEMENTS REGARDING THE 'COMMMERCIAL' STATUS OF CLINICS

COURT	COMPLAINT	PETITIONER	SECTION	RESPONDENT	JUDGEMENT	DATE
Supreme Court of India	The clinic cannot operate in residential area as it is a 'commercial establishment'	Dr Devendra M. Surti	BSEA; sec 2	The State of Gujarat	A private doctor's clinic is not a commercial establishment	2 May 1968
Delhi High Court	Illegal change of use of property to 'commercial' while the sanctioned use was 'residential'	MCD, Delhi (filed the case in 2004)	Section 437 of MCD	Dr D V Chug, Practitioner, Rajouri Garden (New Delhi)	The professional establishment of a doctor cannot come within the definition of commercial activity.	2 July 2012
Mumbai High Court	The clinic cannot operate in residential area as it is a 'commercial establishment'	Dr Shubhada Motwani (filed the writ petition in 2002)	BSEA; sec 2	The State of Maharashtra	A private doctor's clinic is not a commercial establishment	26 June 2014

However some states have imposed certain restrictions like the total area of the clinic cannot be more than 50 sq meters on single floor or 25% of total constructed area (Haryana and Uttar Pradesh).

HEALTH PROFESSIONALS & PHARMACEUTICAL INDUSTRY

Well, before we jump onto the 'latest' MCI recommendations directing the ethical relationship between physicians and the pharmaceutical industry, let us flip a few pages of history and have a glimpse in to the evolution of this concept. The **Indian Medical Council Act, 1956 (102 of 1956)** of the Medical Council of India, forms the basis of professional and ethical regulatory code for doctors. In December 2009, the MCI made an amendment and what came into force was called the "**Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009**." The sub-section 6.8 provided the 'Code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry". The details of this code are mentioned below. However, the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 was amended once again in May 2010. This was then christened "**Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations 2010**"; which currently forms the standard protocol to be followed. Below, find the section 6.8 which gives general description of limitations to acceptance of cash/ kind from the pharmaceutical industry, followed by section 6.8.1, which has objectified the limits.

Code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry

Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009

SECTION 6.8

GIFTS: A medical practitioner shall not receive any gift from any pharmaceutical or allied health care.

TRAVEL FACILTIES: A medical practitioner shall not accept any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME programme etc as a delegate.

HOSPITALITY: A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext.

CASH/MONETARY GRANTS: A medical practitioner shall not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose in individual capacity under any pretext. Funding for medical research, study etc. can only be received through approved institutions by modalities laid down by law/rules/ guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed.

MEDICAL RESEARCH: A medical practitioner may carry out; participate in research projects funded by pharmaceutical and allied healthcare industries. A medical practitioner is obliged to know and adhere to the fulfilment of the regulations imperative for undertaking any research assignment / project funded by industry – for being proper and ethical.

PROFESSIONAL AUTONOMY: In dealing with pharmaceutical and allied healthcare industry a medical practitioner shall always ensure that there shall never be any compromise either with his / her own professional autonomy and / or with the autonomy and freedom of the medical institution.

AFFILIATION: A medical practitioner may work for pharmaceutical and allied healthcare industries in advisory capacities, as consultants, as researchers, as treating doctors or in any other professional capacity. In doing so, a medical practitioner shall always ensure that: 1) His professional integrity and freedom are maintained, 2) The patients' interests are not compromised, 3) Such affiliations are within the law, and 4) Such affiliations/employments are fully transparent and disclosed.

ENDORSEMENT: A medical practitioner shall not endorse any drug or product of the industry publically. Any study conducted on the efficacy or otherwise of such products shall be presented to and / or through appropriate scientific bodies or published in appropriate scientific journals in a proper way.

Now, the Latest.....

Code of conduct for doctors in their relationship with pharmaceutical and allied health sector industry

Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2010

SECTION 6.8.1

FACILITY OFFERED TO THE DOCTOR	LIMIT (incurred in the form of a gift/travel expense/ hospitality expense/cash)	PENALTY
	INR 1,000 – 5,000	Censure
	INR 5000 – 10,000	Removal from Indian Medical Register or State Medical Register for 3 months
	INR 10,000 – 50,000	Removal from Indian Medical Register or State Medical Register for 6 months
	INR 50,000 – 1,00,000	Removal from Indian Medical Register or State Medical Register for 1 year
	More than INR 1,00,000	Removal from Indian Medical Register or State Medical Register for more than 1 year

For the other four components of the code, namely Medical Research, Professional autonomy, Affiliation and Endorsement, if the norms are not adhered to; the penalty is:

First time – Censure;

Thereafter - Removal of name from Indian Medical Register or State Medical Register for a period depending upon the violation of the clause.

ADVERTIZING GUIDELINES FOR A DOCTOR'S CLINIC/ESTABLISHMENT

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"Doing work without advertising is like winking at a girl in the dark. You know what you are doing but nobody else does!"

Every practitioner, especially those with freshly started private practice, need to advertize about their clinic/establishment, its location, available facilities etc. The healthcare system in India is pole apart from that in the Western world. In the US for example, a dermatology patient often has to wait for weeks to months to get an appointment with a dermatologist in a Govt. Hospital or spend a stupendous amount of money to avail the consultation of a private practitioner dermatologist. In contrast, getting the appointment of a private practitioner dermatologist in India does not need a referral, and in metro cities in particular, there are areas where one patient has the 'option' of 4-5 dermatology clinics/establishments within a mile distance. Thus, advertising becomes important!

Once again, the MCI has issued guidelines regarding this aspect of practice. Just have a glimpse. In this article, we are quoting relevant statements from Section 6.1 that deals with this issue.

MCI Code of Ethics Regulations, 2002
(AMENDED UPTO DECEMBER 2009)

- A physician shall not make use of him/her (or his/her name) as subject of any form or manner of advertising or publicity through any mode either alone or in conjunction with others which is of such a character as to invite attention to him or to his professional position, skill, qualification, achievements, attainments, specialties, appointments, associations, affiliations or honours and/or of such character as would ordinarily result in his self aggrandizement.
- A physician shall not give to any person, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report or statement with respect of any drug, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode.
- A physician shall not boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode.

- Printing of self photograph, or any such material of publicity in the letter head or on sign board of the consulting room or any such clinical establishment shall be regarded as acts of self advertisement and unethical conduct on the part of the physician.
- A physician should not contribute to the lay press articles and give interviews regarding diseases and treatments which may have the effect of advertising himself or soliciting practices.
- A medical practitioner is however permitted to make a formal announcement in press regarding the following:
  1. On starting practice.
  2. On change of type of practice.
  3. On changing address.
  4. On temporary absence from duty.
  5. On resumption of another practice.
  6. On succeeding to another practice.
  7. Public declaration of charges.
- Printing of sketches, diagrams, picture of human system on the letter heads or sign board of the consulting room is allowed.
- The physician is open to write to the lay press under his own name on matters of public health, hygienic living or to deliver public lectures, give talks on the radio/TV/internet chat for the same purpose and send announcement of the same to lay press.

CONTENTS OF SIGN BOARD and PRESCRIPTION LETTER PADS

It is improper for a physician to use an 'unusually large' sign board and write on it anything other than his name, qualifications obtained from a University or a statutory body, titles and name of his specialty, registration number including the name of the State Medical Council under which registered. The same should be the contents of his prescription papers.

RECENT LANDMARK CASES AGAINST DOCTORS' ADVERTISEMENTS

AUTHORITY	COMPLAINT	RESPONSE AND OUTCOME
Ethics Committee	Against advertisement given by doctors of Nova Orthopedics Spine Hospital, Nehru Enclave., dated 15.05.2013 in **Hindustan Times**	Chairman and Medical Superintendent of Nova Orthopaedic Spine Hospital, Nehru Enclave, appeared before the Ethics Committee; accepted responsibility for the advertisement and it being unethical. He tendered unconditional apology and stated that they will be putting an advertisement to the Newspaper for withdrawal of the advertisement.
Ethics Committee	Against newspaper Clipping published in the **Times of India** dated 23.08.2013 with regard to Saket City Hospital, New Delhi.	The Medical Director of Saket City Hospital, New Delhi appeared before the Ethics Committee on behalf of Chairman. He apologized for the advertisement given in the newspaper and stated before the Committee that they will be putting an advertisement to the Newspaper for withdrawal of the advertisement.

In both cases, on submission of proof of withdrawal of advertisement published in the newspaper, the apology of the Hospital was accepted by the Ethics Committee. Accordingly, the matter was disposed off by MCI.

CME HOURS ALLOTMENT
NECESSITY & RECENT REGULATIONS

Importance of credit hours and updating knowledge of doctors has been globally accepted and also been approved by all the state medical councils on February 2012 and already endorsed by Medical council of India. This is necessary as the modern medical science is growing leaps and bounds and the update for any medical doctor is necessary for overall societal betterment. The doctrine of patient "deserves the best" has to be respected.

MCI's latest Guidelines on allotment of Credit hours to Doctors

ACTIVITY	NATURE	CONTRIBUTION	CREDIT HOURS
National or regional CME program/ conference /Workshop	8-hours duration*	Delegate	**2**
National or regional CME program / conference /Workshop	The event has to been accredited with a particular number of credit hours	Speaker	**1 per talk** PLUS credit hours of the event as a delegate
International C.M.E.'s/ Conferences	Not specified	Delegate OR Faculty	To be decided by MCI on an individual basis
Undergoing Training	Post Graduate courses**	Trainee	**4 per year** for the course's total duration
Medical teachers	Working in MCI-recognized colleges and universities	Teaching***	**4 per year**
Publication	Medical Text Book	Author/Editor Order – 1st 2nd	 **4** **2**
Publication	Chapter in a Medical Text Book	Author Order – 1st 2nd	 **2** **1**
Publication	International / National indexed Journal	Authored 'Original Article' Order – 1st 2nd	 **2** **1**

*Any CME program / conference / workshop with less than 4 hours duration will not be considered for CME accreditation.
** For example - Diploma, M.D., M.S., D.N.B., M.Ch., D.M., Fellowships, Memberships etc. from recognized/reputed Institutions in India or abroad.
*** Have to produce a certificate from the Head of the Department or Institutional Head

Need for accumulating Credit Hours

The requisite number of credit hours need to be accumulated over a duration of time (as mentioned below) in order to renew MCI or State Medical Council Registration (typically required once every five years). There are some differences in the need and amount of credit hours allotted in certain states.

CATEGORY OF DOCTORS	NUMBER OF CREDIT HOURS	DURATION	RENEWAL OF REGISTRATION
All doctors <65 years of age	6	Per year	-
All doctors <65 years of age	30	In 5 years	Once every 5 years
All doctors >65 years of age	Not required		Once every 5 years

COMMENT: *Although renewal cannot ideally be done without presentation of proof of credit hours, it is considered that as of now, the enactment of this guideline is apparently not very strict. But with radical changes in policies of MCI and guidelines for doctors coming in from various authorities with involvement of the legal system, it is a matter of time that this enforcement will become absolutely mandatory! Enforcement of the CME credit points requirement has already taken a strict turn in states like Maharashtra and Andhra Pradesh. Thus, it is better to be ready for any eventuality. By keeping yourself updated through attendance at CMEs and authoring publications, not only do you become a better doctor, the special need for 'accumulating' credit hours will practically cease and renewal will not be a problem!*

Solving the Enigma

Are Doctors allowed to dispense drugs at their Clinics!!

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"There are black sheep in every profession and medical line is no different. But, this doesn't mean that everyone is tarnished"

Dr Rohit C Agrawal, former president, Indian Academy of Paediatrics

With a majority of dermatologists having an additional facility of dispensing relevant drugs and even appliances at their clinic, this has become the talk of the fraternity! While well-established dermatologists and large centers have separately carved out 'pharmacy' within the premises of their establishment; at smaller and recently-opened clinics, drugs are often dispensed at the reception area itself. Before we jump onto the statutory regulations and legal angle of this issue, lets discuss the merits and demerits of a dermatologist (or a Registered and qualified physician) dispensing his prescription drugs at his own establishment **(Table 1):**

TABLE 1: MERITS AND DEMERITS OF A DERMATOLOGIST DISPENSING HIS OWN PRESCRIBED DRUGS AT HIS CLINIC/ESTABLISHMENT

	
A much better convenience for the patients, who can avail of the consultation as well as collect all the prescribed medicines from one source (the point of care), instead of running from pillar-to-post to different pharmacies. *In personal experience of the author, this is especially convenient for elderly patients who come all by themselves without a supportive younger family member or friend who could have otherwise done running about to collect medicines for them*	Profit margin for doctors – Clinical pharmacies are often given profit margins ranging from 10-40%. The skepticism of this concept tempting them further into unethical prescription of drugs that are expensive (with 'good profit margins') and perhaps unnecessary for the patient.

By purchasing medicines at a doctor's dispensary, the patient can almost be sure that the doctor's writing will not be misread and in case of confusion, the doctor will be around to clarify. *As an example (personal experience of the author), a patient with Parthenium Dermatitis was prescribed Tab Azathioprine 50 mg daily for a month, whereas when the patient bought from an external pharmacy, he was issues Tab Azithromycin 500 mg, which he took for a month! Fortunately, he did not sustain any adverse effect.*	As an extension of the above point, over-prescription and poly-pharmacy may be adopted by 'greedy' practitioners.
Improved patient compliance and adherence to treatment and ease for the doctor to consider follow-up therapy in case of sub-optimal response, as he can be sure that the medicines previously prescribed were of standard quality but still did not provide optimal results	Also, the patient has to buy what is offered by the doctor's dispensary and is left with no choice, even if the prescribed medicine is costly and an alternative medicine might be available outside for a less price.
Since registered pharmacies in India also sometimes function in connivance with certain pharmaceutical companies, there will be no possibility of substitution with another brand whose bioequivalence may be questionable!	Not just for the patient, but maintaining a proper pharmacy with human resource, stock space, records and inventories, regular self-inspections including weeding out expired stock becomes a huge additional task in itself for a busy physician.
Also, just to ensure that he or she doesn't get a bad name, the doctor would be cautious that the medicines dispensed at his or her dispensary is of good quality and is not expired. In case of a mis-hap due to quality of medicine, the primary culprit in this case would be the pharmaceutical company. The doctor is a secondary source to be held responsible as he won't sell medicines from a dubious source, risking his practice and reputation, just to generate some extra profits.	Qualification of the dispensing staff (and his/her knowledge about the prescribed drug) may become an occasional issue

LACUNAE IN OUR UNDERSTANDING AND KNOWLEDGE

There are three critical questions pertaining to this issue:

QUESTIONS THAT NEED TO BE ANSWERED

1) Is a private practitioner allowed to dispense drugs at his clinic?
2) If yes, does he need a special drug license or the clinic/centre registration is sufficient?
3) If allowed to dispense (based on fulfilment of the criteria mentioned above)
   - What all drugs are allowed to be dispensed?
   - What are the specifications w.r.t. the amount of area dedicated for this purpose e.g. need for a separately designated area as 'pharmacy' or can the reception itself may be used for this purpose?
   - Are there any minimal qualification standards for the person dispensing the drug?
   - Are there any specifications regarding the stocking of drugs – area allotted, number/cost worth of drugs allowed to be kept at a time, maintenance of a particular format of registers etc.

Unfortunately, the questions which are obviously very relevant have dubious and unclear answers. MCI regulations (*vide infra)* address this issue with extremely insensitivity. At the same time, this issue has often become an unsolicited source of harassment of doctors by the police or other local authoritative bodies, followed by prolonged legal discourse. In the ensuing discussion, I have tried to answer some of these questions by accumulating information and regulations from various sources dealing with the subject.

LESSONS FROM HISTORY: OVERVIEW OF NON-PRACTIONER FRIENDLY CASES AND PETITIONS

The Landmark case of Kerala State Drugs Control Department VS Kerala's Qualified Private Medical Practitioners Association

7 August 2014, Additional Sessions Court, Kollam, Kerala

Dr P Kamalasanan, a private medical practitioner from Kollam in Kerala was punished for dispensing drugs without a license. Additional Sessions Judge, Kollam on **7 August 2014**, sentenced Dr Kamalasanan of one-day "imprisonment" and also fined him Rs 1.20 lakh on the charges of running a pharmacy without a license from his clinic. [1] At the time of inspection by the state drugs control department, Dr Kamalasanan was reported to have found practicing along with his wife at his single-doctor clinic, Nava Bharat Hospital, at Kollam in Kerala. The petitioner in this case was the state drugs control department, and the implicated doctor responded with support from an umbrella association called Qualified Private Medical Practitioners Association (QPMPA), Kerala.

IN FAVOR OF THE PETITION

The state drugs control department (SDCD) stands to its interpretation that ***only a single-doctor clinic can keep medicines and dispense them to patients***, but he cannot open a separate pharmacy in his premises or sell drugs across the counter, for which it would be mandatory for him to obtain a license under the rules. As per them, a doctor cannot dispense medicines on the prescription given by another doctor, neither can a visiting doctor dispense medicines from that clinic. In case a doctor couple practices together and found dispensing drugs to the patient from the same counter without a license, they shall also be liable to punishment. The Kerala chapter of Indian Medical Association (IMA) also stood by the interpretation of the state drugs control department.[2]

AGAINST THE PETITION

Dr Kishore Kumar, national secretary, QPMPA, told India Medical Times, "*The Drugs & Cosmetics Act, 1940 & Rules, 1945 is extremely clear in every sense.* ***The lack of clarity is with the drugs department*** *which badly needs an entry into private clinics. Dr Kamalasanan is a victim of misinterpretation of the Drugs Act, 1940. The Drugs Act is very clear that private clinics, the place where professional activities of registered medical practitioners take place, are exempted from the drug licence. Private clinics are fully protected from harassment of drug controllers.*" Dr Asokan further argues, "*Though, under the Drugs and Cosmetic Rules, a doctor has a privilege to dispense drugs at his disposal without the need of a license, the difference here is quite clear. A clinic run by single doctor is different from a hospital where more than one doctor or consultants visit.*"

UPDATE: Unfrotunately, after losing the case in the Kerala High Court and then in the Supreme Court of India, the QPMPA informed the President of India Pratibha Patil and the Chief Justice of India that

due to the ignorance of the bureaucracy one clause in item 5 of Schedule K in the D&C Act 1940 and Rules 1945 is misinterpreted and it needs amendment. Following it, the Central Drugs Standard Control Organisation (CDSCO) invited the QPMPA office-bearers for a detailed discussion and interpretation of the clause in item 5 of the Schedule K of the Drugs & Cosmetics Act (D&C Act).

COMMENT: *While the medical fraternity remains divided on the interpretation of the rules by the judiciary and the drugs control department, this has become a landmark case for this issue and initiated a very pertinent debate to clarify this issue once and for all! The discussion below will attempt to crystallize few concepts regarding this ongoing debate.....*

Other notable attempts to curb the Practitioner's right to dispense drugs from his/her clinic

Pharma trade associations from Maharashtra approached the state government requesting them to formulate guidelines to ensure stronger policing of the drug distribution system in the state to restrict doctors from indulging in unethical practice of distribution of medicines to the patients directly.[3] It was suggested that steps should be taken to correct the loophole in Schedule K, so that it can prevent misinterpretation by the doctors for their benefit. The other reason quoted was that clinics do not have proper storage facility for stocking the medicines which is essential for maintaining the stability and efficacy of the drugs.

In the recent years, the Gujarat Food & Drugs Control Administration (FDCA) has also raided and seized over huge quantity of drugs from over three to four such doctors from across Gujarat who were running pharmacy shops parallel to their clinics to dispense medicines.[3]

What is the real state-of-affairs?

Let's now discuss the different statutory and legal positions taken by relevant authorities and attempt to summarize the concept, as it stands today.....

Laws related to manufacture, sale, import, export and clinical research of drugs and cosmetics in India

- The MCI Code of Ethics Regulations, 2002 (amended in 2009)
- The Drugs and Cosmetics Act, 1940
- The Pharmacy Act, 1948
- The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
- The Narcotic Drugs and Psychotropic Substances Act, 1985
- The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
- The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act)

Let's start with what our apex guide, the MCI has to say about it [4]:

MCI Code of Ethics Regulations, 2002

(Amended till December 2009)

SECTION 6.3

It is **not unethical** for a physician to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient. Drugs prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the **drug**.

A physician should not run an open shop for sale of medicine for dispensing prescriptions **prescribed by doctors other than himself** or for sale of medical or surgical appliances.

COMMENT: The ambiguity of these guidelines has been highlighted. The ethicality of the whole concept has been rendered confusing the quadruple negative of "NOT UNETHICAL". Further, there is no definition of "DOCTORS OTHER THAN HIMSELF". What about a Senior dermatologist working in a group practice with junior consultants prescribing drugs during their consultation slots. What if the centre is catering to two or more related specialties, which is a common case when doctor couples run a clinic or centre together, e.g. dermatologist-dentist, dermatologist-gynaecologist etc. Will such additional doctors come under the purview of 'doctors other than himself'. Alas, there is no clarity at least from the MCI. But let's read further.....

Clinical Establishment Act Standard for Clinic/Polyclinic with Dispensary Standard No. CEA/Clinic-009 [5]

SECTION 6

6.1 The clinic/polyclinic shall have essential equipments as per Annexure 3 and emergency equipment as per Annexure 4.

6.2 Other equipments as per the scope of service being practiced shall also be available. **6.3** Adequate space for storage of equipments and medicines shall be provided and if available medicines shall be stored as per manufacturer's guidelines. The equipment shall be of adequate capacity to meet work load requirement.

6.4 All equipment shall be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment shall be done.

6.5 The clinic/polyclinic shall have basic minimal essential drugs as per Annexure 6, ***however other drugs as per the scope of service being practiced may also be available!***

COMMENT: Although CEA deals primarily with aspects of clinic establishment, the last highlighted statement in **para 6.5** lends indirect support to a practitioner having drugs '*as per the scope of the service being practiced*'.

Drugs and Cosmetic Rules, 1945

(EXEMPTION to Chapter IV of THE DRUGS AND COSMETICS ACT, 1940; 30 Nov 2004)

SCHEDULE 5K (Rule 123)

Part XI of the THE DRUGS AND COSMETICS RULES, 1945; (as corrected up to the 30th November, 2004) details on the **EXEMPTION to Chapter IV** of **THE DRUGS AND COSMETICS ACT, 1940.**[6]

- The drugs specified in schedule K shall be exempted from the provisions of Chapter IV of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule.
- **Table 2** enumerates further details on this issue, once again reiterating that a practicing doctor/ dermatologist, does not need a license to dispense his own prescribed drugs with few exceptions:

TABLE 2: CLASS OF DRUGS THAT MAY OR MAY NOT BE ALLOWED TO BE DISPENSED FROM A DOCTOR'S CLINIC AND THE ASSOCIATED EXTENT AND CONDITIONS OF EXEMPTION FROM NEEDING A PHARMACY LICENSE

CLASS OF DRUGS	EXTENT & CONDITIONS OF EXEMPTION
[5] Drugs supplied by a registered medical practitioner to his own patient or any drug specified in Schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the registered medical practitioner is not (a) keeping an open shop or (b) selling across the counter or (c) engaged in the importation, manufacture, distribution or sale of drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules thereunder.* * Amended by Notification No. F. I-22/59-D dt.. 9-4-1960.	All the provisions of Chapter IV of the Act and the Rules made thereunder, subject to the following conditions: (1) The drugs shall be purchased only from a dealer or a manufacturer licensed under these rules and records of such purchases showing the names and quantities of such drugs together with their batch numbers and the names and addresses of the manufacturers shall be maintained. Such records shall be open to inspection by an Inspector appointed under the Act, who may, if necessary, make enquiries about purchases of the drugs and may also take samples for test.* *Amended by Min. of Health & F.W. Notification No. X- 11013/3/76-D & MS In the case of medicine containing a substance specified in 1 [Schedule G, H or X] the following additional conditions shall be complied with]: (a) the medicine shall be labelled with the name and address of the registered medical practitioner by whom it is supplied; (b) if the medicine is for external application, it shall be labelled with the words "For external use only" or if it is for internal use with the dose; (c) the name of the medicine or ingredients of the preparation and the quantities thereof, the dose prescribed, the name of the patient and the date of supply and the name of the person who gave the prescription shall be entered at the time of supply in register to be maintained for the purpose; (d) the entry in the register shall be given a number and that number shall be entered on the label of the container; (e) the register and the prescription, if any, on which the medicines are issued shall be preserved for not less than two years from the date of the last entry in the register or the date of the prescription, as the case may be. The drug will be stored under proper storage conditions as directed on the label.* *Omitted G.S.R. 462(E), dt. 22.6.1982.

[16] **Cosmetics*** *Ins. by Notification No. 1-36/64-D, dt. 17.8.1964	The provisions of Chapter IV of the Act and the Rules made thereunder, which require them to be covered by a licence for sale provided that the cosmetics sold, if of Indian origin, are manufactured by licensed manufacturers.
[28] **White or Yellow Petroleum Jelly I.P. (Non-perfumed)*** *Ins. by G.S.R. 753(E), dt. 4.11.1999	The provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered by a sale licence, subject to the condition that such a product has been manufactured under a valid drug manufacturing licence.]
Drugs supplied by a **hospital** or dispensary maintained or supported by Government or local body	The provisions of Chapter IV of the Act and the Rules thereunder which **require them to be covered by a sale licence**

COMMENT: My interpretation of the above:

- ✓ *Private Practitioners are **ALLOWED to dispense** or sell any drug without a license, provided the drugs are dispensed to their **OWN patients** within the premises and not sold to outsiders under the sign of "Pharmacy", "Pharmacist," "Dispensing Chemist" or "Pharmaceutical Chemist" or any other sign that indicates sale of medicines.*

- ✓ *It should **not be an open pharmacy which dispenses other drugs**, prescribed by other physicians.*

- ✓ *It is important to note that **drugs that come under the category of "COSMETICS" need a license for sale!** Dermatologists need to take cognizance of this, since we often prescribe 'cosmetic' grade drugs to our patients. It is important to know that drugs being sold at your pharmacy ideally fall in the "medical" and not "cosmetic" category as defined by the Drug Controller of India (DCI). Else, they **need to obtain a license for legally-approved dispensation of cosmetic brand products** through the proper channel by filling forms 20-A, 20-B etc.*[7]

- ✓ *Since a pharmacy license is not required by clinics, other issues such as amount of stock store allowed, space needed, qualification of the dispensing person, maintenance of records and inventories remains a grey area!*

LOOKING INTO THE FUTURE

The Drug Consultative Committee (DCC) will soon examine the provisions listed under Schedule K of the Drugs and Cosmetics (D&C) Act, with a view to control the practice of registered medical practitioners engaged in stocking and dispensing of medicines directly to the patients without license.[8]

TAKE HOME MESSAGES

- ✓ Private Practitioners are ALLOWED to dispense or sell any drug without a license, provided the drugs are dispensed to their OWN patients within the premises and not sold to general population.
- ✓ It should not be an open pharmacy which dispenses other drugs, prescribed by other physicians.
- ✓ The acts mentioned and amended from time to time under clauses of MCI, D&C, and CEA support the above-mentioned statement; to the best of the author's understanding, logic and knowledge of legal know-how. However, this paper should not be considered sacrosanct, and one must go through the references mentioned below to empower themselves more regarding this subject.
- ✓ It is important to note ***that drugs that come under the category of "COSMETICS" need a license for sale!*** Dermatologists need to take cognizance of this, since we often prescribe 'cosmetic' grade drugs to our patients. It is important to know that drugs being sold at your pharmacy ideally fall in the "medical" and not "cosmetic" category as defined by the Drug Controller of India (DCI). Else, they need to obtain a license for legally-approved dispensation of cosmetic brand products through the proper channel.
- ✓ Since a pharmacy license is not required by clinics, other issues such as amount of stock store allowed, space needed, qualification of the dispensing person, maintenance of records and inventories, remains a grey area!
- ✓ Unlike clinics, hospitals need to obtain a proper pharmacy license through proper channel. So please check if your establishment comes under the purview of a clinic or a hospital!

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Practice Updates

भारतीय आयुर्विज्ञान परिषद्
MEDICAL COUNCIL OF INDIA
पॉकेट – 14, सेक्टर – 8, द्वारका, नई दिल्ली – 110 077
Pocket – 14, Sector – 8, Dwarka, New Delhi – 110 077 URGENT

No.MCI-211(2)(G-circular)/2014-Ethics/ 122213. Date: 31/07/2014

To,

1. Presidents/Registrars of all the State Medical Councils.
2. Principal Secretary/Secretary of Health of all the State Govts.
3. Principal/Dean/Director of all the Medical Colleges in the Country/Director Generals/Directors of Health Services of State Govts.

Sir,

The Medical Council of India had received a complaint with regard to various Diagnositc Centres giving cuts and commissions to doctors for referring patients to diagnostic centers and also prescribing the investigations unnecessarily which are not required. While the Ethics Committee of MCI has been investigating on the sting operation carried out by News Nation Channel against the nine Diagnostic Centres, the Council has taken the matter seriously and it is impressed upon all the State Medical Councils to ensure that –

1. They should investigate all the complaints received with regard to unethical practice adopted by the Registered Medical Practitioners in the respective State Medical Councils under Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, under clause 6.4.1 & 6.4.2 for prescribing the investigations and referring to Diagnostic Centres for their personal benefits. Using & keeping Agents/Touts for procuring patients for diagnosis or treatment by medical practitioners is also unethical as mentioned under clause 7.19. The State Medical Councils should also send the necessary directions/Advisory to all the medical practitioners registered with their Councils to refrain from such unethical/illegal practices and action taken against the medical practitioners for violating the ethical regulations.

THE TIMES OF INDIA
Dt. 19th August, 2014

MEDICAL COUNCIL OF INDIA
Pocket-14, Sector-8, Phase-1, Dwarka, New Delhi-110077

This is for the information of the public at large that Indian Medical Council (Professional Conduct Etiquette & Ethics) Regulation, 2002 of Medical Council of India is required to be strictly adhered to by all the registered medical practitioners under the IMC Act, 1956. Public is hereby informed that whenever they come across any unethical act or medical misconduct (commission / cuts) advertisements / illegal abortion, unnecessary investigation & nexus with drug companies etc.), should immediately approach and lodge a complaint with the appropriate Medical Council with which the Medical Practitioner is registered.

Dr. Reena Nayyar
Secretary (I/c)

The Indian Medical Association is drawing up a digital code of conduct for doctors to help them maintain the profession's code of ethics as a growing number of portals connect them with patients.

The doctors' body says soliciting patients through websites, paying fees to agents that host such portals and doctors boasting of achievements in the social media would be dubbed unethical under this code.

While some portals and digital directories say their goal is to empower patients, the IMA says many are programmed to divert patients from one doctor to another and some charge a fee from doctors - acts that are unethical and illegal.

"Many portals which aggregate doctors' databases and host them seeking to fix appointments with one doctor over the other are violating the law by advertising and soliciting patients, which is not allowed under Medical Council of India's ethics regulations," KK Aggarwal, secretary general of the IMA, toldET. Over a fifth of 6 lakh practising doctors in India are part of some form of online database today, according to industry estimates.

Many times, doctors don't realise that it's not legal, said Aggarwal, citing this as the primary reason for preparing a digital code of conduct. The code will help clarify that ethics that apply in the real world also extend to the virtual world, he said.

When patients search for a doctor, some portals and apps display the address of three of four other doctors with the same specialty in the area, he said. "That is not allowed under MCI ethics regulations, which prohibit doctors from soliciting patients directly or indirectly," said Aggarwal.

So is paying a cut to an agent, he said. "Many portals also charge a fee from the doctors for registration and hosting them on their sites and that is illegal as well. At times, they also promise a certain flow of patients. We know this because we also get calls from many of these portals, seeking a cut or commission," Aggarwal adds.

Bragging about medical achievements by posting details of patients on Facebook, Twitter and other social media platforms compromises privacy and would be dubbed unethical. Portals such as Practo and Help-MeDoc told ET they don't charge doctors for registration. Many tech startups in health care say they offer consumers more choice and help them to make informed decisions. Such a code of conduct, if framed, shouldn't stifle innovation and throw the baby out with the bath water, they said.

UPA regime's strategy to buy time – in 2005, entrusting a national commission to study the issue and in 2011, deciding

damentals of human dignity, human self-respect and even some of the attributes of human personality". Linking

adding it would be "iniquitous" to grant "converts" the benefits targeting SCs.

receiving a list of names from the French government few years back. PTI

the financial details of damaged crops. A final decision about compensation will be

farmers in Timeli, one of the worst affected villages in Bundi district.

farmers from SDRF, which has Rs 5,270 crore for utilization in this fiscal.

Doctors upload pics online, violate patient confidentiality

Ekatha.Ann@timesgroup.com

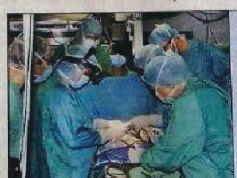
Chennai: Six months after a massive tumour was removed from his heart, Mohammad Faizal saw his innards on public display on social networking site Facebook. The culprit who posted the picture was the same man who saved him—his surgeon.

Although Faizal's name wasn't mentioned, there was enough information in the doctor's descriptive 150-word caption to make the 45-year-old squirm. "There were even a few comments poking fun at my condition," he said, adding he had no clue the photo had been uploaded online. The surgeon later apologized and removed the picture when he protested.

The entry of gadgets into operation theatres might help doctors provide educational insights for other medical professionals, but it has also led to a spike in violations of patient confidentiality. While Faizal had chanced upon his photo, in most cases patients are in the dark about their pictures being posted by the people they trust their bodies with.

"We don't have a number as very few know their photos are being circulated without their consent, but there's a definite increase in the number of doctors using social networking sites as a forum to showcase their surgeries, caring little about their patients' confidentiality," said national coordinator, academic wing of Indian Medical Association J A Jayalal.

Although there is no law that addresses the issue, the code of ethics laid down by the Medical Council of India states that the patient's name and personal details should not be revealed without their consent unless asked for by the courts.



In many cases, the violation is subtle. Many doctors admitted to having used public online platforms to brainstorm about specific cases with fellow practitioners and some put them up as trophies. While names are withheld, they inadvertently supply other details like age and personal description that allow patients to be identified

Sometimes the violation is obvious with the patient's personal details like name and age being revealed, along with a picture of the face: "I recently put a photo of a 33-year-old woman with a tumour on her tongue on my Facebook wall. My intention was only to start a discussion among my colleagues," said a senior oncologist in Chennai. "A doctor from the US messaged me to say I was violating the patient's confidentiality and I ought to remove the photo. I did," he said.

"Even if it's an X-ray or an imaging used to diagnose the patient, his or her consent must be sought," said former editor of Indian Journal of Medical Ethics Dr George Thomas. "Do we have adequate guidelines? Yes. Are they followed? Not really. Are violators punished? Rarely," he said.

In Sept 2014, three doctors in Kerala were suspended on charges of taking pictures of a caesarean section procedure on their mobile phones and circulating them on WhatsApp. "In the case, the woman stumbled upon the pictures and approached the police. Some patients give their consent, but doctors don't really explain where or what they are going to use it for," said Dr Jayalal. Senior doctors attribute the trend to technological naiveté, carelessness and ignorance of ethics. "Almost every surgery is described as extraordinary and posted on social networking sites. We keep asking IMA members to curb this practice unless done specifically for educational purposes," said Dr Jayalal.

Madras HC advocate Richardson Wilson said the courts had no direct power over doctors unless the patient filed a petition to claim damages. "If there is a clear breach of the code as laid down by Medical Council of India, disciplinary action can be initiated against the doctor by the state medical council. The court steps in only if the patient has faced a loss, like his or her job, because of the act. Then the doctor will have to pay damages, in addition to facing disciplinary proceedings," he said.

Put on your thinking caps

Concluding Editorial Note:

My dear friends; I hope having flipped through the pages of this issue of DERMAPRACTICE must have rung some bells, perhaps a frown here n there, or goose bumps on realizing something you never knew; or rather never game importance too. Well this issue deals with just the tip of the iceberg; i.e. few aspects of a successful, ethical, rewarding practice. But there is practically no end to the know-how and technicalities of a safe and ethical practice. Some of the following questions may have intrigued you at some point of time, or you would face them soon.

- **Managing your clinic with limited space and resources**
- **What equipment to buy in the beginning and how to prioritize your equipment shopping**
- **Running and handling day-to-day clinic issues**
- **Need and handling of staff or clinic personnel; and labour laws pertaining to them**
- **How to handle competition with fellow dermatologists of your area amicably**

- **How to handle quacks and beauty parlours that provide unlicensed services like peels and laser treatments**
- **Use of social media and internet portals for advertising yourself – whats the ethical and legal limit!**
- **Practice and its association with the consumer protection act – implications**
- **Right to Information (RTI) act and its influence on your practice**
- **CME credit hours – how vigilant do we need to be. What about online CMEs – can they earn accreditation?**
- **Which Practice management software should one invest in?**
- **Are online consultations within India and to patients abroad legal? What all websites have a valid permission from the Indian Government to allow online consultation?**
- **What other advertising channels are allowed and fruitful to expand my practice – yellow pages, portals like justdial or askme, webpages etc.?**
- **Online sharing of patient's lesional photographs for discussion and opinion –legally approved**

measures of keeping patient identity safe.

- **Generic VS Branded drug names, especially in dermatology where many topical are multi-combinations.**
- **Advice regarding taking loans for clinic enhancement or buying equipment**
- **Group practice – the pros and cons**
- **Managing multiple clinics – the sops and headache**
- **Installation of CCTV vigilance in your clinic – which areas are MUST and which are ALLOWED?**
- **Minimum qualification required to be able to perform the rapidly upcoming procedures**
- **Whether clinical trained staff can do procedures; if yes, what should be his/her minimum qualification and experience!**
- **Who can open a training institute and provide valid certificates for advanced sub-specialty courses in dermatology like – dermatopathology, dermatoscopy, aesthetics, lasers etc.**
- **Protection against mishandling of doctors by rude patients; assault on doctors – prevention and legal measures available for our own safety.**
- **Managing a 'difficult' patient**
- **Influence of upcoming health insurance models on dermatosurgical procedures**
- **Conducting human research – whether retrospective study or therapeutic trial at a non-Govt. clinic or centre – Is it allowed; if yes, then whom to approach for protocol clearance and ethical approval?**
- **The balancing act - How to maintain a personal & professional balance for a satisfying and enjoyable profession**

Well, do not worry.....future editions of DERMAPRACTICE will precisely deal with all these aspects.

Please mail your remarks about this issue as well as other pertinent topics you wish to be covered in future bulletins.

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