FOGSI FOCUS

Medicolegal Issues in Obstetrics and Gynecology Practice

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The Health Sciences Publisher

New Delhi | London | Panama

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FOGSI FOCUS Medicolegal Issues in Obstetrics and Gynecology Practice / Jaideep Malhotra, MC Patel, RN Goel, Narendra Malhotra

First Edition: **2018**

ISBN: 978-93-5270-397-5

Printed at

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Message

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Medical profession is a noble profession, dealing with the most complicated science of human life. It is unpredictable and uncertain, varies from person to person and in the same person, from time to time. It also varies from drugs to drugs, from dose to dose, from investigations to investigations, and from procedure to procedure.

Doctor works in emergency 24 hours a day and 7 days a week. Expectations of patients and relatives are high. So, in spite of all efforts on part of a responsible doctor, if anything goes wrong or expected result is not achieved, it is all likely that doctor may have to face litigations. Litigations are increasing in number constantly and steadily. One will realize the magnitude of the problem by referring the figures from professional protection scheme run by Indian Medical Association, Gujarat State Branch. On 31st March, 2017 total registered members were 11,979. Out of those, 2,359 members were facing litigation in one way or other, which comes to almost 19.69%.

Numbers of complaints filed against doctors before medical council of respective state during year 2016–17 are also eye catching and matter of great worry.

So, it is need of the time to have basic medicolegal knowledge to practice medicine safely. Ignorance of law is no excuse.

Dr Jaideep Malhotra, President, FOGSI (2018) is much worried about the magnitude of the problem. She is keen to come out with small book, Medicolegal Issues in Obstetrics and Gynecology Practice.

In this situation, E Focus "Medicolegal Issues in Obstetrics and Gynecology Practice—No more litigation, Please....." would be of great help in difficult time. We have tried to justify the subject at our best possible way. Let us hope, this book will be of ready reference book in any given situation.

For any further assistance, you may please contact us.

Wishing you all litigation free practice.

Foreword

Sanjay Gupte MD DGO FICOG LLB FRCOG

FIGO Ethics committee Co-Chair
President, FOGSI 2010

The medical litigation scenario is fast changing. Earlier there were civil complaints and civil courts used to deal with them. Considering the amount of time and money involved, very few cases of medical negligence reached the civil courts. Unfortunately, this was also the time when the professional organizations could have started looking at reasonable self-regulation which did not happen. This led public and the authorities to demand alternative solutions for their grievances which landed us with the consumer protection act.

Recently, it appears that the society at large is still unhappy with the health care providers. This may be due to highly inflated expectations and misconceptions regarding curability of medical conditions as well as wrong assumptions regarding callousness of the whole medical system. This is leading us to a very disturbing scenario of criminal complaints against the doctors, which have increased substantially in our country. Fortunately for us, our own supreme court in the landmark judgment of Jacob Mathew vs. State of Punjab and Others Appeal (CRL) 144–45 of 2004 has supported us hugely by differentiating between other types of negligence under section 304 A and criminal negligence in medical cases. The supreme court has said that for criminal negligence to be adduced, the degree of negligence should be gross and there should be flagrant violation of the standard of care. This is the important point which our "expert committees" forget when the case is referred to them, by the police seeking their opinion to decide *prima facie* negligence.

Under these trying circumstances, it becomes imperative for us to have knowledge of all the statutory laws and requirements. This is where this particular FOGSI Focus which guides us regarding litigations and registrations, is of timely importance. I would advise you to learn these guidelines and adhere to them to save yourself from the major challenges in your practice.

Preface

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Dear FOGSIANS

Greetings and Regards

This second FOGSI Focus of 2018 comes to you on the occasion of a unique conference only planned for FOGSI Fraternity.

Today in the changing times, we doctors are faced with a lot of Medicolegal and social issues.

We present to you this FOGSI FOCUS on "Medicolegal Issues in Obstetrics and Gynecology Practice".

I congratulate all the participating editors and contributors for the wonderful collection of articles they have put together in this book.

FOGSI FOCUS.

My message for you all is

"Work for HER (Health, Empowerment, and Respect) with QED (Quality, Ethics, and Dignity)".

Happy reading!

Keep yourself and your patients healthy.

Jaideep Malhotra

Jaydeep D Tank

Acknowledgement

We are thankful to all the 3 editors for the wonderful compilation of the articles on important issues in daily practice. The authors are experienced and well-read. They simplified the understanding of complex laws.

Thank you FOGSI for FOGSI FOCUSES.

Jaideep Malhotra

Jaydeep D Tank

Contents

1

CHAPTER

Pre-conception and Pre-natal Diagnostic Techniques Act—No More Litigations

Pradyuman Vaja

INTRODUCTION

Using diagnostic techniques for sex selection or detection is discriminatory and violates the fundamental right to equality apart from violating the Pre-Conception (PC) and Pre-Natal Diagnostic Techniques (PNDT) Act.

The Pre-Natal Diagnostic Techniques (regulation and prevention of misuse) Act, 1994 (PNDT), as amended in 2003 to the Pre-Conception and Pre-Natal Diagnostic Techniques (prohibition of sex selection) Act, is a legislation to curb the abhorrent practice of sex determination and sex selection, which has its roots in India's long history of strong patriarchal influence in all spheres of life. This has translated into an obsessive preference for sons and discrimination against the girl child and women. It has spawned practices such as female infanticide, bride-burning, and sati and lead to the neglect of the girl child in terms of nutrition, education, health care and her overall development.Thus the "elimination" of girls and women is not entirely new to Indian sociocultural fabric. The obvious result is a sex ratio increasingly adverse to women. (The sex ratio is the ratio of females to thousand males in a population. According to 2001 census, this ratio is 933 women for every 1,000 men). The current all India sex ratio in the 0–6 age group, also called the child sex ratio is 927:1,000. The situation could probably have been worse, but for the valiant efforts of some social reformers. However, they have been more successful in some parts of the country than others, as can be seen from the sharp variations in the child sex ratio across regions, with the north and west of India showing larger deficits of girls. The last few decades have seen the situation getting worse, despite the progress the country has been making in almost all other spheres and indicators.

One of the main reasons for this is, sadly and ironically, advances in medical technologies. In recent years the misuse of medical technologies that have the potential to detect the sex of the fetus in the pre-natal period or even fix the sex of the child at the pre-conception stage, have added a new dimension to this issue of falling child sex ratios. Prenatal diagnostic techniques like amniocentesis and ultrasonography have been used all over the world for detection of genetic abnormalities. However, in India, they are being misused for the past three decades for detection of the sex of the unborn child and subsequently for sex selection—that is to eliminate fetuses selectively, if they are female. The disturbing child sex ratios in the 1991 census and consistent campaigning on this issue by women's groups and other civil society groups all over the country led Parliament to enact the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act – PC and PNDT Act in 1994. However, this was not followed up by effective implementation. Moreover, the need for smaller families – led to even more intensified misuse of such technologies, cutting across barriers of caste, class, religion, and geography to ensure that at least one child, if not more, is a son.

With the advent of new sophisticated preconception sex selection technologies like sperm separation, the girl child's elimination started becoming more subtle, refined and probably also more socially acceptable. Not surprisingly, the 2001 census revealed a further drastic fall in the child sex ratio, signaling the precipitation of a demographic catastrophe on a nation-wide scale. Alarmed by these happenings, and in response to the directives of the supreme court (SC) in a public interest litigation filed on this issue, the government amended the act to provide it more teeth and to cover the new pre-conception sex selection techniques (also known as sex pre-selection techniques). Thus the PNDT Act (regulation and prevention of misuse) 1994, as amended in 2003, PC and PNDT (prohibition of sex selection) Act, 1994 came into effect from february 14, 2003.

NO MORE LITIGATIONS PLEASE

Even after enactment of this act, which most of the practitioners are afraid of, a genuine practitioner has no

reason to fear this act, if he follows the guidelines laid down in the act. We as doctors are very casual in our approach which leads us in to trouble.

We are expected to have knowledge of everything including laws, business, and social sciences. Ignorance of law is no excuse. We doctors are highly criticized "not because of the treatment and medical management of the patients" but because of the poor understanding of laws, unethical business practices, and poor record maintenance.

Author's humble effort here is to make you aware of this act to pursue the practice as per the conditions of the act which will relieve our mental stress. This article leads to suggestions on litigation free practice.

Accordingly there are various situations that need to tackle brilliantly:

- Hospital management system
- Staff behavior and unnecessary discussion of cases by staff members
- Keep safe during the mishaps
- Role of our colleagues during complications.

In addition to the general points mentioned above, following are simple stepwise basic tips to avoid litigation in case of PC and PNDT Act, an act which every fellow of our fraternity is afraid of.

Registration of Place

- An institute, hospital, nursing home or any other place, by whatever name called, which provides genetic counseling irrespective of whether prenatal diagnostic procedures are carried out or not is to be registered as "genetic counseling center"
- Place where PND procedures are carried out, is to be registered as "genetic clinic" and place for conducting analysis of or tests of samples received from genetic clinic is to be registered as genetic laboratory
- In short all the practicing gynecologists have to register their place of practice under one of the categories mentioned above
- This also includes a vehicle where portable ultrasonography machine is used. The registration of a clinic also includes the registration of each and every mobile genetic clinic as a part of medical mobile unit. Such a vehicle has to be registered as a mobile genetic unit
- "Prenatal Diagnostic procedures include" include procedures such as ultrasonography, fetoscopy, taking or removing samples of amniotic fluid, chorionic villi, embryo, blood or any other tissue of a man or a woman before or after conception, for being sent to a genetic lab. All the places where these procedures are carried out must be registered to avoid litigations under this act
- Every application for registration shall be made to the appropriate authority, in duplicate, in Form A in such form and in such manner and shall be accompanied by such fees as may be prescribed. It shall be accompanied by an affidavit containing:
  - An undertaking to the effect that the center shall not conduct any test or procedure for sex selection or detection except for the diseases mentioned in Section 4 (2)
  - An undertaking that the center shall display prominently a notice that they do not conduct any such tests.

Certificate of Registration

- The appropriate authority grants a certificate of registration, in duplicate, in Form B. The certificate of registration must be displaced by the registered place in a conspicuous place at its place of business
- An inquiry for registration by appropriate authority, including inspection at the premises, shall be carried out only after due notice is given to the applicant
- Grant or rejection of certificate of registration shall be communicated to the applicant in Form B or C, respectively, within a period of 90 days from the date of receipt of the application
- The certificate shall be nontransferable. In the event of change of ownership or management of the place, the new owner or the manager of that place shall apply afresh for certificate
- Every certificate is valid for a period of 5 years from the date of issue.

Renewal, Cancellation or Suspension of Registration

Renewal

- An application for renewal shall be made in duplicate in Form A, to the appropriate authority 30 days before the date of expiry. Acknowledgement of receipt of such an application shall be issued by the authority in the manner specified
- The authority, after being satisfied and regard to the advice of the advisory committee renew the certificate for a further period of 5 years from the date of expiry of the earlier certificate
- Fees payable for the renewal is one half the fees for new registration
- On receipt of the renewed certificate or rejection of application for renewal, both copies of earlier certificates shall be surrendered immediately to the appropriate authority
- In the event of failure to renew the certificate or rejection of application within a period of 90 days from the date of receipt of the application, the certificate shall be deemed to have been renewed.

Cancellation or Suspension

- The appropriate authority may suo moto or on complaint, issue a notice to the center to show cause why its registration should not be suspended or cancelled for the reasons mentioned in the notice

- After hearing the center and on advice of the advisory committee, if the appropriate authority is satisfied with the breach of the act or the rules, it may cancel or suspend its registration for such a period it may think fit
- Notwithstanding anything contained in above, if the authority is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reasons to be recorded in writing, suspend he registration without issuing such a notice.

Public Information

- A notice in english and in the local language, to the effect that disclosure of sex of the fetus is prohibited under law shall be displayed in the premises of the registered place
- At least one copy each of the act and the rules shall be available on the premises of the registered place
- Name and designation of the person should be displayed prominently on the dress
- Name and designation must be written under the signature.

Qualifications of the Persons

The qualification of the persons or employees shall be as under.

For a Genetic Center

Any person being or employing:

- A gynecologist or a pediatrician having 6 months experience or 4 weeks training in genetic counseling or
- Medical geneticist
  - Having adequate space and educational charts/models/equipments may set up a genetic counseling center.

For a Genetic Laboratory

Any person having adequate space and being or employing:

- A medical geneticist
- A lab technician having a bachelor of science degree in biological sciences or a degree diploma in medical lab course with at least 1 year experience
  - May set up a genetic lab.

Such lab should have necessary equipments for carrying out chromosomal studies, biochemical, and molecular studies.

For a Genetic Clinic

Any person having adequate space and being or employing:

- Gynecologist with experience of at least 20 procedures under supervision of an experienced gynecologist
- A sonologist having degree recognized under the Indian Medical Council Act, 1956 (102 of 1956) or a post graduate qualification in ultrasonography or imaging technique or any registered medical practitioner who has undergone six months training under PC PNDT Rules, 2014—The fundamentals in abdomino pelvic sonography: Level one for doctors or
- A medical geneticist
  - May set up a genetic clinic which must acquire necessary equipments.

Each person shall be permitted to be registered with a maximum of two such clinics within a district. His consulting hours must be clearly specified for each clinic.

Sale of Ultrasound Machine

- No organization or a person shall sell, distribute, supply, rent, allow, or authorize use of imaging machine or any other equipment capable of detecting sex of the fetus in any manner, whether on payment or otherwise, to any genetic counseling center, clinic or laboratory or any other body or person unless such center is registered under this act
- The provider of such machine shall send to the concerned State/union territory appropriate authority and to the central government once in three months, a list of those to whom the machine has been provided
- Such a provider shall take an affidavit from the concerned purchasing center, clinic, lab, person or both that the machine/equipment shall not be used for detection of sex of fetus or selection of sex before or after conception.

Regulation of Portable Machines

- Use of portable machine shall be permitted only in the following conditions:
  - The portable machine being used, within the premises it is registered, for providing services to the indoor patients
  - As a part of mobile medical unit, offering a bouquet of other health and medical services like:
    - Curative services like referral of complicated cases, early detection of some endemic communicable and noncommunicable diseases; minor surgical procedures
    - RCH services
    - Family planning services
    - Diagnostic services like investigation of hemoglobin, urine, clinical detection of leprosy and tuberculosis, screening of cancer etc.
    - Specialized facilities and services like X-ray, electrocardiography, and ultrasound test etc.
    - Emergency services and care in times of disaster or epidemic or public health emergency or accident etc.
- Regulation of services to be offered by mobile genetic clinic:
  - It shall operate only as a part of mobile medical unit offering a bouquet of other health and medical services in urban slums or rural or remote or hilly or hard to reach areas for improved access to health care services by underserved
  - The stand-alone mobile ultrasonography clinic offering only PND facilities are prohibited
  - The mobile unit shall have adequate space

- The machine shall not be used for sex determination of fetus
- Copy of certificate of registration shall be displayed inside the vehicle at a conspicuous place clearly specifying:
  - The area of operation not exceeding the district wherein it is registered
  - No of portable machines installed in the vehicle
  - Make and model number of the portable machine
  - Registration no of the vehicle
  - Full address of the service provider
- In case of breakdown of the vehicle or for any other reason for which the registered unit cannot be used as a genetic clinic, the appropriate authority has to be informed within a period of seven days.

Counseling, Communication, and Consent

Prenatal diagnostic techniques cannot be conducted unless:

- All side and aftereffects of the procedures are explained
- Written consent (specified in Form G) to undergo such procedure is obtained in the language she understands
- A copy of the consent is given to her.

A person conducting ultrasonography shall give a declaration that he has neither detected no disclosed the sex of the fetus. The pregnant woman shall declare that she does not want to know the sex of the fetus. Communication of sex of the fetus by words, signs or in any other manner to any person is prohibited. The state government may issue translation of Form G in languages used in the state or in the language woman understands.

Determination of Sex of the Fetus

No genetic centre, clinic or laboratory or any person can conduct PND techniques for the purpose of determining the sex of the fetus or even selection of the sex before or after conception. The registered place shall on no account conduct or allow/cause to be conducted female feticide.

Maintenance Records

- Each and every registered place shall maintain a register showing in serial orders, the names and addresses of the men or women given genetic counseling, subject to PND tests, the names of their spouse or father and the date on which they first reported
- The record by genetic counseling center, in respect of each woman counseled shall be specified in Form D
- The record by genetic lab for each man or woman subjected to any PND test shall be specified in Form E
- The record by genetic clinic shall be in Form F
- All records, required to be maintained under this act and the rules, shall be preserved for a period of 2 years or for such a period as may be prescribed. All such records shall be made available to the appropriate authority or any other person authorized by the appropriate authority on his behalf
- In case of legal proceedings against the center, the documents shall be preserved till the final disposal of the proceedings or for 2 years whichever is later
- In case of E records, a printed copy shall be taken and preserved after authentication
- The report must be sent to the concerned appropriate authority in respect of each month by the 5th day of the following month.

Different Forms under the Act

- FORM A (to be submitted in duplicate with supporting documents)—application for registration or renewal
- FORM B (in duplicate)—certificate of registration
- FORM C—form for rejection of the application
- FORM D—for maintenance of records by the genetic counseling center
- FORM E—for maintenance of records by the genetic lab
- FORM F—maintenance of record in case of PND test by genetic clinic.
- FORM G—consent for invasive techniques
- FORM H (for the appropriate authority)—form for maintenance of permanent record of applications under the PC PNDT Act.

Intimation of Changes in Employees, Place, or Equipments

The registered place shall intimate every change of employee, place, address, and equipment installed to the appropriate authority at least 30 days in advance of the expected date of such a change and seeks reissuance of certificate of registration with the changes duly incorporated.

Appeal

- Any one aggrieved by the decision of the appropriate authority at sub-district level may appeal to the authority at district level within 30 days of the order of sub district level authority
- Any one aggrieved by the decision of the appropriate authority at district level may appeal to the authority at state/union territory level within 30 days of the order of district level authority
- Each appeal shall be disposed off within 60 days of its receipt
- If such appeal is not made within time, the appropriate authority may condone the delay in case he is satisfied that the appellant was prevented for sufficient cause from making such appeal.

Offences and Penalties

- Advertisement, in any form, and visible representation made by means of hoarding, wall painting, signal, sound, smoke or gas relating to sex detection or sex selection, is prohibited. Contravention is punishable with imprisonment up to 3 years and a fine up to Rs 10,000

- Any person who owns a genetic center, lab or clinic or is employed therein to render his services and who contravenes any of the provisions of the act or rules shall be punishable with imprisonment up to 3 years and a fine up to Rs 10,000
- On subsequent conviction, imprisonment up to 5 years and fine up to Rs 50,000
- The name of the medical practitioner shall be reported to the concerned State Medical Council for taking necessary action
- If any person seeks aid for sex selection or detection, he shall be punishable as above. But this shall not apply to the woman who was compelled to undergo such tests
- Whoever contravenes any of the provisions of this act or rules made there under, for which no penalty has been mentioned in this act, shall be punishable up to 3 months imprisonment or with fine up to 1,000 or with both. In the case of continuing contravention additional fine may extend up to 500 for every day during which such contravention continues after first conviction.

Offences by Companies

Where any offence, punishable under this act, has been committed by a company, every person who was in charge at the time of commitment of the offence and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence unless such person proves that the offence was committed without this knowledge or that he had exercised all due diligence to prevent the commission of such offence.

Every offence under this act shall be cognizable, non bailable and non compoundable and no court other than that of a metropolitan magistrate or a first class judicial magistrate shall try any offence under this act.

CONCLUSION

To conclude, in short, all persons including the owners, employees or any other person associated with the registered places under the act should observe the code of conduct keeping in mind the above narrated facts to avoid any further litigation and for safe and peaceful practice. They must ensure that no provision of the act or the Rules mentioned above in this article is violated in any manner. So knowledge of the act and its implementation in practice will help us to avoid litigations or defend ourselves in court.

2

CHAPTER

The Clinical Establishments (Registration and Regulation) Act, 2010

Meenakshi A Deshpande

INTRODUCTION

The Clinical Establishments (Registration and Regulation) Act, 2010 ("Act") has been enacted by the central government to provide for registration and regulation of all clinical establishments in the country. The aim of the Act is to register all clinical establishments in India to make it easier to regulate them and implement standard practices, with a view to prescribing the minimum standards of facilities and services provided by them.

With the exception of the establishments under the military forces, all public and private establishments, including Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) establishments, are required to register. According to Chapter I Clause 2 (c), a clinical establishment may be a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or any other institution that offer services for diagnosis, care, or treatment of patients.

As of march 2015, the following states have adopted it: Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, Bihar, Rajasthan, Uttar Pradesh, and Uttarakhand.

OBJECTIVE OF THE ACT

The specific objectives are:

- To establish digital registry of clinical establishments at national, state, and district level
- To prevent quackery by unqualified practitioners by introducing registration system, which is mandatory
- To improve quality of health care through standardization of healthcare facilities by prescribing minimum standards of facilities and services for all categories of health care establishments (except teaching hospitals) and ensuring compliance of other conditions of registration like compliance to standard treatment guidelines, stabilization of emergency medical condition, display of range of rates to be charged, maintenance of records etc., the act makes all clinical establishments to provide medical care and treatment necessary to stabilize any individual who comes or is brought to the clinical establishment in an emergency medical condition, particularly women who come for deliveries and accident cases.

IMPLEMENTATION OF THE ACT

The Act lays down establishment of a Council Body called The National Council for Clinical Establishment which is responsible primarily for setting up standards for ensuring proper healthcare by the clinical establishment and develop the minimum standards and their periodic review.

REGISTRATION OF THE CLINICAL ESTABLISHMENT

Section 11 of the act mandates that no person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of the act.

In september 2014, the Government of India, the Ministry of Health and Family Welfare issued the application format for permanent registration of clinical establishments which requires the applicant to provide information such as, among others, establishment details, types of service, system of medicine, etc.

- Standard application form: Application for registration may be made by post, in person or online through website
- Registration is mandatory under the Act: Within one year from commencement of act, every existing clinical establishment has to apply for registration within one year from commencement of act and every new clinical establishment i.e., which has come into existence after commencement of act has to apply for registration within six months from the date of its establishment

- Registry: Digital registry of clinical establishments at National, State, and District level.
- Act provides for two types of registration.

Provisional Registration

No enquiry is to be done prior to grant of certificate of provisional registration, which is granted for one year at a time. The provisional registration shall not be renewed after a period of two years from the date of notification of minimum standards, in case of existing clinical establishments and the same shall not be renewed after a period of six months in case of new clinical establishments (i.e., which come into existence after date of notification of minimum standards).

Permanant Registration

Permanent registration is to be considered after notification of minimum standards. Clinical establishments will be required to meet minimum standards before grant of permanent registration. Certificate of permanent registration is granted for five years at a time.

Minimum Standards to be Followed by Clinical Establishments

Conditions to be fulfilled by every clinical establishment for grant of registration (permanent) and continuation (Section 12 of the act)

- Minimum standards of facilities and services
- Minimum requirement of personnel
- Provision and maintenance of records and reports
- Every clinical establishment is required to provide treatment "within the staff and facilities available" to stabilize the emergency medical condition of an individual who comes or is brought to the clinical establishment
- Other conditions (as prescribed under central government rules):
    - Details of rates charged and facilities available to be prominently displayed at a conspicuous place in local and in english language
    - Maintain and provide electronic medical records or electronic health records of every patient as may be determined and issued by central/state government
    - Clinical establishments shall charge the rates for procedures and services within the range of rates determined by the central government from time to time in consultation with the state governments
    - Clinical establishments shall ensure compliance to standard treatment guidelines as may be issued by central/state government (details given below)
    - Every clinical establishment shall maintain information and statistics in accordance with all applicable laws and rules
    - Shall establish mechanisms for review and audit for the purpose of provision of rational practice and service shall carry out every prescription audits every 3 months.

Fee for Registration, Renewal, and Appeal

- Shall be specified by respective state government/union tertiary administration under section 54
- State/union tertiary may charge fee category wise
- Enhanced fee may be charged if renewal not applied within the time frame.

Inspection

The authority may enter and search in the prescribed manner after giving notice of its intention to the clinical establishment, if it suspects that an establishment is operating without registration.

- The registering authority may authorize an inspection or an inquiry of any registered clinical establishment to be made by a multi-member inspection team
- A show cause notice may be issued if the authority feels that a clinical establishment is not complying with the conditions of its registration
- It may also cancel the registration. Information pertaining to compliance with standards and conditions of registration by clinical establishments is to be displayed in the public domain
- If there are objections about the authenticity of the information, this would be duly investigated by the registering authority
- Any person, aggrieved by an order of the registering authority, refusing to grant or renewal certificate of registration or revoking a certificate of registration may, in such manner and within such period as may be prescribed, can refer an appeal to the state council.

Validity of Permanent Registration

Every permanent registration shall be valid for a period of five years from the date of issue of the certificate of registration and such registration shall be renewable.

Renewal of Permanent Registration

The application for renewal of permanent registration shall be made six months before the expiry of the validity of the certificate of permanent registration and, in case the application of renewal is not submitted within the stipulated period, the authority may allow renewal of registration on payment of such enhanced fees and penalties as may be prescribed.

PENALTIES UNDER THE ACT

No imprisonment under this act but monetary penalties: Rs 10,000 to 5 lakh; depends on size, category, type, and local conditions (Table 1).

TABLE 1: Offence penalty in rupees

Offences	*First offence*	*Second offence*	*Subsequent offence*
Running clinical establishment without registration	50,000	200,000	500,000
Contravention of any other provision of the act	10,000	50,000	500,000
Whoever knowingly serves in an unregistered clinical establishment	25,000	–	–
Minor deficiencies which do not pose imminent danger	10,000	–	–

Accordingly, for Standard Treatment Guidelines the Draft Document Issued by the Government this September Divided Hospitals into 4 levels of Hospitals, Namely

Hospital Level 1

Hospital level 1 is the primary healthcare services provided by qualified doctors. It includes services such as general medicine, pediatrics, first aid to emergency patient and outpatient services, obstetrics and gynecology nonsurgical and minor surgery and has a bed strength of not more than 30 which can be provided through trained and qualified manpower with support/supervision of registered medical practitioners with the required support systems for this level of care.

Hospital Level 2

This level includes services of surgery and anesthesia in addition to the services provided at level 1 through registered medical practitioner under supervision and with support of specialists. It will also have other support systems required for these services like pharmacy, laboratory, diagnostic facility, etc.

Hospital Level 3

This level includes all the services provided at level 1 and 2 and in addition the following as well such as multispecialty clinical care with distinct departments, general dentistry, intensive care unit. Tertiary healthcare services can be provided through specialists. It will also have other support systems required for these services like pharmacy, laboratory, and imaging facility.

Hospital Level 4

This level will include all the services provided at level 3. It will however have the distinction of being teaching/training institution and it will have multiple superspecialties. Tertiary healthcare services that can be provided through specialists. It shall have other support systems required for these services. It shall also include the requirements of Medical Council of India/other registering body.

Template for Display of Rates

The Hospitals are required to follow a particular template for display of the various rates related to probability of default, investigation/diagnostic, emergencies, etc. which is detailed in the draft documents issued by the ministry.

HARMFUL EFFECTS OF THE CLINICAL ESTABLISHMENTS ACT

- Doctor to be booked by police and case goes directly to the court of law
  - Fines to the Tune of Lakhs (Chapter VI, Clause 40)
  - Penalty for first offence of not following any of the provisions is up to Rs. 10,000, for second time up to Rs. 50,000, for subsequent offences up to Rs. 5 Lakhs.
- Running an establishment without registration can attract penalty up to Rs. 5 Lakhs
  - This provision can be enforced during period of renewal i.e., from the date of expiry of certificate to date of renewal of certificate (Chapter IV Clause 34; Chapter VI Clause 41 (1))
- Same rules pan-India (regarding staff, space, instruments, and facilities) for all the hospitals irrespective of geographical differences. Because of the congestion in bigger cities, space is not available, or if available, the cost is very high
- Retrospective implementation—applying all the clauses to the old establishments will do injustice to them
- Supply of enough qualified paramedical and nursing workforce is required—may not available due to paucity of training facilities to all over the country
- Inspectors/authorities can visit your clinic at any reasonable time for ensuring that you comply with all rules and regulations laid down. Thus in effect, even a sub-divisional magistrate can threaten you with a fine of Rs 5,00,000 on any pretext under Clause 42 (1) and (2). This opens up unlimited avenues for undue extortion.
- Stabilization of patient's health in Emergency (Chapter I, Clause 2 (d),(o))
  - (Chapter III, Clause 12 (2))—any patient brought to hospital must be attended. The patient must be 'stabilized' before referring to another hospital
  - Doctor will be responsible if patient's condition deteriorates during transit
- The state councils will have only one representative of Indian Medical Association (Chapter III, Clause 8 (2) (e), (f))
  - However, systems of Indian medicine including Yoga, Siddha, and Unani will have three representatives on the said council

- The district health officer/chief medical officer also a police officer shall exercise the powers of the district health authority
- The License Raj starts: On submission of evidence of compilation of prescribed minimum standards and if authority is satisfied, it will issue permanent registration certificate for 5 years. (Chapter IV, Clause 25, 28, 30)
- To ensure compliance of standard treatment 'guidelines' (Rule 9 (iii))—determined and issued by central/state government; significant deviation not allowed. That means:
  - A doctor does not have absolute freedom to change the treatment line depending on his clinical assessment. (no respect to clinical acumen of the doctor)
- Electronic medical and health records; statistics will be checked every 3 months; audit of prescriptions will be taken 3 monthly: Escalation of treatment cost—establishment cost, maintenance cost, and salary, equipments, etc.
  - Routine medical treatment will become costly and unaffordable to common patient.

Indian Medical Association Demands are as Follows

Single doctor establishments, with indoor facilities, shall be registered without applying strict rules. Rules shall be flexible depending upon the speciality, geographical location, development stage of the city, and local culture. Nonavailability of qualified paramedical nursing staff will render smaller clinics and hospitals nonoperational, so the minimum requirement of number of nurses and paramedical staff and other personnel should be implemented wherever possible by appointing experienced and well trained persons required for the particular type of clinical establishment. The provision of fine provided in this Act is more than the many illegal crimes. Increase the budgetary provision for health.

It would be prudent for the government to accept the demands of Indian Medical Association regarding the Clinical Establishments Act, to keep the escalation in control.

3

CHAPTER

Birth and Death Registration Act

Charu Mittal

INTRODUCTION

The Registration of Births and Deaths Act, 1969 is an act to provide for the regulation of registration of births and deaths and for matters connected therewith. This act provides for a uniform law across the country on the registration of births and deaths. It ensures compulsory reporting and registration of all births and deaths. Implementation of the act is the responsibility of the state governments. Rules framed by the state governments are based on a model set of rules provided by the central government (Registrar General, India). It has following chapters and sections.

CHAPTER I – Preliminary Sections

1. Short title, extent, and commencement
2. Definitions and interpretation.

CHAPTER II – Registration Establishment

3. Registrar-General, India
4. Chief Registrar
5. Registration divisions
6. District Registrar
7. Registrars.

CHAPTER III – Registration of Births and Deaths

8. Persons required to register births and deaths
9. Special provisions regarding births and deaths in a plantation
10. Duty of certain persons to notify births and deaths and to certify cause of death
11. Informant to sign the register
12. Extracts of registration entries to be given to informant.
13. Delayed registration of births and deaths
14. Registration of name of child
15. Correction or cancellation of entry in the register of births and deaths.

CHAPTER IV – Maintenance of Records and Statistics

16. Registrars to keep registers in the prescribed form
17. Search of births and deaths register
18. Inspection of registration offices
19. Registrars to send periodical returns to the chief registrar for compilation.

CHAPTER V – Miscellaneous

20. Special provision as to registration of births and deaths of citizens outside India
21. Power of registrar to obtain information regarding birth or death
22. Powers to give directions
23. Penalties
24. Power to compound offences
25. Sanction for prosecution
26. Registrars and Sub-Registrars to be deemed public servants
27. Delegation of powers
28. Protection of action taken in good faith
29. Act not to be in derogation of Act 6 of 1886
30. Power to make rules
31. Repeal and saving
32. Power to remove difficulty.

CHAPTER I – PRELIMINARY SECTIONS

This act may be called the Registration of Births and Deaths Act, 1969. It extends to the whole of India.

a. Birth means live-birth or still-birth. Live-birth means the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes or show any other evidence of life, and each product of such birth is considered live-born; Still-birth

means fetal death where a product of conception has attained at least the prescribed period of gestation

b. Death means the permanent disappearance of all evidence of life at any time after live-birth has taken place

c. Fetal death means absence of all evidence of life prior to the complete expulsion or extraction from its mother of a product of conception irrespective of the duration of pregnancy.

Plantation means any land not less than four hectares in extent which is being prepared for the production of, or actually produces, tea, coffee, pepper, rubber, cardamom, cinchona or such other products approved by Government Superintendent of the Plantation means the person having the charge or supervision of the laborers and work in the plantation, whether called a manager, superintendent or by any other name.

CHAPTER II – REGISTRATION ESTABLISHMENT

- Registrar-General, India: The central government may appoint Registrar-General, India
- Chief registrar: The state government may appoint a chief registrar for the State
- Registration divisions: The state government may prescribe different rules for different registration divisions
- District registrar: The state government may appoint a district registrar for each revenue district and such number of additional district registrars
- Registrars: The state government may appoint a registrar for each local area comprising the area within the jurisdiction of a municipality, panchayat or other local authority or any other area or a combination of any two or more of them—provided that the state government may appoint in the case of a municipality, panchayat, or other local authority, any officer or other employee thereof as a registrar.

Duties of Registrar

Every Registrar shall, without fee or reward, enter in the register maintained for the purpose all information given to him under section 8 or section 9 and shall also take steps to inform himself carefully of every birth and of every death which takes place in his jurisdiction and to ascertain and register the particulars required to be registered.

Every registrar shall attend his office for the purpose of registering births and deaths on such days and at such hours as the chief registrar may direct and shall cause to be placed in some conspicuous place on or near the outer door of the office of the registrar a board bearing, in the local language, his name with the addition of registrar of births and deaths for the local area for which he is appointed, and the days and hours of his attendance.

The registrar may, with the prior approval of the chief registrar, appoint sub-registrars and assign to them any or all of his powers and duties in relation to specified areas within his jurisdiction.

CHAPTER III – REGISTRATION OF BIRTHS AND DEATHS

Section 8

As per provisions of the Registration of Births and Deaths Act, 1969 registration of every birth and death is compulsory. The persons who are responsible, are to report the events of births and deaths to their nearest registration units within 21 days of occurrence of such events failing which late fees for delayed registration are charged. Persons required to register births and deaths:

a. In respect of births and deaths in a house, whether residential or nonresidential, The head of the house or, head of the household, nearest relative of the head present in the house, the oldest adult male

b. With reference to births and deaths in a hospital, health center, maternity or nursing home or other like institution, the medical officer in charge or his delegate

c. With reference to births and deaths in a jail, the jailor in charge

d. With reference to births and deaths in choultry, chattram, hostel, dharmasala, boarding-house, lodging-house, tavern, barrack, toddy shop or place of public resort, the person incharge thereof

e. With reference to any new-born child or dead body found deserted in a public place, the headman or other corresponding officer of the village in the case of a village and the officer incharge of the local police station elsewhere

f. In any other place, such person as may be prescribed.

Section 9

Special provision regarding births and deaths in a plantation—In the case of births and deaths in a plantation, the superintendent of the plantation shall give or cause to be given to the registrar the information.

Section 10

1. Duty of certain persons to notify births and deaths and to certify cause of death. It shall be the duty of:
   i. Midwife or any other medical or health attendant at a birth or death
   ii. Keeper or the owner of a place set apart for the disposal of dead bodies or any person required by a local authority to be present at such place
2. Registrar may obtain certificate as to the cause of death or information giver may collect death certificate from a medical practitioner, the medical practitioner shall issue and the certificate shall be received and delivered by such person to the Registrar at the time of giving information.

Section 11

Informant to sign the register—Every person who has orally given to the registrar any information required shall write in the register maintained in this behalf, his name, description and place of abode, and, if he cannot write, shall put his thumb mark in the register against his name, description and place of abode, the particulars being in such a case entered by the registrar.

Section 12

Extracts of registration entries to be given to informant—The Registrar shall, as soon as the registration of a birth or death has been completed, give, free of charge (or at a prescribed fee) to the person who gives information under section 8 or section 9 and extract of the prescribed particulars under his hand from the register relating to such birth or death.

Section 13

Delayed registration of births and deaths—

a. Any birth or death of which information is given to the Registrar after the expiry of the period specified therefor, but within 30 days of its occurrence, shall be registered on payment of such late fee as may be prescribed
b. Any birth or death of which delayed information is given to the Registrar after thirty days but within one year of its occurrence shall be registered only with the written permission of the prescribed authority and on payment of the prescribed fee and the production of an affidavit made before a notary public or any other officer authorized in this behalf by the state government
c. Any birth or death which has not been registered within one year of its occurrence shall be registered only on an order made by a magistrate of the first class or a presidency magistrate after verifying the correctness of the birth or death and on payment of the prescribed fee.

Section 14

Registration of name of child—Where the birth of any child has been registered without a name, the parent or guardian of such child shall within the prescribed period give information regarding the name of the child to the Registrar either orally or in writing and thereupon the Registrar shall enter such name in the register and initial and date the entry.

Section 15

Correction or cancellation of entry in the register of births and deaths—To the satisfaction of the Registrar that any entry of a birth or death in any register is erroneous in form or substance, or has been fraudulently or improperly made, he may, correct the error or cancel the entry by suitable entry in the margin, without any alteration of the original entry, and shall sign the marginal entry and add thereto the date of the correction or cancellation.

Section 16

Every Registrar shall keep in the prescribed form a register of births and deaths—Copy of such forms of certificate in the local language shall be posted in some conspicuous place on or near the outer door of the office of every Registrar.

Section 17

Search of births and deaths register—Any person may search for any entry in a register of births and deaths; and obtain an extract from such register relating to any birth or death, no extract relating to any death shall disclose the particulars regarding the cause of death as entered in the register. All extracts given shall be admissible in evidence as per Indian Evidence Act, 1872 and shall be proof of birth or death Inspection rules, returns and publication of statistical report on the regd. births & deaths during the year at such intervals & in form.

CHAPTER V – MISCELLANEOUS

Section 20

Special provision as to registration of births and deaths of citizens outside India—Information received of births and deaths of citizens of India outside India by Indian Consulates shall be information and they may issue birth and death certificate. In the case of any child born outside India and if the parents of the child return to India they may, at any time within sixty days from the date of the arrival of the child in India, get the birth of the child registered (as if the child was born in India)

Section 21

Power of registrar to obtain information regarding birth or death—The registrar may either orally or in writing require any person to furnish any information within his knowledge in connection with a birth or death in the locality within which such person resides and that person shall be bound to comply with such requisition.

Section 23

- Penalties—Any person who fails without reasonable cause to give any information which it is his duty to give under any of the provisions or gives or causes to be given, for the purpose of being inserted in any register of births and deaths, any information which he knows or believes to be false regarding any of the particulars required to be known and registered; or refuses to write his name, description, and place of abode or to put his thumb mark in the register shall be punishable with fine which may extend to fifty rupees. Any registrar or subregistrar who neglects or refuses, without reasonable cause, to register any birth or death occurring in his jurisdiction or to submit any returns as required shall be punishable with fine which may extend to fifty rupees

- Any medical practitioner who neglects or refuses to issue a certificate and any person who neglects or refuses to deliver such certificate shall be punishable with fine which may extend to fifty rupees. Any person who, without reasonable cause, contravenes any provision of this Act for the contravention of which no penalty is provided for in this section shall be punishable with fine which may extend to ten rupees. Registrars and subregistrars to be deemed public servants. They are public servants within the meaning of section 21 of the Indian Penal Code (45 of 1860).

Section 28

Protection of action taken in good faith—Act not to be in derogation of Act 6 of 1886.

Section 30

Power to make rules—forms of registers, period certificate as to cause of death, extract, search and the fees, returns and the statistical report, the custody, production and transfer of the registers and other records, the correction of errors and the cancellation of entries in the register of births and deaths.

Section 32

Power to remove difficulty—If any difficulty the State may, with the approval of the central govt. by order make such provisions or give such directions not inconsistent with the provisions of this Act as appears to the state government to be necessary or expedient for removing the difficulty. No order after the expiration of 2 years from the date on which this act comes into force.

CONCLUSION

A birth or death has to be reported for registration, within 21 days of occurrence. Free copy of the certificate can be obtained at the time. Birth and death registration is to be done at the place of occurrence. Any death, after the expiry of twenty one days, but within thirty days of occurrence, shall be registered on payment of late fees. After thirty days of occurrence, but within one year shall be registered only with the written permission of the officer prescribed in this behalf and on payment of late fee. Not been reported within one year of its occurrence, shall be registered only on orders of the first class judicial magistrate and on payment of a late fees.

4

CHAPTER

Counseling – How and When?

Alka V Kuthe

INTRODUCTION

Doctor-patient relationship is as old as the origin of human race. It is often said that practice of medicine started as an art then evolved as a science and has now become a trade. But in reality it is the combination of all the three. The doctor-patient relationship is central to the practice of medicine and is essential for the delivery of high quality of health care. For this counseling skill more than any other professional field is the core factor that does the function of cementing the doctor-patient bond. Communication skills form the basis of counseling whereby medical practitioner can understand patients, their problems, their beliefs, their illnesses. Counseling creates an ability to explain the illness, illicit relevant information, explain different diagnostic modalities, treatment options clearly and completely, so that patients are able to make informed decisions about the treatment. All this is done in a language that patients can easily understand. Confidentiality is paramount to successful counseling. Patient remains comfortable and this develops a relationship of trust between him and the treating doctor.

LET US DEFINE COUNSELING

Counseling falls under the umbrella term "talking therapies" and allows people to discuss their problems and difficult feelings they encounter, in a safe, confidential environment. It is a process people seek when they want to change something in their lives or simply explore their thoughts and feelings in more depth. The counselor (medical practitioner) encourages client (patient) to talk about what's bothering him in order to uncover any root cause. It is an art which deals with understanding of thoughts, emotions, problems, situations in an effective way so as to enable the participants to act as per the informed decision. It is not an order or just plain suggestion but it is the help, support given by one of the participants which enables other to make a choice. In medical field, it is the support given by health care provider to a patient in order to make informed choice about the treatment voluntarily, based on the information passed on to him after listening to his/her complaints, in a clear, simple language, easily understandable by him, without any force or compulsion. Counseling skills also help to decrease strain between doctors and patients which indirectly help in decreasing complaints against doctors if something goes wrong in the future or if the patients do not respond as per the expectations.

Counseling is not:

- Getting emotionally involved with the client (patient)
- Looking at a client's (patient's) problems from counselor's own perspective, based on his/her own value systems
- Just giving advice
- Being judgmental
- Expecting or encouraging a client (patient) to behave in a way in which the counselor may have behaved when faced with a similar problem.

In general, there are varieties of counseling formats

- Face to face: In this type, appointment with counselor is taken to meet him/her in person. It is most popular therapy format as it provides an opportunity to react to any emotions then and there only
- Group: Instead of meeting a counselor alone, one can join a counseling group where the issues can be discussed with the group members who are going through similar problems.(support groups for diabetes, asthma, breast-feeding)
- Telephonic: This means talking to counselor over phone instead of in person. This is more flexible format and is useful for too busy people
- Online: In this format, instead of speaking physically, clients (patients) want to utilize technology and they email their problems to counselors. This type of counseling offers chance to protect one's anonymity.

HOW CAN COUNSELING HELP?

In general, as a therapy, counseling offers safe and confidential environment to speak in and freedom to explore with an unbiased party. It helps client to uncover his/her own insight and understanding of problems with the tools which will help to resolve them on their own. It is a journey and it takes time. The more armed with information one is, the easier it gradually becomes to navigate one's way through any difficulties one is facing so that eventually one can come out the other side feeling more positive.

There is no evidence to suggest that counseling in cancer patient will help to treat, cure or to prolong her life but there is lot of evidence that counseling can help her to cope better with the difficulties she may face during and after cancer diagnosis and treatment. It can also help to reduce the stress by providing emotional and psychological support and it also improves quality of life. Counseling can help some people to overcome depression and anxiety that cancer can cause. It also helps people deal with phobias about having cancer treatment.

In today's era of consumerism and E patients, counseling has become part and parcel of day to day medical practice. Therefore it is required in almost all patients in all situations. Obstetrics and gynecology practice starts with counseling. Obstetrics is the only specialized branch which deals with two lives at a time. Counseling is very much needed and beneficial to save both the lives. Practicing obstetrician with this skill is more likely to have happy, satisfied patients than an equally competent, technologically sound friend, who is least bothered about this skill. Indirectly it will also help to decrease the violence/number of litigations against doctors. Presently even government hospitals have posts of counselors who are trained in this art.

WHEN TO COUNSEL?

In General

- Before and after advising pathological tests especially human immunodeficiency virus, hepatitis B surface antigen, sexually transmitted diseases, tests for cancer detection (Papanicolaou smear, fine needle aspiration cytology, cancer antigen 125, etc.)
- Before undertaking any invasive diagnostic/therapeutic procedure: Explaining advantages, associated risks or complications due to procedure/anesthesia (laparotomy, endoscopy)
- While advising various treatment modalities: Pros and cons of, conservative versus surgical, route of operation (transabdominal/transvaginal/combined), laparotomy versus laproscopy, radical operation versus conservative surgery, medical/surgical/radiotherapy/combined
- Counseling of the relatives when the patient is serious, needs urgent referral/transfer to intensive care unit, or is, in the terminal state
- Counseling for organ donation

Counseling in Obstetrics and Gynecology

- Prepregnancy/pregnancy counseling, genetic counseling:
  - Prepregnancy counseling for all women aims to provide women with information about the health of themselves and their fetus in pregnancy, facilitating an informed decision by the woman regarding future reproduction (includes issues regarding diet and folic acid supplementation, exercise, smoking, alcohol, and screening for infections and genetic diseases)
  - Prepregnancy counseling for women with medical or obstetric complications in a previous pregnancy such as preeclampsia or placental abruption and for women with preexisting medical problems such as diabetes, hypertension, renal, and cardiac disease.
- Obstetrical conditions: High risk pregnancy. Pregnancy associated with medical disease: Pregnancy-induced hypertension, eclampsia, anemia, heart disease, endocrine disorders most commonly diabetes, thyroid dysfunction, eutoimmune disorders, intrauterine growth restriction, vaginal birth/assisted vaginal delivery versus cesarean,vaginal birth after previous cesarean section, operating upon previous scarred uterus, intrauterine fetal death, disseminated intravascular coagulation etc.
- Gynecological disorders: Medical/surgical management of endometriosis, medical/palliative/radical/surgical management of various cancers like cancer of cervix, endometrium, ovary, breast, respectively
- Counseling in infertile couples while advising various diagnostic/treatment modalities to offer them chance to conceive: intrauterine insemination, *in vitro* fertilization, surrogacy
- Antenatal and postnatal counseling for breastfeeding and Infant and Young Child feeding (IYCF)
- Counseling for human milk acceptance from and donation to Human milk bank
- Counseling on family planning methods

And the list is nonending.

Mostly proper counseling is followed by informed/real consent which becomes easier and patients and relatives are very much receptive to listen to the advice.

HOW TO COUNSEL?

Counseling can be learnt in two parts:

- Part I: Listening and learning
- Part II: Building up the confidence and giving support

Let us study each in details.

Part I: Listening and Learning

Doctor must listen to what patient is trying to explain. Many times, because of hurry and lack of time, doctor/health care provider, tries to interrupt patient's deliberations and asks for focused dialogue. This may lead to fear or inhibition in patient's mind. At times, shy patient may not open up at all. Therefore to avoid this, health care provider must acquire the

art of listening and learning. This can be done by acquiring six skills as follows:

- Skill 1: Nonverbal communication
- Skill 2: Ask open ended questions
- Skill 3: Attention giving gestures
- Skill 4: Reflected speech
- Skill 5: Empathy
- Skill 6: Avoid decisive/judgmental words

Skill 1: Nonverbal Communication

It includes:

- Warm welcome
- Keep levels and respectable distance
- Pay attention
- Remove obstacles
- Devote time
- Caring, appropriate touch.

Skill 2: Ask Open Ended Questions

It is desirable to ask open ended questions to your patient either at the beginning or during talk in order to get detail information or in depth information regarding disease. It also encourages patient to talk more and more about her illness. These questions usually begin with the letters why, when, how, which, where

Closed questions: These questions are usually not desirable. They stop the conversation. The answer is either 'yes' or ' no.'

Skill 3: Attention Giving Gestures

Patient should feel that you are paying attention to what she is complaining about and you are serious about that. You can make them feel so by listening with concentration, showing expressions, e.g., nodding, smiling or counter questioning, using responses like ok yes, oh! etc.

Skill 4: Reflected Speech

In order to illicit maximum useful information, patient's statement can be reflected back, using same words, without changing meaning of words/statement. Patient feels comfortable and becomes happy to know that doctor has understood what she is talking about. By this she gets inspired to talk further and in this way conversation continues.

For example,
Patient: I am suffering with excessive menstrual blood loss.

Gynecologist: You are suffering with excessive menstrual bleeding!

Skill 5: Empathy

Sometimes while talking about illness, patient opens up and expresses her emotions/feelings. In that case, in order to convince her that doctor has understood her feelings, doctor should speak something which would also increase her confidence. Empathy can be shown to happy as well as sad feelings. At this juncture, it is important to note that there is difference between 'empathy' and 'sympathy'. Counselors need to be empathetic, seeing things from the client's (patient's) point of view rather than sympathetic (feeling sorry for their clients).Empathy can help the counselor to ask/respond appropriately and lead the client to positive conclusion.

Showing empathy.

Mrs. Gupta: Good morning, Doctor.

Obstetrician: Good morning! Please sit down. How are you?

Mrs. Gupta: Doctor, this is my 8th month of pregnancy. I get frequent lower abdominal pain. Am I having some problem?

Obstetrician: I can understand, you must be worried about premature delivery. It must have restricted your activities also.

Mrs. Gupta: Yeah. I am unable to do my routine work.

Obstetrician: Ok I will first examine u and if needed I will do sonography. This calls for detail investigations.

In the exercise given above, you can understand that by empathetically responding to patient's complains, the patient would always wholeheartedly respect your advice and would also feel that you are the real caretaker of her sufferings. This would lead to improvement in doctor-patient relationship and a bond of trust would develop between doctor and the patient. In future if some mishap or unexpected event happens, they would consider that mishap as just an accident and could have happened at any body's hands. This would avoid unnecessary damage to hospital or comments on the hospital/staff.

Skill 6: Avoid Decisive/Judgmental Words

Health care provider should always avoid decisive/judgmental words in his/her talk with the patient as it may influence the patient's submission of his history of illness with preconceived thoughts.

For example,
Question: Do you feel better now? Instead of this, the question should be,
How do you feel now?

Let us see the situation and the dialogue between doctor and the pregnant lady.

Situation: Deepa, a 2nd Gravida patient with previous cesarean section having been done for cephalopelvic disproportion, approaches to nearby gynecologist for pain in lower abdomen at late hours in the night.
Listen to the dialogue between the two.

Deepa: Hello Madam.

Gynecologist: Hello! Please sit down.

Deepa: Madam, I am having pain in lower abdomen since afternoon and it has increased now. I am also feeling uneasy since then.

Gynecologist: O.K. Your expected date is one week ahead. Take rest. Come tomorrow morning. Till then take this tablet. You will immediately feel relief. It is common to get abdominal pain in last couple of days.

One can easily understand the possible medicolegal problem the doctor may face if patient comes next day with no fetal movements and rupture uterus.

Part II: Building up the Confidence and Giving Support

To be confident is important in every field of life. Confidence can overcome hurdles. It creates an ability to face the problem if it arises. In case of patient, it is very important in making her to be able to express the ailments of her disease. It also helps to build up the will power to survive, to fight with the disease. After all doctor's treatment works well in patients who are destined to live.

Many times, trivial things can decrease the confidence of the mother. In such situation, health staff need to be well versed with the skills of counseling that brings back her confidence and she feels like somebody is behind her, supportive all the time. Let us study these skills.

- Skill 1: Accept thoughts and feelings.
- Skill 2: Identify good things and admire
- Skill 3: Help by action.
- Skill 4: Provide requisite information
- Skill 5: Use simple language
- Skill 6: Do not order but suggest one or two things.

Skill 1: Accept Thoughts and Feelings

In order to maintain conversation keep going and to keep patient's morale raised up, you have to accept whatever patient thinks or feels. You may feel it as totally absurd. Sometimes you may feel that patient has many misconceptions that may affect her health adversely You need not approve or disapprove that time. You have to just remain neutral, neither say right nor wrong, but just show sheer acceptance.

Skill 2: Identify Good Things and Admire

It is an art to identify good things/qualities in others, admire and encourage. Patient gets encouragement to express fully.

- She gets inspired to continue the good things which were appreciated
- It leads to development of strong doctor-patient relationship. It creates a bond of trust between the two.

Situation 1: Breastfeeding mother approaches her gynecologist to seek advice to stop breastfeeding and start bottle feeding as she wants to resume her service. Her baby's weight has increased properly as per the growth chart. In this situation gynecologist can provide information regarding advantages of breastfeeding/disadvantages of bottle/formula feeding etc. but before that she can very well appreciate mother's efforts of breastfeeding which made baby grow properly and she came to gynecologist to seek advice instead of stopping breastfeeding and starting bottle feeding on her own.

Situation 2: A pregnant woman regularly visits obstetrician and takes medicines and proper diet as per the advice. In her latest antenatal care profile, Hemoglobin percentage is 13 g/100 mL. Out of these 3 responses.

Response 1: In pregnancy it is very essential to have proper diet and take medicines as per the doctor's advice.

Response 2: Good! It is because you came regularly for antenatal check up and took medicines and proper diet as per advice, your hemoglobin percent is excellent.

Response 3: Pregnant woman needs her antenatal care profile done as per doctor's advice.

The correct response will be number 2.

As discussed previously, appreciation of good things in patient is necessary to build up the confidence of the patient as well. Also it will be beneficial in a long run to decrease the grievances against doctors for a trivial mistake or error in judgment due to bond of trust developed between the two.

Skill 3: Help by Action

Sometimes instead of just verbal soothing talk, your one simple act can play a magic. It can make patient relaxed, comfortable and happy.

Situation 1: If pregnant patient visits your clinic on summer days in the afternoon. You just can ask her to sit down comfortably. If possible and necessary, you can ask your staff to switch on the fans and offer a glass of cold drinking water. You can then examine her systematically and explain the treatment and give instructions for follow up.

Situation 2: A pregnant patient, who just got delivered after a prolonged labor. She looks very much exhausted. You can help her by asking your staff to give her sugar water/drinking water/tea/coffee or start intravenous drip depending upon necessity.

Situation 3: A breastfeeding mother is not able to breastfeed her child. You can direct your staff to help her by showing different breastfeeding positions, by making the baby latch on properly.

Skill 4: Provide Requisite Information

Only that much information which is scientifically accurate and useful at that moment/in that situation. If the patient is just delivered and has only one issue then she can be counseled on copper-T insertion, its advantages, possible complications etc.

Skill 5: Use Simple Language

While talking with the patient or while providing him information, instead of using technical/scientific words, the gynecologist/health staff should use simple words, preferably in local language. Otherwise the patient may find it difficult to understand.

Skill 6: Do not Order but Suggest One or Two Things at a Time

While giving information to the patient, doctor should never use imperative words or give orders like—do this, you must not do this. Instead, you have to suggest one or two things useful in that particular situation. Patient needs just guidance from you. Finally she has to decide what to do or what not to do in that particular circumstance. You have to just create an ability in her to take appropriate decision and act accordingly. One should not impose his/her ideas or notions upon patients.

For example, If doctor tells pregnant lady who is anemic, Sunita! you must consume green leafy vegetables and Iron tablet daily. This becomes an order. Instead if doctor says, Sunita! it would be better, or you will feel better if you consume green vegetables and Iron tablet daily. This becomes a suggestion.

Sunita would definitely accept the second advice because ultimately she has to decide whether she wants to feel better or not. The first is just an order. She may ignore it. She may not pay attention.

CONCLUSION

By using counseling skills we, the gynecologists, can be the best communicators. Ultimately we are meant for offering humanized care which should be our main goal. That way we can do a lot for our needy patients. Ultimately care which means:

- C: Cheer with positive and encouraging messages
- A: Accepting with nonjudgmental attitude
- R: Referring if necessary
- E: Evidence-based knowledge is the crux of treatment.

We all must be committed to offer such care to our patients. By offering such care gynecologist/health staff can build up the confidence and give support to the patient. Effective counseling reduces confusion, allows the patient to make effective decisions leading to positive changes in their attitude and/or behavior. It is not advice giving and is not acting on someone else's behalf. The ultimate aim of counseling is to enable the patients to make their own choices, reach their own decisions and to act upon them accordingly. At the same time, it would leave good impression on the patients and relatives who would indirectly help to improve strained doctor-patient relationship in a true manner and ultimately this will definitely reduce the number of litigations against the medical fraternity.

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5

CHAPTER

Records and Documentation – Always at Your Rescue

Girish Kumthekar

INTRODUCTION

A medical record is documentation of medical and health care services provided to a patient at the directions of a physician, nurse or other caregiver. These records include documentation of medical observations and opinions by these professionals as well as the treatment and diagnostic documentation, such as X-rays, electrocardiography, and laboratory work. These records can be a paper record, electronic record or both. Thus a medical record is the who, what, why, where and when of patient care in the hospital.

McGibony has said, "A chronicle of the pageantry of medical and scientific progress is found in the hospital records. There may be found the running commentary, disconnected, it is true, of the drama, the comedy, the mystery, the miracles of medicine and hospital of the 20th century.

The primary purpose of medical records is to provide means of communication among physicians, nurses and other allied health professionals. It also serves as an easy reference for providing continuity in patient care. It is also helpful in quality review of patient care and documentary evidence of care provided by the establishment. It helps to protect patient, physician and institute in the event of litigation. The dictum is "People forget and records remember."

Medical record can be either a personal document, which contains identity, history of illness, physical findings, and treatment. This information is confidential and may not be released even to the next of the kin without permission and authorization of patient or to the legal agencies when ordered to do so by courts of law. It can also be an impersonal document which contains data and information used for research purpose. If it used only by physician or students permission of the patient is not necessary but the doctors are bound by professional secrecy.

WHAT ARE MEDICAL RECORDS?

Anything pertaining to the patient during the course of treatment and follow-up later on forms the medical record. They are outpatient/inpatient department papers, various investigation reports, image copies, nursing charts, discharge summary, referral letters if any, certificates issued and also electronic records or images soft copies. Add to it the various forms such as A, B, C, D , F ....., and so on which are legally required.

HOW LONG TO PRESERVE?

What Medical Council of India Has to Say?

Maintenance of Medical Records

- Every physician shall maintain the medical records pertaining to his/her indoor patients for a period of 3 years from the date of commencement of the treatment in a standard pro forma laid down by the Medical Council of India, and attached as Appendix 3 (MCI).
- If any request is made for medical records either by the patients/authorized attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours
- A registered medical practitioner shall maintain a register of medical certificates giving full details of certificates issued. When issuing a medical certificate he/she shall always enter the identification marks of the patient and keep a copy of the certificate. He/she shall not omit to record the signature and/or thumb mark, address and at least one identification mark of the patient on the medical certificates or report. The medical certificate shall be prepared as in Appendix 2.
- Efforts shall be made to computerize medical records for quick retrieval.

  As per guidelines in various enactments the stipulated time for preserving records is
  - Indoor case paper records for 3 years
  - Outdoor patient records in a hospital for 5 years and in GP for 2 years
  - All required registers such as OT register, fumigation register etc. for 2 years
  - For medicolegal cases—until demanded by the courts or till the case is decided.

- Obstetric records should preferable be stored for 21 years
- PCPNDT records for 2 years
- Medical termination of pregnancy (MTP) records for 5 years after the last entry in the register.

However it is recommended that keep them forever. They may be useful to you in defending litigations against you at any time or later on for retrospective research purpose. In case you have records, what you say is believed by the courts and if you don't have them, then what patient says is taken into consideration.

If you really want to destroy records, get them scanned and store them in electronic formats so that they are stored for ever and occupy a very small space. While destroying the records you have to follow a procedure. You must give notice in a local newspaper that you are destroying records for a certain period and whosoever wants them can take them away in a stipulated time. This is because the records have a property interest in it by the patients and they can claim that any time.

WHY RECORDS?

"Hombre apercebido medio combatido."
A man well prepared has already half fought the battle.
Miguel de Cervantes (1547–1616)

As per Evidence Act the medical records are treated as'primary evidence' in the court of law. Incomplete records are a poor defense and no records is no defense. Please remember that in the consumer courts the onus of proof of your negligence is on the complainant and not on you. In other words it is the patient who has to prove that you are negligent and hence they want to tear you apart with the help of your records. It is not up to you to prove that you are not negligent and hence your records must speak for themselves. The records must be able to reveal on face of it, your care, prudence and thoroughness in treating the patient. However in criminal proceedings, it is you who have to prove your innocence and that there is no criminality on your part. Here also records help you to get absolved from the charges.

ELECTRONIC RECORDS

Even MCI recommends going electronic way. The advantage of electronic records is that they are valid in the courts of law with certain criteria as defined in Indian Evidence Act. They are easy to generate and can be stored indefinitely. They can be retrieved and analyzed easily. However the flip side is that they can be discredited easily because they can be tampered with easily. Sometimes forensic evaluation is needed to prove their authenticity.

FABRICATION OF RECORDS

Records can be prepared, changed, modified, or authored to prove our innocence and suit litigation. But please remember that it amounts to fabrication of evidence and is a violation of Indian Evidence Act as well as Indian Penal code. So try to keep the records timely, legible, uncomplicated, and as clean as possible so that they cannot be discredited easily. Secondly tampering of the records can be detected very easily and this discredits the doctor in particular and medical fraternity in general. Recently one reputed hospital has been penalized for fabrication of records.

WHAT ARE IDEAL RECORDS?

According to me there is nothing like ideal records. The records must be maintained in a way suitable to that establishment and one's own working pattern. They must reflect your way of working and discipline you follow. The only requirement is the uniformity in keeping the records your way. The records must be clean, legible, and in chronological order. Overwriting and scratching are not welcome. Also remember too scanty documentation is dangerous and excessive documentation is equally dangerous. Court will question incomplete and scanty records and may try to fill in the blanks by themselves or if excessive record keeping is noticed, applicant may try to prove that they are fabricated records.

RECORDS PERTAINING TO OBSTETRICS

In Obstetrics we have to handle additional records such as antenatal care register, delivery register, neonatal papers, birth information reports, Preconception and Prenatal Diagnostic Technique (PCPNDT) registers, MTP registers etc.. It is recommended that all records pertaining to birth be preserved for 21 years. You may safely destroy MTP and PCPNDT records after stipulated limit. Intrapartum records must be meticulously preserved including partograms, cardiotocography, ultrasound soft copies or printouts.

CONCLUSION

Remember the patient and patient's authorized person have a property interest in the records and copies must be issued to them on demand within 72 hours. Records should be kept tidy, clean, legible, and in chronological order and properly indexed manner for the easy retrieval of data. Records should be completed as early as possible, because there are chances of error if completed at a later date thereby increasing mistakes. Unnecessary alteration, addition, deletion, overwriting of the notes should be avoided, because such alteration can be detected very easily. Doing so, records can be discredited and one is left with no defense. Do not mention a disease which cannot be proved or substantiated with investigations and clinical findings. 'Amniotic fluid embolism' is the most quoted cause of sudden death for which there is no clinical or laboratory evidence. One should always remember, "records are your best defense, incomplete records is poor defense, and no records is no defense."

Remember "records are your best defense," "incomplete records is poor defense," and "no records is no defense".

6

CHAPTER

Medical Termination of Pregnancy Act: Provisions and Penalties

MC Patel

INTRODUCTION

Medical termination of pregnancy (MTP) is day to day common practice for obstetrician and gynecologist. In ordinary course it is very simple procedure usually, which is uneventful normally, but whenever there is complication, of a serious nature, it may endanger life of the pregnant woman. A woman's death resulting as a consequence of a termination procedure is not palatable to any family. If it occurs, is likely to lead the physician in to litigation which could be, either in civil or criminal or both and before medical council and/or in human commission.

BEFORE MEDICAL TERMINATION OF PREGNANCY ACT 1971

1. Absolute prohibition of termination of pregnancy
2. No consideration for any circumstances whatsoever, required/compelled the woman to procure the abortion.

ABORTION OR INDUCED MISCARRIAGE: UNDER THE PURVIEW OF THE INDIAN PENAL CODE SECTIONS 312-316

Both were considered guilty:

1. Person performing the abortion or causing the miscarriage
2. Woman undergoing abortion.

Excuses were only:

1. Abortion done in good faith
2. In order to save the life of woman.

Section 312: Causing miscarriage with or without consent of pregnant woman

- Punishment: 3–7 years imprisonment
- Offenders: Both person causing miscarriage and pregnant woman

Section 313: Causing miscarriage without consent of pregnant woman:

- Punishment: Up to 10 years imprisonment
- Offenders: Person causing miscarriage.

Section 314: Act with the intent of causing miscarriage resulting in the death of the woman.

Section 315: Act with the intent of causing death of the unborn child or causing a child to die after birth.

Section 316: Act to cause the death of a pregnant woman resulting in the death of the unborn child.

AFTER MEDICAL TERMINATION OF PREGNANCY ACT 1971

In India practice of termination of pregnancy is legally governed usually by 'The medical termination of pregnancy act 1971 and in some of the cases Indian Penal Code (IPC) section 312 to 316.

Many a times question comes in our mind "why we should discuss the issue?"

Let us see one case happened.

- In 2003 a couple visits gynecologist for MTP
- Following consent, MTP was done
- In 2004 there was some dispute in family, so patient filed complaint against in-laws for forceful abortion
- Doctor was called as a witness. He was arrested in the court under IPC 312
- Doctor was put behind the bar.

After 3 days.

- Parties had compromise
- Case was withdrawn
- Doctor was free from bar

Where thing went wrong?

- Can one be prosecuted under IPC 312–316?
- There is provision under MTP act 1971.

"Notwithstanding anything contained in the IPC a registered medical practitioner shall not be guilty of any offence under that code or any other law for the time being in force, if any pregnancy is terminated by him in accordance with the provisions of this Act"

If in this case, this provision would have been taken in defense, story would have been different. So, it is very essential to know provisions of the act and practice accordingly to avoid any litigation.

In Panchatantra rightly said,

"A small slip can make big trouble so an ounce of prevention is worth more than a ton of cure".

OBJECTIVES OF MEDICAL TERMINATION OF PREGNANCY ACT

1. To liberalize provisions of termination of pregnancy
2. To protect the registered medical practitioner who perform abortion as per the provisions under this Act
3. To keep the record of a woman undergoing MTP secret.

So, let us understand the provisions of this act to practice medical termination of pregnancy safely and litigation free.

- Place: Where pregnancy can be terminated (Section 4 of the MTP Act and the rules)
  - i. A hospital established or maintained by the government
  - ii. A place approved by government or a district level committee
- Who can terminate first trimester pregnancy? (Section 2(d) of the act)
  - a. Medical practitioner, registered in a state medical register immediately before the commencement of MTP act, having experience in the practice of gynecology and obstetrics for a period of not less than three years
  - b. Medical practitioner, registered in a state medical register
    - i. If he has completed six months of house surgery in gynecology and obstetrics, or
    - ii. If he had experience at any hospital for a period of not less than one year in the practice of obstetrics and gynecology; or
    - iii. If he has assisted a registered medical practitioner in the performance of twenty five cases of medical termination of pregnancy of which at least five have been performed independently, in a hospital established or maintained, or training institute approved for this purpose by the government.

    Note: This training would enable the registered medical practitioner (RMP) to do only 1st trimester terminations.

  - c. Medical practitioner, registered in a state medical register and who holds a post graduate degree or diploma in gynecology and obstetrics, and has the experience or training gained during the course of such degree or diploma.
- A registered medical practitioner is one who has a recognized medical qualification under section (2) clause (h) of Indian Medical Council act 1956,and his/her name is in the state medical register
- Person other than allopathic doctor can never be eligible for practicing medical termination of pregnancy.

Proposed Amendment in Act by Government of India

Ministry has recommended allowing homeopaths, nurses, and midwives to conduct noninvasive abortions with training.

- Can RMP running only consulting room prescribe RU 486?
  - Yes, but he/she should have access at any registered center under MTP act
  - Certificate of approval for access should be displayed at conspicuous place of clinic.

  Note: Prescribing RU - 486 is one of the procedures of MTP and all rules and regulations of this Act will apply.

INDICATIONS FOR MEDICAL TERMINATION OF PREGNANCY ACT

Any one of the following indications under the act is acceptable.

- Risk to the life of the pregnant woman or of grave injury to her physical or mental health
- Risk to child born—physical or mental abnormalities leading to serious handicap
- Pregnancy caused by rape—a grave injury to the mental health of the woman
- Pregnancy due to failure of contraception method by male or female—unwanted child presumed—a grave injury to the mental health of the woman.

In deciding the risk of injury to health of the pregnant woman her actual or reasonable foreseeable environment may be taken into account.

Proposed Amendment in Act by Government of India

Ministry has recommended one more indication i.e., unplanned/unwanted pregnancy: For single or unmarried woman.

Consent

- Under Section 3(4) of the act and rule 9
- To take consent on Form C is mandatory
- Consent taken on any other paper is not valid
- It should be an informed consent
- It should be written consent
- Who can give consent?
  - a. Any major female who is mentally sound

b. In case of minor and/or mentally challenged, a guardian can give consent.

Opinion

- Opinion of the RMP is to be put on the record in prescribed Form I
- The number of opinion will vary according to the stage of pregnancy
- In 1st trimester termination opinion of one RMP is sufficient
- In 2nd trimester termination opinion of two RMP is mandatory
- To terminate pregnancy more than 20 weeks is illegal (exception under section 5 in special circumstances)
- One can approach court for special permission. If permitted then only one can terminate pregnancy more than 20 weeks.

Proposed Amendment in Act by Government of India

Ministry has recommended extending the gestational period from 20 to 24 weeks for special categories which may include single woman with unwanted pregnancy.

- Law would allow abortion any time during pregnancy for selective fetal abnormality which cannot be detected during 20 weeks gestation

So, if this amendment passes in government gazette, really indicated patient will have great relief.

Is Medical Termination of Pregnancy right of Patient?

In case of V Krishanan versus G Rajan; MAD LW (DB) court has clarified

- The MTP Act does not confer or recognize any right on any person to perform an abortion or termination of pregnancy
- Even the pregnant woman cannot terminate the pregnancy except under the circumstances mentioned in the Act
- Even during the 'first trimester', the woman cannot abort at her will and pleasure, there is no question of "abortion on demand".

Section 3 [18] is only an enabling provision to save the RMP from the purview of the IPC. Court further added that "termination of pregnancy under the provision of the Act, is not the rule and it is only an exception.

Conditions which Need to be Satisfied

Termination of pregnancy should be performed under safe and hygienic conditions.

The following facilities are provided there in namely

- A gynecological examination/labor table
- Instruments for performing abdominal or gynecological surgery
- Resuscitation and sterilization equipment,
- Drugs and parental fluid
- Back up facilities for treatment of shock
- Facilities for transportation.

Registration of the Center

Registration is done after

- Application in form A is submitted to chief district medical officer with necessary documents
- On inspection and verification, if he is satisfied, chief district medical officer (CDMO) will recommend the approval of the place to the district level committee
- District level committee may after considering the application and the recommendations of the CDMO approve such a place and issue a certificate of approval in Form B.

The certificate of approval (Form B) is to be displayed at a conspicuous place of clinic easily visible to persons visiting the place.

Suspension or Cancelation of Registration

- This may happen after CDMO prepares a report enumerating the defect and deficiency found at the approved place
- Report than be placed before district level committee. Committee if satisfied cancels or suspends the approval
- Opportunity must be given to the owner of the place to make a representation before cancellation. Suspension commences from the date of communication.

Record Keeping

Absolute confidentiality of records is to be maintained.

Under the MTP act Rules and regulations it is mandatory to keep the following records

- Consent Form in Form C
- Opinion of RMP in Form I
- Maintenance of admission register in Form III
- Monthly reporting to CDMO in Form II.

Every head of the hospital or owner of the approved place is obligated under the MTP rules to send the record to the CDMO as a monthly statement of the MTP cases performed in the hospital in Form II regularly at the end of month in reasonable time.

How to Maintain Record (Custody of Forms)?

- Form C (consent) and Form I (opinion recorded under section 3 or section 5 and intimation of termination of pregnancy) should be placed in an envelope and envelope is sealed by RMP
- On envelop there shall be noted the serial number assigned to the woman and name of the RMP(s) by whom pregnancy is terminated and such an envelope shall be marked "SECRET"
- Envelopes shall be sent to the head of the hospital or approved place within three hours from the termination of pregnancy by the RMP who terminates any pregnancy and he will certify such termination in Form I

- They should be kept in safe custody by the head of the hospital or at an approved place
- Every head of the hospital or owner of the approved place is obligated under the MTP rules to send the record to the CDMO as a monthly statement of the MTP cases performed in the hospital in Form II in reasonable period.

Maintenance of Admission Register (Form III)

- Admission register is a secret document. Information therein is to be kept strictly confidential
- It is to be kept in the custody of the head of the hospital or owner of the approved place
- It is not to be opened to inspection except in some special circumstances
  - When a working/employed woman applies for a certificate for the purpose of obtaining leave (In this circumstances employer is requested to keep data confidential and not to disclose)
  - Under authority of law
- No entry of the name of the pregnant woman can be made in case sheet, operation theatre register, follow up card or any other documents
- References to the pregnant woman in such places other than the admission register is to be made by serial number assigned to the woman
- The entries in the admission register shall be made serially and a fresh serial shall be started at the commencement of each calendar year and the serial number of the particular year shall be distinguished from the serial number of other years by mentioning the year against the serial number i.e., serial number of 6 of 2010 and serial number of 6 of 2011 shall be mentioned as 6/2010 and 6/2011.

Reporting and Record Maintenance in Emergency (Under section 5)

In case of MTP done to save the life of a woman, where pregnancy is not terminated in an approved place or hospital

- Envelop should be sent to the CDMO by registered post on the same day or on the next working day
- Envelop marked secret shall contain the name and address of the RMP who did termination
- In Form I leave blank column pertaining to the hospital or the approved place and the serial number assigned to the pregnant woman in the admission register.

If pregnancy is terminated in an approved place

- Procedure will be the same as provided in regulation 6 (1) (as shown in previous para of custody of forms).
- Pregnancy exceeding 20 weeks may be terminated even without the opinion of 2 registered medical practitioners where:
  a. The registered medical practitioner is of opinion, formed in good faith
  b. That the termination is immediately necessary to save the life of the pregnant woman. But burden of proof is on shoulder of RMP to prove the situation.

Preservation of Record

- Admission register should be preserved for a period of 5 years from the end of the calendar year it relates to
- In case of litigation records are to be preserved till final disposal of litigation.

Offences and Penalties

- Termination of pregnancy by any person at un approved place or termination of pregnancy by any person other than RMP will be liable for imprisonment not less than 2 years may extend up to 7 years
- Any contravention of the requirement of record keeping will invite a fine which may extend to Rs 1000.

WORDS OF CAUTION

- Rule out ectopic pregnancy and if it is ectopic manage the situation accordingly
- If patient is Rh -ve treat her accordingly with injection Anti D
- If it is partial or complete molar pregnancy manage patient accordingly
- Take valid consent
- Practice MTP at registered place only
- Comply with the provisions of MTP Act 1971
- Use of RU486 also needs complying with all these provisions of MTP act.

It is essential to comply with the provisions of MTP act. This will result in litigation free practice.

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7

CHAPTER

Pharmacy Licensing

Rajendrasing Pardeshi

DECIDING THE TYPE OF PHARMACY

Before registering for a traditional pharmacy, a person must decide on the type of pharmacy that he wants to run.

Hospital Pharmacy

This pharmacy is set-up inside a hospital to cater to the in-hospital needs of medicine.

Standalone Pharmacy

This is the most common set-up and includes all the pharmacies that are present in a residential area.

Chain Pharmacy

Chain pharmacies are usually present in malls and are part of a chain of pharmacies.

Township Pharmacy

If a pharmacy is set-up in a township then it is acknowledged as the township pharmacy.

REGISTRATION OF PHARMACY BUSINESS

The registration of a traditional pharmacy is governed by the Indian Pharmacy Act of 1948. It states that a pharmacist must register all his particulars to the state government through an official gazette. After the submission, a registration tribunal decides on the registration.

How to Start a Medical Store?

For opening the retail drug store some legal requirements should be fullfilled as mentioned below.

Minimum Qualification

The person should be registered pharmacist with the state pharmacy council. For this registration minimum qualification is diploma in pharmacy, bachelor in pharmacy, doctor of pharmacy.

Usually hospital, chain and township pharmacies are setup under private limited company constitution whereas standalone pharmacies are set up under proprietorship or partnership constitution.

Presently, Limited Liability Partnership constitution has gained immense popularity among standalone pharmacists as it promotes the rights of partners unlike a partnership constitution.

Registration of Tax

In India the most important tax registration includes goods and services tax (GST) registration, therefore a pharmacist must contact the GST Department for the same.

Obtaining Drug License

Before selling medicines, a drugstore must obtain drug license from the Central Drugs Standard Control Organization and State Drugs Standard Control Organization.

Mainly there are two major drug license issued by the Drugs Control Organization

- Retail drug license: This license is required to run a general chemist shop. To get this license you must deposit a requisite fee and must possess a degree or diploma in pharmacy from a recognized institute or university
- Wholesale drug license: This license is issued to people or agencies who wish to set up a wholesale business for drugs and medicines. Unlike retail drug license, there are no stringent conditions to get this license.
    - Apart from these special requirements, there are some minimum conditions that must be followed by pharmacists to procure any drug license

- For a retail drugstore the minimum requirement of area is 10 square meters, and that for a common retail and wholesale pharmacy is 15 square meters
- A drugstore must have a refrigerator and air conditioner.
- Both retail and wholesale pharmacies must have a registered pharmacist who must be present while selling the medicines.

Documents Required for Registration

- Application forms
- Challan of fee deposited
- Declaration form
- Site plan (blue print)
- Key plan (blue print)
- Basis of possession of the premises
- Proof of ownership of the premises, if rented
- Proof of constitution of the firm (certified copy)
- Affidavit of nonconviction of proprietor/partners/directors under Drugs and Cosmetics Act, 1940
- Certified copy of resignation, certificate of city pharmacy, council/experience certificate of the registered pharmacist/competent person and qualification certificates
- Biodata form
- Affidavit of registered pharmacist/competent person regarding full-time working with the firm duly attested by notary.
- Appoint.

Legal Procedures for Setting up an Online Pharmacy

Lately, people are shifting towards online pharmacies as they are most convenient method of buying medicines. Through online pharmacies customers can procure even rare medicines with utmost ease and privacy. Loads of online pharmacies have become prevalent in India but they too need to abide by certain legal procedures before being functional.

Setting up an Online Pharmacy

Any person can set up an online drugstore only if he is registered with a licensed traditional drugstore or if it has partnered with a licensed dealer to execute the online orders.

Green Zone

According to the Indian laws, the following practices are legal for online pharmacies:

- Except over-the-counter drugs, all other drugs require a prescription
- The contact details of an online drugstore must be of the state from which they have procured the drug license
- The licensed drugstore has to verify and certify the delivered drugs.

Grey Zone

These practices are uncertain as per the Indian law.

- Shipping of medicines from one state to another
- The provision of taking the money prior to delivery of medicine.

Red Zone

These practices are illegal as per Indian laws:

- Selling schedule H and schedule X medicines without prescription
- Selling medicines to minors
- Selling medicines that are not approved by State Drug Control Organization
- Exporting medicines without approval from the drug department of the respective country.

Though traditional pharmacies cater to the medicinal needs of the major population of India but still there is a need for online pharmacies that fit into the Indian legal system because the online pharmacies create an advantageous situation for both consumers as well as pharmacists.

Pharmacy for Doctors

The Food and Drug Administration (FDA) has been asking doctors to follow the Drugs and Cosmetics Act 1940 verbatim, and even launched an educational and awareness campaign, especially in taluka places. The act has always had clear cut directions for practicing doctors. The FDA was just trying to ensure that these directives are being followed strictly. "Every doctor must maintain a detailed purchase and use record of every schedule H and G medicines, which includes drugs like antibiotics, sedatives, and general drugs. They also need to store the drugs as per rules and keep a record of every drug consumed by patients," he said. Doctors were expected to maintain bills of each purchase and not sell the medicines procured as samples from medical representatives or sell them across the counter. Doctor is not directly licensed to sell drugs, nor do they require a license.

What the Law Prescribes?

- Doctor allowed to dispense medicines to patients, does not require any drug license
- Drugs shall be purchased only from licensed dealer or manufacturer, and records of such purchases showing names and quantities of drugs, batch numbers and names and addresses of manufacturer should be maintained
- Doctors should not keep an open shop or sell across the counter or engage in import, distribution, manufacture or sale of drugs without valid FDA license.

Chapter IV of the Drugs and Cosmetics Act, 1940 (as amended by the Drugs (Amendment) Act, 1955, the Drugs (Amendment) Act, 1960, the Drugs (Amendment) Act, 1962, the Drugs and Cosmetics (Amendments) Act, 1964, the Drugs and Cosmetics (Amendments) Act, 1972, the Drugs and Cosmetics (Amendments) Act, 1982, the Drugs and Cosmetics (Amendments) Act, 1986 and the Drugs and Cosmetics (Amendments) Act, 1995) deals with manufacture, sale, and distribution of drugs 1 (and cosmetics).

Part XI of the the Dugs and Cosmetics rules, 1945 (as corrected up to the 30th november, 2004) deals with exemption to chapter IV of the Dugs and Cosmetics Act, 1940. Rule 123. 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.

SCHEDULE K (SEE RULE 123)

Class of Drugs

4[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 the provision of chapter IV of the Act and the rules thereunder.

Extent and Conditions of Exemption

All the provisions of chapter IV of the Act and the Rules made thereunder, subject to the following conditions: 5[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.

RULES REGARDING KEEPING AND DISPENSING OF DRUGS BY THE RMP

- A license is required for sale, distribution etc. of drugs as per Drugs and Cosmetics Act (DCA) and Drugs and Cosmetics Rules (DCR). However, considering the nature, manner, and conduct of Medical Practice in India and also considering the emergencies and other related contingencies often encountered by the registered medical practitioner (RMP), while treating the patients, the law has exempted the RMPs from having a license in the interest of public health. This exemption is for the following categories of drugs:
  - All drugs supplied by RMPs to his patients only, or
  - Any drug specified in schedule C (biological and special products) of DCR, supplied by a RMP on the request of another RMP if it is specifically prepared with reference to the condition and for the use of the individual patient
- Thus, though the RMPs enjoy the exemption, they are required to strictly follow the following conditions when they keep and dispense the drugs:
  - RMPs should not (a) Keep an open shop or (b) sell across a counter, or (c) engage in importation, manufacture, distribution, or sale of drugs in India to a degree which makes him liable to provisions of chapter IV (it refers to manufacture, sale, and distribution of drugs and cosmetics) of DCA and DCR
  - (a) The drugs shall be purchased only from a dealer or a manufacturer licensed under DCR and (b) records of such purchases showing the names and quantities of such drugs, together with their batch numbers and names and addresses of manufacturers should be maintained. Such records shall be open to inspection by a drug inspector who may, if necessary, make enquiries about the purchases of drugs and may also take samples for test
  - The drug should be stored under proper storage conditions as directed on the label of the drug
  - No drug should be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper
  - Additional conditions in case of medicine containing substance specified in schedule G, H, or X of DCA and DCR:
    - The medicine shall be labeled with the name and address of the RMP by whom it is supplied
    - Medicine for external application should be labeled with the words 'For External Use Only'. If it is for internal use, it should be labeled with dose
    - 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 the register to be maintained for the purpose
    - The entry in the register shall be given a number and that number shall be entered on the label of the container
    - 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 maybe.

Note: The law has contemplated the practices followed by RMPs in the past namely, to purchase the drugs in the bulk and dispense them in small quantities to the patients and at times, compound and dispense the drugs to the patients. Though this practice is presently on the wane, the conditions given above, at (a) to (e) are still required to be followed by the RMPs. Registered medical practitioners may prepare a stamp containing full name, address and registration number and stamp it on (a) and (b) above, while dispensing. Information regarding (c), (d), and (e) may be kept in soft for inspection of drug inspector etc.

- This also applies to drugs received as not for sale physician's samples
- The intention of the law, as reflected in the above conditions, is to account and trace the drugs as per the batch number, in case of any instance of substandard drug and to take further action in accordance with law and also to trace the consumer/patient who could be a likely victim. Any violation of conditions given in I to VI above is punishable under the DCA. The concerned State Medical Councils may also take disciplinary action against the RMPs, as they deem fit, if reported by the regulatory agencies.

Register format for entering drugs you/your hospital, purchased from outside

Serial number	*Date and time of supply*	*Name and address of patient*	*Name of medicine*	*Quantity of medicine*	*Dose prescribed*	*Remarks*

Details of Schedule "K"

373 *Drugs and Cosmetics Rules, 1945*

SCHEDULE K

[*See* rule 123]

Class of Drugs Extent and Conditions of Exemption

(1) Drugs falling under clause (b)(i) of Section 3 of the Drugs and Cosmetics Act not intended for medicinal use.
All the provisions of Chapter IV of the Act and the Rules thereunder subject to the conditions that the drug is not sold for medicinal use or for use in the manufacture of medicines and that each container is labeled conspicuously with the words "not for medicinal use"[1]

[2][2A] Quinine and other antimalarial drugs. Persons selling the drug by retail under arrangements made by State Government for sale and distribution of the drugs will be exempted from the requirement to take out licenses for retail sale under clause C**3** of Section 18 of the Act[3]
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 (i) keeping an open shop or (ii) selling across the counter, or (iii) engaged in the importation, manufacture, distribution or sale of[4]
All the provisions of Chapter IV of the Act and the Rules made thereunder, subject to the following conditions:

[5][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.

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1. Omitted by Government of India Notification No. F.1-56/47-D, dated 16.1.1950).
2. Added by Notification No .F. I-2/47-D dated 13-2-1950.
3. Amended by Notification No. F. I-22/59-D dated 9-4-1960.
4. Omitted by Notification No. F.I-6/62-D dated 2-7-69.
5. Amended by Min. of Health & F.W. Notification No. X- 11013/3/76-D & MS, dated 19-8-1978.

Drugs and Cosmetics* 374 *Rules, 1945

Class of Drugs Extent and Conditions of Exemptions

Drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules thereunder.

(2) 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 labeled 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 labeled with the words[2] "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

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(e) The register and the prescription, if any, on which the medicines are issued shall be preserved for not less than 2 years from the date of the last entry in the register or the date of the prescription, as the case may be.

[3][3] The drug will be stored under proper storage conditions as directed on the label

[5A]. Drugs supplied by a hospital or dispensary maintained or supported by government or local body.[4]
The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale license, subject to the following conditions.

1. Subs. by G.S.R. 462(E), dated 22.6.1982.
2. Omitted G.S.R. 462(E), dated 22.6.1982.
3. Ins. G.S.R. 460(E), dated 22.6.1984.
4. Omitted G.S.R. 812(E), dated 14.11.1994.

Drugs and Cosmetics* 375 *Rules, 1945

Class of Drugs Extent and Conditions of Exemptions

(1) The dispensing and supply of drugs shall be carried out by or under the supervision of a [1][registered pharmacist]

(2) The premises where drugs are supplied or stocked shall be open to inspection by an Inspector appointed under the Drugs and Cosmetics Act who can, if necessary, take samples for test.

(3) The drugs shall be stored under the proper storage conditions.

[2][4] The drugs shall be purchased from a manufacturer or a dealer licensed under these rules or received as transferred stocks from hospital stores for distribution. Records of such purchases or receipts shall be maintained

[3][5B] Whole Human Blood I.P. and/or its components stored for transfusion by a First Referral Unit, Community Health Centre, Primary Health Centre and Hospital.

The provisions of Chapter IV of the Act and the rules made thereunder which require obtaining of a license for operation of a blood bank or processing Whole Human Blood and/or its components subject to the following conditions, namely:

(1) The First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall be approved by the State/ Union Territory Licensing Authority after satisfying the conditions and facilities through inspection

(2) The captive consumption of Whole Human Blood I.P or its components in the First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall not be more than 2000 units annually

(3) The Whole Human Blood and/or its components shall be procured only from Government Blood Bank and/or Indian Red Cross Society Blood Bank and/or Regional Blood Transfusion Centre duly licensed

(4) The approval shall be valid for a period of 2 years from the date of issue unless sooner suspended or cancelled and First Referral Unit, Community Health Centre, Primary Healthy Centre or the Hospital shall apply for renewal to the State Licensing Authority three months prior to the date of expiry of the approval

(5) The First Referral Unit, Community Health.

1. Subs. by G.S.R. 676(E), dated 6.9.1994.
2. Ins. by G.S.R. 648(E), dated 16.9.2002 (w.e.f. 1.10.2002).
3. Ins. by G.S.R. 909(E), dated 20.12.2001.

Drugs and Cosmetics* 376 *Rules, 1945

Class of Drugs Extent and Conditions of Exemptions Centre, primary health centre and/or any hospital shall have the following technical staff for storage of blood or its components:

(a) A trained medical officer for proper procurement, storage and cross matching of blood and/or its components. He/she shall also be responsible for identifying hemolysis blood and ensure non-supply of date expired blood or its components

(b) A blood bank technician with the qualification and experience as specified in Part XII B of Schedule F or an experienced laboratory technician trained in blood grouping and cross matching.

(6) The first referral unit, community health centre, primary health centre and hospital shall have an area of 10 sq meters. It shall be well lighted, clean and preferably air-conditioned. Blood bank refrigerator of appropriate capacity fitted with alarm device and temperature indicator with regular temperature monitoring shall be provided to store blood units between 2°–8°C and if the components are proposed to be stored, specialized equipments as specified in Part XII B of Schedule F shall also be provided

(7) The first referral unit, community health centre, primary health centre and hospital shall maintain records and registers including details of procurements of Whole Human Blood I.P and/or blood components, as required under Part XII B of Schedule F

(8) The first referral unit, community health centre, primary health centre and hospital shall store samples of donors blood as well as patients sera for a period of seven days after transfusion[1]

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Drugs and Cosmetics* 377 *Rules, 1945

Class of Drugs Extent and Conditions of Exemptions

[7] Quinine sulphate: The provision of subsection (a)(i) of section 18 of the Act to the following extent:

(a) The color of the drug may be pink, owing to its being colored with an edible pink coloring matter

(b) The BP tests for readily carbonizable substances produce a yellow color of an intensity about four times the color produced with quinine sulphate conforming to the BP standard

(c) Other Cinchona alkaloids present shall not exceed 6%

(d) The residue on incineration shall not exceed 0.14%.

[1][9] Magnesium sulphate: The provisions of sub-clause (i) of clause (ii) of section 18 of the Act to the following extent

Chlorides present in the salt shall not exceed 0.12% in the case of, the produce prepared from sea water.

1. Item 6 omitted by G.S.R. 681(E), dated 5.12.1980.

[2][10] The following substances which are used both as articles of food as well as drugs:

All the provisions of Chapter IV of the Act and the Rules thereunder

(i) All condensed or powdered milk whether pure skimmed or malted, fortified with vitamins and minerals or otherwise

(ii) Farex, Oats and all other similar cereal preparations whether fortified with vitamins or otherwise excepting those for parenteral use

(iii) Virol, Bovril, Chicken essence and all other similar predigested foods

[1](iv) Ginger, pepper, cumin. cinnamon and all other similar spices and condiments unless they are specially labeled as conforming to the standards in the Indian Pharmacopoeia or the official pharmacopoeias and *Drugs and Cosmetics* 378 *Rules, 1945 Class of Drugs Extent and Conditions of Exemptions* official compendia of drug standards prescribed under the Act and rules made thereunder.

[3][12] Substances intended to be used for destruction of vermin or insects, which cause disease in human beings or animals viz. insecticides and disinfectants.

The provisions of chapter IV of the Act and the Rules thereunder which require them to be covered by a sale license 1 [subject to the conditions that provisions of condition (17) of rule 65 of the drugs and Cosmetics Rules, 1945 are complied with by the person stocking or selling such substances]

[13] [2]The following household remedies, namely:

[3](1) Asprin tablets

[4](2) Paracetamol tablets

(3) Analgesic balms

(4) Antacid preparations

(5) Gripe water for use of infants

(6) Inhalers, containing drugs for treatment of cold and nasal congestion

The provision of chapter IV of the act and the rules thereunder which require them to be covered with a sale licence in Form 20 A subject to the following conditions:

(a) The drugs are sold only in a village having population of not more than one thousand persons and where there is no licensed dealer under the Drugs and Cosmetics Act

(b) The drugs do not contain any substance specified in 5 [Schedule G, H, or X].

(7) Syrups, lozenges, pills, and tablets for cough

(8) Liniments for external use

(9) Skin ointments and ointments for burns

(10) Absorbent cotton wool, bandages, absorbent gauze, and adhesive plaster

(11) Castor oil, liquid paraffin, and epsom salt

(12) Eucalyptus oil

(13) Tincture Iodine, tincture compound tincture of benzoin, and Mercurochrome solution in containers not exceeding 100 mL

(14) Tablets of quinine sulphate I.P.

(15) Tablets of Iodochlorohydroxy quinoline 250 mg

(c) The drugs are sold in the original unopened containers of the licensed manufacturers

(d) When the drugs are sold under clause (a) condition 3 under "Conditions of licence" of Form 20 B shall not apply.

1. Added by Notification No.F.I-19/50-DS, dated 30.3.1953.

2. .Added by. Notification No. DR/Sch. Ddk/F. I-40/54-DS, dated 27.1.1955.

3. Amended by Notification F. 1-20/60-D, dt.24.1.1964.

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Drugs and Cosmetics* 379 *Rules, 1945 Class of Drugs Extent and Conditions of Exemptions

[6][14] Mechanical contraceptives: The provisions of Chapter IV of the Act and rules thereunder, which require them to be covered by a sale licence, 7 [subject to the condition that the provisions of condition (17) of rule 65 of the Drugs and Cosmetics Rules,1945 are complied with by the person stocking or selling mechanical contraceptives]

[1][14A] Vaginal contraceptive pessaries containing nonoxynol.

The provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered by a sale license subject to the condition that the provisions of clause (17) of rule 65 of the Drugs and Cosmetics Rules, 1945 are complied with by the person stocking or selling this contraceptive

[2][15] Chemical contraceptive having the following composition per tablet:

[2](1) DL-Norgestrel – 0.3 mg
Ethinyloestradiol – 0.03 mg

(2) Levonorgestrel – 0.15 mg
Ethinylestraditol – 0.3 mg

(3) Centchroman – 30 mg

[3](4) Desogestrel – 0.150 mg
Ethinyloestradiol – 0.030 mg

(5) Levonorgestrel – 0.1 mg
Ethinyloestradiol – 0.02 mg.

The provisions of Chapter IV of the Act and the rules made thereunder which required them to be covered with a sale licence.

[4][16] Cosmetics: 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.

[5][17] Ophthalmic ointments of the tetracycline group of drugs.[6]

Persons authorized by the Government to distribute or sell the drugs under the National Trachoma Control Programme shall be exempted from the provisions of Chapter IV of the Act and the rules made thereunder, which require the drugs to be covered by a sale licence.

[7][19] Hair Fixers, namely mucilaginous preparations containing gums, used by men for fixing beard.

The provisions of Chapter IV of the Act and the rules thereunder.

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1. Added by G.S.R. 926, dated 16.7.1977.
2. Ins. by Notifn No. F.1-19/59/D,, dated 13.6.1961.
3. Amended by Notifn No. S.O. 2139, dated 12.8.1972.
4. Subs. by Notifn No. 1060(E), dated 5.9.1986.
5. Subs. by G.S.R. 462(E), dated 22.6.1988.
6. Ins. by Notifn No. F. 1-39/61-D, dated 23.3.1964.
7. Subs. by G.S.R. 926, dated 16.7.1977.

Drugs and Cosmetics* 380 *Rules, 1945
Class of Drugs Extent and Conditions of Exemptions

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1. Ins. by G.S.R. 784(E), dated 28.8.1989.
2 . Subs. by G.S.R. 730 (E), dated 10.12.1991 and corrected by G.S.R. 305(E), dated 4.3.1992.
3. Ins. by G.S.R. 648(E), dated 16.9.2002.
4. Ins. by Notification No. 1-36/64-D, dated 17.8.1964.
5. Ins. by . Notification No. I-21/63-D, dated 4.1.1965.
6. Omitted by Notification No. G.S.R. 1594, dated 13.11.1976.]
7. Ins. by Notification No. S.O.2139, dated 12.8.1971.

[1][20] Radio pharmaceuticals: All the provisions of Chapter IV of the Act and the rules made hereunder.

[2][21] Tablets of chloroquine salts. The provisions of Chapter IV of the Act and the Rules thereunder, which require them to be covered by a sale licence, provided the drug in strip pack is sold under the Commercial Distribution Scheme of the National Malaria Eradication Programme and duly labeled as "National Malaria Eradication Programme–Ministry of Health and Family Welfare, Government of India."

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[3][22] Sales from restaurant cars of trains and from coastal ships of household remedies, which do not require the supervision of a registered pharmacist for their sale.

The provisions of Chapter IV of the Act and the rules thereunder which require them to be covered with a sale licence, subject to the following conditions, namely:

(a) The records of purchase and sale of drugs shall be maintained by the person in charge of sale of such drugs, which shall be available for inspection by an Inspector appointed under the act

(b) The place where such drugs are stocked shall be open to inspection by an Inspector appointed under the act who can, if necessary, take samples for test.

[4][23] Drugs supplied by: (i) Multipurpose workers attached to primary health centers/sub-centers, (ii) Community health volunteers under the Rural Health Scheme[5] (iii) Nurses, auxiliary nurse, midwives and lady health visitors attached to urban Family Welfare centers/primary health centres/sub-centers, and [6](iv) Anganwadi workers.

The provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale licence, provided the drugs are supplied under the health or family welfare programme of the central or state government.

Drugs and Cosmetics* 381 *Rules, 1945 Class of Drugs Extent and Conditions of Exemptions

[2][25] Preparations applied to human body for the purpose repelling insects like mosquitoes

The provisions of Chapter IV of the Act and Rules thereunder which require them to be covered by a sale licence subject to conditions that such a product has been manufactured under a valid drug manufacturing licence.

[26] [3][Medicated dressings and bandages for first aid]

The provisions of Chapter IV of the Act and rules thereunder which require them to be covered by a sale licence subject to the conditions that such a product has been manufactured under a valid drug manufacturing licence]

[4][27] Oral Rehydration Salts (Manufactured as per the following formula):

Sodium chloride 3.5 g/L

*Trisodium citrate dihydrate 2.9 g/L

Potassium chloride 1.5 g/L

**May be replaced by sodium bicarbonate (sodium hydrogen carbonate) 2.5 g/L*

The provisions of Chapter IV of the Act and rules thereunder which require them to be covered by a sale licence, subject to the conditions that such a product has been manufactured under a valid drug manufacturing licence.

Drugs and Cosmetics* 382 *Rules, 1945 Class of Drugs Extent and Conditions of Exemptions

when citrate salt is not available.

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1. Ins. by G.S.R. 680(E), dated 5.12.1980.
2. Ins. by. G.S.R. 1060(E), dated 5.9.1986.
3. Subs. by. G.S.R. 371(E), dated 24.3.1988.
4. Ins. by. G.S.R. 677(E), dated 2.6.1988.

[1][28] White or Yellow Petroleum Jelly I.P. (Nonperfumed).

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.

[2][29] Morphine tablets: 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 following conditions, namely:

(i) The drug shall be supplied by the palliative care centers approved by the State Government to terminally-ill cancer patients

(ii) The drug shall be kept under the custody of the medical officer incharge of the said center

(iii) The drug shall be purchased from a dealer or a manufacturer who holds license under these rules, and records of such purchases showing the names and quantities together with their batch numbers, and names and addresses of the manufacturers or dealers and the names and addresses of the patients to whom supplies have been made shall be maintained. Such records shall be open to inspection by an Inspector appointed under the Act, who may also take samples for test.

[30] Whole Human Blood collected and transfused by centers run by Armed Forces Medical Services in border areas, small mid-zonal hospitals including peripheral hospitals, field ambulances, mobile medical units and other field medical units including blood supply units in border, sensitive and field areas.

All the provisions of Chapter IV of the Act and rules made thereunder which require them to be covered by a licence to operate a Blood Bank for collection, storage and processing of whole human blood for sale or distribution subject to the following conditions:

(i) These centers shall collect, process and transfuse blood in emergent situations which require lifesaving emergency surgeries/or transfusion

(ii) These centers shall be under the active direction and personal supervision of a qualified

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Drugs and Cosmetics* 383 *Rules, 1945 Class of Drugs Extent and Conditions of Exemptions

Medical Officer, possessing the qualifications and experiences specified in condition (i) of rule 122-G

(iii) Each blood unit shall be tested before for freedom from HIV I and II antibodies, Hepatitis B surface antigen, malarial parasites and other tests specified under the monograph "Whole Human Blood" in current edition of Indian Pharmacopoeia.

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1. Ins. by G.S.R. 753(E), dated 4.11.1999.
2. Ins. by. G.S.R. 6(E), dated 4.1.2001

(iv) These centers shall have adequate infrastructure facilities for storage and transportation of blood.

(v) The blood collected and tested by such centers shall be transfused by the Centre itself and may be made available for use of other peripheral Armed Forces hospitals or centers during operational circumstances.[1]

First Aid Kit supplied along with motor vehicle by the manufacturer or its distributor at the time of first sale of vehicle. Nicotine gum containing up to 2 mg of nicotine.

The provisions of Chapter IV of the Act and rules made thereunder which require them to be covered by a sale licence,subject to the condition that the drug items are procured from a manufacturer or dealer licensed under the rules.

The provisions of Chapter IV of the Act and the rules made thereunder which require them to covered by a sale licence subject to the condition that such a product has been manufactured under a valid drug manufacturing licence.

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1. Ins. by G.S.R. 648 (E), dated 16.9.2002.
2. Ins. by G.S.R. 549(E), dated 16.67.2005.

SUGGESTED READINGS

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8

CHAPTER

Biomedical Waste (Management and Handling) Rules, 1998: Amendment, 2000 and Rules, 2016

RN Goel

THINGS MANDATORY IN HOSPITAL PREMISES

- Needle destroyer
- Syringe destroyer
- Three colored bag red, yellow, and blue
- Sodium hypochlorite solution (bleaching powder)
- Segregation training of staff by the service provider.

ADVICES

- First registration under Biomedical Waste Act is mandatory by Pollution Control Board (PCB) for three years including initial trial period of one year.
- Send annual report of state PCB every year before 31st January
- Renewal of PCB certificate every 3 years
- Display of PCB certificate-not mandatory.
- Display of service provider certificate, i.e., common biomedical waste treatment facility (CBWTF) not mandatory
- Preserve the bills and receipt of payment of every month of service provider
- Make a habit to give certificate if you are handling over a missed fetus.

Fee structure (depend upon state to state)

- Bedless hospital Rs 500–1000
- Upto 50 beds hospital Rs 500–2000

PRESCRIBED AUTHORITY

Regional officer PCB (as per area).

AUTHORIZATION

- Every occupier of an institution gathering, collecting, storing, receiving, transporting, treating, disposing, and/or handling biomedical waste in any other manner, shall make an application in Form 1 to the prescribed authority for grant of authorization.
- Every occupier of a biomedical waste facility shall make an application in Form 1 to the prescribed authority for grant of authorization
- Every application in Form 1 for grant of authorization shall be accompanied by a fee may be prescribed by the government of the state or union tertiary.

OCCUPIER

Hospital, nursing home, maternity home, pathology lab, blood bank, clinic/dispensary or any establishment generating biomedical waste.

A. Generation from dressing room, plaster room, vaccination room, patients ward, patient room, routine/emergency room, outpatient department, laboratory, blood bank, labor room, MTP Room, intensive care unit/neonatal intensive care unit/intensive cardiac care unit, veterinary institutions, and animal house
B. Segregation, reception, and storage as per Biomedical Waste Rule 2016.

YELLOW BAG

Category No. 1	Human anatomical waste (human tissues, organs, and body parts)
Category No. 2	Animal waste (animal tissues, organs, body parts carcasses, bleeding parts, fluid, blood, and experimental animals used in research, waste generated by veterinary hospitals/colleges, discharge from hospitals, animal houses).
Category No. 5	Discarded medicines and cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines).
Category No. 6	Soiled waste (items contaminated with blood, and body fluids including cotton, dressing, soiled plaster casts, linen, beddings, and other material contaminated with blood).

RED BAG

Category No. 3	Microbiology and biotechnology wastes and other laboratory waste (wastes from clinical samples, pathology, biochemistry, hematology, blood bank, laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and industrial laboratories, wastes from production of biological, toxins, dishes, and devices used for transfer of cultures)
Category No. 4	Waste sharps (needles, glass syringes or syringes with fixed needles, scalpels, blades, glass, etc. that may cause puncture and cuts. This includes both used and unused sharps)
Category No. 7	Infectious solid waste (wastes generated from disposable items other than the waste such as tubings, hand gloves, saline bottles with intravenous (IV) tubes, catheters, glass, and intravenous sets etc.)

BLUE BAG

Category No. 8	Chemical waste (chemicals used in production of biologicals, chemicals used in disinfection, as insecticides, etc.).

OPERATOR

Hospital having its own incinerator or CBWTF duty to treat this biomedical waste transported from storage.

TREATMENT

Yellow bag	Categories 1, 2, 5, and 6	Incineration deep burial
Red bag	Categories 3, 4, and 7	Autoclaving/microwaving, shredding, and recycling
Blue bag	Category 8	Chemical treatment

ANNUAL REPORT

Every occupier/operator submits an annual report to the prescribed authority in Form 2 by 31st january every year to include information about the categories and quantities of biomedical waste handled during the prescribed year. The prescribed authority shall send this information in a compiled form to the Central Pollution Control Board by 31st March every year.

MAINTENANCE OF RECORDS

- Every authorized person shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal, and/or any form of handling of biomedical waste in accordance with these rules and any guidelines issued
- All records shall be subjected to inspection and verification by the prescribed authority at any time.

ACCIDENTAL REPORTING

When any accident occurs at any institution or facility or any other site, where biomedical waste is handled, or during transportation of such waste, the authorized person shall report the accident in Form 3 to the prescribed authority forth with.

FORM 1

APPLICATION FOR AUTHORIZATION

(To be submitted in duplicate)

To

The Prescribed Authority

(Name of the State Governmant/UT Administration) Address.

1. Particulars of Applicant:
   - (i) Name of the Applicant:
     (In BLOCK letters and in full)
   - (ii) Name of the Institution:
     Address:
     Tele No., Fax No., Telex No.
2. Activity for which authorization is sought:
   - (i) Generation
   - (ii) Collection
   - (iii) Reception
   - (iv) Storage
   - (v) Transportation
   - (vi) Treatment
   - (vii) Disposal
   - (viii) Any other form of handling
3. Please state whether applying for fresh authorization or for renewal (In case of renewal previous authorization number and date):
4. (i) Address of the institution handling biomedical wastes:
   (ii) Address of the place of the treatment facility
   (iii) Address of the place of disposal of the waste
5. (i) Mode of transportation (in any) of biomedical waste:
   (ii) Mode(s) of treatment
6. Brief description of method of treatment and disposal (attach details):
7. (i) Category (see Schedule 1) of waste to be handled:
   (ii) Quantity of waste (category-wise) to be handled per month
8. Declaration

I do hereby declare that the statements made and information given above is true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfill any conditions stipulated by the prescribed authority.

Date:.....

Signature of the Applicant:.....

Place:.....

Designation of the Applicant:.....

FORM 2

ANNUAL REPORT

(To be submitted to the prescribed authority by 31st January every year).

1. Particulars of the applicant:
   (i) Name of the authorized person (occupier/operator):
   (ii) Name of the institution:
   Address
   Tel. No
   Telex No.
   Fax No.
2. Categories of waste generated and quantity on a monthly average basis:
3. Brief details of the treatment facility:
   In case of off-site facility:
   (i) Name of the operator
   (ii) Name and address of the facility:
   Tel. No., Telex No., Fax No.
4. Category-wise quantity of waste treated:
5. Mode of treatment with details:
6. Any other information:
7. Certified that the above report is for the period from

Date:.....
Signature of the Applicant:.....

Place:.....
Designation of the Applicant:.....

FORM 3

ACCIDENT REPORTING

1. Date and time of accident:
2. Sequence of events leading to accident:
3. The waste involved in accident:
4. Assessment of the effects of the accidents on human health and the environment:
5. Emergency measures taken:
6. Steps taken to alleviate the effects of accidents:
7. Steps taken to prevent the recurrence of such an accident:

Date:.....
Signature of the Applicant:.....

Place:.....
Designation of the Applicant:.....

9

CHAPTER

Medical Council of India–Registration

Manisha A Kakade

PRIMARY ELIGIBILITY FOR REGISTRATION UNDER MEDICAL COUNCIL OF INDIA

(4A) A person who is a citizen of India and obtains medical qualification granted by any medical institution in any country outside India recognized for enrolment as medical practitioner in that country after such date as may be specified by the Central Government under subsection (3), shall not be entitled to be enrolled on any Medical Register maintained by a State Medical Council, or to have his name entered in the Indian Medical Register unless he qualifies the screening test in India prescribed for such purpose and such foreign medical qualification. After such person qualifies the screening test shall be deemed to get the recognized medical qualification for the purposes of this Act, for that person.

(4B) A person who is a citizen of India shall not, after such date as may be specified by the Central Government under subsection (3), be eligible to get admission to obtain medical qualification granted by any medical institution in any foreign country without obtaining an eligibility certificate issued to him by the Council and in case any such person obtains such qualification without obtaining such eligibility certificate, he shall not be eligible to appear in the screening test referred to in subsection (4A): Provided that an Indian citizen who has acquired the medical qualification from foreign medical institution or has obtained admission in foreign medical institution before the commencement of the Indian Medical Council (Amendment) Act, 2001 shall not be required to obtain eligibility certificate under this subsection but, if he is qualified for admission to any medical course for recognized medical qualification in any 7 medical institution in India, he shall be required to qualify only the screening test prescribed for enrolment on any State Medical Register or for entering his name in the Indian Medical Register.

(4C) Nothing contained in subsections (4A) and (4B) shall apply to the medical qualifications referred in section 14 for the purpose of the section (5) Any medical institution in India which is desirous of getting a medical qualification granted by it included in part I of the third schedule may apply to the Central Government to have such qualification recognized. The Central Government, after consulting the Council, may get notification in the Official Gazette, amend Part I of the third schedule so as to include such qualification therein. Any such notification may also direct that an entry shall be made in the last column of Part-I of the Third Schedule against such medical qualification declaring that it shall be a recognized medical qualification only when granted after a specified date.

SPECIAL PROVISION IN CERTAIN CASES FOR RECOGNITION OF MEDICAL QUALIFICATIONS GRANTED BY MEDICAL INSTITUTIONS IN COUNTRIES WITH WHICH THERE IS NO SCHEME OF RECIPROCITY

14 (1) The Central Government after consultation with the Council, may, by notification in the Official Gazette, direct that medical qualifications granted by medical institutions in any country outside India in respect of which a scheme of reciprocity for the recognition of medical qualifications is not in force, shall be recognized as medical qualification for the purposes of this Act or shall be so only when granted after a specified date. Provided that medical practice by persons should possess such qualifications: (i) shall be permitted only if such persons are enrolled

as medical practitioners in accordance with the law regulating the registration of medical practitioners for the time being in force in that country; (ii) shall be limited to the institution to which they are attached for the time being for the purpose of teaching, research or charitable work; and (iii) shall be limited to the period specified in this behalf by the Central Government by general or special order.

(2) In respect of any such medical qualification the Central Government, after consultation with the Council may, by notification in the Official Gazette direct that, it shall be a recognized medical qualification only when granted before a specified date.

RIGHT OF A PERSON QUALIFICATIONS IN THE SCHEDULES TO BE ENROLLED

15 (1) Subject to the other provisions contained in this Act, the medical qualifications included in the schedules shall be sufficient qualification for enrolment on any State Medical Register.

(2) As provided in section 25, no person other than a medical practitioner should be enrolled on a State Medical Register.

- Shall hold a office as physician or surgeon or any other office (by whatever designation called) in Government or in any institution maintained by a local or other authority
- Shall practice medicine in any State
- Shall be entitled to sign or authenticate a medical or fitness certificate or any other certificate required by any law to be signed or authenticated by a duly qualified medical practitioner
- Shall be entitled to give evidence at any inquest or in any court of law as an expert under section 45 of the Indian Evidence Act, 1872 on any matter relating to medicine.

(3) Any person who acts in contravention of any provision of subsection (2) shall be punished with imprisonment for a term which may extend to one year or with fine, which may extend to one thousand rupees, or with both.

PROVISIONAL REGISTRATION

25 (1) A citizen of India possessing a medical qualification granted by a medical institution outside India included in part II of the third schedule, who is required to undergo practical training as prescribed under subsection (3) of Section 13. They shall, on production of proper evidence that they have been selected for such practical training in an approved institution be entitled to be registered provisionally in a State Medical Register and shall be entitled to practice medicine in the approved institution for the purpose of such training and for no other purpose.

(2) A person who has passed the qualifying examination of any university or medical institution in India for the grant of a recognized medical qualification shall be entitled to be registered provisionally in a State Medical Register for the purpose of enabling him to be engaged in employment in a resident medical capacity in any approved institution, or in the Medical Services of the Armed Forces of the Union, and for no other purpose, on production of proper evidence, that he has been selected for such employment.

(3) The names of all persons provisionally registered under subsection (1) or subsection (2) in the State Medical Register shall be entered therein separately from the names of other persons registered therein.

(4) A person registered provisionally as aforesaid who has completed practical training referred to in subsection (1) or who has been engaged for the prescribed period in employment in a resident medical capacity in any approved institution or in the Medical service of the Armed Forces of the Union, as the case may be, shall be entitled to registration in the State Medical Register under section 15.

REGISTRATION OF ADDITIONAL QUALIFICATIONS

26 (1) If any person whose name is entered in the Indian Medical Register obtains any title, diploma or other qualification for proficiency in sanitary science, public health or medicine which is a recognized medical qualification, he shall, on application made in this behalf in the prescribed manner be entitled to have any entry stating such other title, diploma or other qualification made against his name in the Indian Medical Register, either in substitution for or in addition to any entry previously made.

(2) The entries in respect of any such person in a State Medical Register shall be altered in accordance with the alterations made in the Indian Medical Register.

PRIVILEGES OF PERSONS WHO ARE ENROLLED ON THE INDIAN MEDICAL REGISTER

27 Subject to the conditions and restrictions laid down in this Act, regarding medical practice by persons possessing certain recognized medical qualifications, every person whose name is for the time being borne on the Indian Medical Register shall be entitled according to his qualifications to practice as a medical practitioner in any part of India, and to recover in due course of law in respect of such practice, any expenses, or charges in respect of medicaments or other appliances, or any fees to which he may be entitled.

PERSONS ENROLLED ON THE INDIAN MEDICAL REGISTER TO NOTIFY CHANGE OF PLACE, RESIDENCE OR PRACTICE

28 Every person registered in the Indian Medical Register shall notify any transfer of the place of his residence or practice to the Council and to the State Medical Council concerned, within thirty days of such transfer failing which his right to participate in the election of members to the Council or a State Medical Council shall be liable to be forfeited by order of the Central Government either permanently or for such period as may be specified therein.

REMOVAL OF NAMES FROM THE INDIAN MEDICAL REGISTER

24 (1) If the name of any person enrolled on a State Medical Register is removed, therefrom, in pursuance of any power conferred by, or under any law relating to medical practitioners for the time being in force in any state, the Council shall direct the removal of the name of such person from the Indian Medical Register

(2) Where the name of any person has been removed from a State Medical Register on the ground of professional misconduct or any other ground except that he is not possessed of the requisite medical qualifications or where any application made by the said person for restoration of his name to the State Medical Register has been rejected, he may appeal in the prescribed manner and subject to such conditions including conditions as to the payment of a fee as may be laid down in rules made by the Central Government in this behalf, to the Central Government, whose decision, which shall be given after consulting the Council, shall be binding on the State Government and on the authorities concerned with the preparation of the State Medical Register.

PROCEDURE FOR REGISTRATION FOR MEDICAL UNIVERSITIES ABROAD FROM MEDICAL COUNCIL OF INDIA

This is to inform to all those concerned that the requirement of obtaining eligibility certificate to pursue primary medical qualification (MBBS or its equivalent) by an Indian citizen/ oversees citizen of India is mandatory in terms of section 13(4B) of the Indian Medical Council Act, 1956. It is also brought to attention that the requirement of obtaining Eligibility Certificate was dispensed by the Indian Medical Council (amendment) First and Second Ordinance, 2013. However, with the lapse of the Indian Medical Council (amendment) Second Ordinance, 2013, the requirement of obtaining eligibility certificate from the Medical Council of India (MCI) stands revived with effect from (w.e.f) 04.01.2014.

The Executive Committee of the Council has decided to restart issuance of eligibility certificate w.e.f the current academic year i.e. 2016-2017.

Accordingly, public at large is hereby informed that in terms of Section 13(4B) of the Indian Medical Council Act, 1956 and clause 4(2) of the Screening Test Regulation, 2002, an Indian national/overseas citizen of India who desires to take admission into Bachelor of Medicine, Bachelor of Surgery (MBBS) or its equivalent course in a medical university/ institution outside the country is required to obtain eligibility certificate from the Medical Council of India, New Delhi before leaving the country. It is not permissible for holder of a primary medical qualification to appear in the screening test without obtaining an eligibility certificate from Medical Council of India.

Therefore, all the applicants who have taken and/or desire to take admission into MBBS or its equivalent course in a medical university/institution outside the country may apply for eligibility certificate to the Medical Council of India, New Delhi on the prescribed application Form No. 1 along with all relevant documents and fee. The said application form may be downloaded from the MCI website.

FOR STUDENTS TO STUDY ABROAD

It has come to the notice of the Medical Council of India that some agents are providing misleading/false/fabricated information to the Indian nationals who are desirous of taking admission in MBBS or its equivalent course in a university/institution located outside India with regard to the fee structure, recognition/approval of the particular medical university/institution, or duration of the course etc.

The public at large is advised that before taking admission in MBBS or its equivalent course in a university outside India, confirmation of the fee structure and duration of the course should be directly obtained from the university/institution concerned.

As far as status of recognition of a particular university/ institution is concerned, it is informed that as per clause 4(1) of the Screening Test Regulation, 2002, any primary medical qualification which is confirmed by the Indian embassy concerned to be a recognized qualification for enrolment as medical practitioner in the country in which the institution is awarding such qualification where situated, that can be considered to be a recognized medical qualification by the Medical Council of India for the purposes of issuance of eligibility certificate, entitle a candidate to appear in the screening test and grant of provisional/permanent registration by the concerned State Medical Council. Therefore, the candidates concerned are hereby, advised to confirm the status of the medical qualification and its awarding university/institution from the Indian Embassy concerned and/or from the Medical Council of India. Prior to taking admission the candidates must make enquiries regarding fee structure from the institution/university concerned.

Based upon the information received from the Indian embassy/High Commission of India concerned, the list of foreign universities/institutions as approved/recognized by the authorities concerned in respective countries you can find on the Medical Council of India website.

It is further informed that the Medical Council of India has neither appointed nor authorized any agent/broker/ Liasioning Officer for admission of students into any medical course in India and abroad.

To pursue a medical course abroad, aspirants will soon have to clear the National Eligibility cum Entrance Test (NEET).

According to a senior official in the Union Health Ministry, a proposal regarding this is on the table and it will be implemented from next year if it gets clearance.

The proposal is aimed at preventing mediocre medical aspirants from getting a degree from foreign medical colleges merely on the basis of money or connections. "Most of them fail to pass the test required to practice in India," citing reasons for making NEET mandatory for studying medicine abroad.

The data speaks for itself. In the last five years, the percentage of foreign medical graduates who have cleared the Foreign Medical Graduate Examination (FMGE) has varied from 13.09 per cent to 26.9 per cent. The absence of entrance tests in foreign medical institutes is also a key factor for suboptimal performance by foreign medical graduates in screening tests.

There are two reasons for poor results. First, the quality of medical education imparted in many countries is substandard. Second, the students are not competitive enough to qualify for medical education in India, the official explained.

There are around 472 medical colleges having 65,000 seats across the country. Close to a million doctors are registered with the Medical Council of India (MCI), the country's medical education regulator.

When compared to the curriculum notified by the MCI in Graduate Medical Regulations, it has been noted that the students pursuing foreign medical studies don't get sufficient clinical exposure. This is one of the most important reasons for poor performance in subjects like community medicine, obstetrics & gynecology, and pediatrics, as told by the official.

According to data from the National Board of Examinations (NBE) which conducts the FMGE, around 63,000 foreign medical graduates have taken the FMGE in the last five years.

As per records, since 2011, China has been the most-preferred destination for obtaining primary medical qualification for Indian students travelling outside India. Russia, formerly the top choice, is now the second favorite. Ukraine and Nepal are the other popular choices.

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10

CHAPTER

Consumer Protection Act,1986 and Medical Negligence

Manish Y Machave

INTRODUCTION

The Consumer Protection Act, 1986 is an act to provide better protection of the interests of the consumers and for that purpose to make provisions for establishment of consumer councils and other authorities for the settlement of consumers dispute and for matters connected therewith. The Consumer Protection Act (CPA) was passed in 1986 and amended in1993.

SERVICE PROVIDER, CONSUMER, COMPLAINT AND COMPLAINANT

Service, section 2(1)(o)

- 'Service' means service of any description including the provision of facilities in connection with banking, financing, insurance, transport, processing, electrical or other energy board or lodging or both, housing construction, entertainment, amusement, purveying of news or other information, but
- Does not include rendering of service free of charge or under a contract of personal service

Consumer, section 2(1)(d)(ii)

- Means any person who hires or avails of any services for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment

Complaint, section 2 (c)

Any allegation in writing made by a complainant in regard to following for obtaining relief under the act

- Unfair trade practices (UTPs)/Restrictive trade practices (RTPs)
- Defects in goods
- Deficiency in services
- Excess price
- Hazardous goods being offered for sale

Nominal fee is prescribed.

Complainant:

a. A consumer
b. Any voluntary consumer association registered under a company's act or under any other law for time being in force.

The patient being a consumer; doctor, the service provider, and the charges as consideration, hence, CPA became applicable to medical profession after the land-mark Supreme Court judgment of VP Shantha versus Indian Medical Association**.**

Who Can File A Complaint?

- The patient who hires the services of a medical practitioner can file a complaint
- It should be in writing
- No oral complaints can be filed.

Who is Held Liable Under CPA?

It is not only the medical practitioner who may be found negligent but the hospitals are also bound by the law and in certain circumstances the hospitals are also found negligent or deficient in services.

Doctors with independent practices, all private hospitals charging, all hospitals having free as well as paying patients are liable under the act.

Doctors or hospitals paid by an insurance firm for treatment of a client or an employer for the treatment of an employee are also liable under the act.

Who is not liable under CPA?

Doctors in hospitals, who do not charge their patients.

Hospitals offering free services to all patients.

Redressal for a Under CPA

The redressal agencies have a three-tier structure.

1. District level: At this forum person can claim for compensation towards damage up to a maximum limit of Rs 20 lakh. A district judge and 2 other members chair this of which one of whom shall be a woman
2. State level: At this level the claim for compensation is enhanced to Rs 20–100 lakhs and high court judge and 2 other members chair it
3. National level: Here the compensation claimed is more than 100 lakhs. This forum constitutes of a supreme court judge, and 4 other members.

Advantages of Consumer Fora Over Civil Courts

1. Limited time is needed for decision and action taking (period of 3 months)
2. No court fee is payable.

Provision of Appeal

Within 30 days from the date of decision, appeal can be filed in the higher commission

1. Appeal against district forum → before state commission
2. Appeal against state commission → before national commission
3. Against national commission → before supreme court.

Protection Against False and Frivolous Complaints

Where a complaint is instituted before the district forum, the state commission and the national commission it is found to be frivolous or vexatious, it shall, for reasons to be recorded in writing,dismiss the complaint and make an order that the complaint shall pay to the opposite party such cost, not exceeding Rs 10,000 as may be specified in the order.

Limitation Period

The district forum, the state commission or the national commission shall not admit a complaint unless it is filed within 2 years from the date on which the cause of action has arisen.

Reliefs that may be Awarded by Consumer Redressal Fora

- Award compensation for loss or injury suffered due to negligence; and/or order opponent to
- Remove deficiency in service
- Discontinue the unfair trade practice
- Pay sum towards loss or injury suffered by large number of people
- Provide for adequate cost to parties.

Medical Negligence—Basic Concepts

Medical negligence is a shortcoming in the service agreed to be rendered by medical professional.

Deficiency in Service

Deficiency of service means any fault, imperfection, short-coming or inadequacy in the quality, nature, and manner of performance which is required to be maintained by or under any law for the time being in force, or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service .

Negligence consists in the omission to do something which a reasonable man guided upon those considerations which ordinarily regulate human affairs, would do, or doing something which a prudent and reasonable man would not do.

Medical negligence is also a 'tort' which calls for a reasonable degree of care expected of a professional like doctor or pathologist.

Three ingredients of medical negligence:

1. Duty to take care–contract between doctor and patient.
2. Breach in this duty–competency of doctor and standard of care.
3. Consequential damage–causans of the breach in duty.

LANDMARK CASES

Medical Fraternity Brought Under CPA-V.P. Shantha and ORS. Cosmopolitan Hospitals (P) Ltd and ORS. (Kerala SCDRC)

- Facts: The complainant's husband aged 59 years and had a fall from his cot on 4.7.1990. As he went to the Cosmopolitan Hospital, Trivandrum where the 2nd opposite party examined him and opined that he had fracture of left neck of femur for which he was operated on 6.7.1990. Simultaneously, he was also operated upon his salivary gland.

  During the postoperative period, it was noticed that he had some respiratory difficulty but the duty doctors did not took it seriously and the operating surgeon also, had already left. Ultimately, the 5th opposite party came to the hospital, and examined the patient and announced that he was dead.

  The behavior of the hospital authorities after the death was highly suspicious. They sent a copy of the bill only after repeated requests, but refused to part with the X-ray films
- Allegation: It was alleged that this was on account of the fear of the fact that providing these X-rays would have revealed that conservative treatment like traction and medication would have cured the problem; but, in order to increase the number of operations and to augment income, the decision to operate was taken. The hospital

had also failed to carry out necessary preoperative investigations and the services of a cardiologist were not obtained.

- Held: A compensation of Rs. 25000/- with interest at the rate of 12% p.a. from the date of death till payment was awarded. This amount was to be paid by the hospital, as no negligence could be established against the doctors.

Honorable Supreme Court made the Following Observations-OBITER DICTA

Medical practitioners, though belonging to the medical profession are not immune from a claim for damages on the ground of negligence. The fact that they are governed by the Indian Medical Council Act and are subject to the disciplinary control of the Medical Council of India and/or State Medical Council is no solace to the person who has suffered due to their negligence and the right of such person to seek redress is not affected.

The order further said that the medical practitioners, government hospitals/nursing homes and private hospitals/ nursing homes broadly fall in three categories:

1. Where services are rendered free of charge to everybody availing the said services
2. Where charges are required to be paid by everybody availing the services
3. Where charges are required to be paid by persons availing the services but certain categories of person who cannot afford to pay are rendered from the service free of charge.

The categories (2) and (3) above constitute service and should be under the purview of CPA.

Spring Madows Hospital and ANR versus Harjol Ahluwalia

- Facts: Cardiac arrest occurred in minor with typhoid fever following high dose injection chloroquine given intravenously instead of chloromycetin. This caused hypoxic brain damage
- Held: Hospital, duty doctor, and nurse all were held liable. Nurse should have been qualified. The Supreme court of India confirmed the order of the national commission, which awarded a compensation of Rs 12.5 lakhs
- Lesson: The concept of vicarious liability the liability of employer for negligent act of employee was established in this case. Needless to say appointment of qualified staff is of paramount importance.

Nizam Institute of Medical Sciences (NIMS) vs Prashanth Dhanaka

- Facts: Case of fever and neurofibroma in chest with erosion of rib. Ultrasograph/computed tomography guided fine needle aspiration cytology attempts failed. Cardiothoracic surgeon did surgical excision with removal of ribs. Patient had paraplegia. Rs 4,61,31,152/- compensation was demanded
- Held: Preoperative investigations were not completed – intraspinal extension was missed magnetic resonance imaging/computed tomography/myelography was not done. Consent was only for biopsy and not for complete excision and removal of 4th rib. Neurosurgeon should have been involved from the beginning keeping the provisional diagnosis of neurofibroma in mind. Also the postoperative care was not proper as patient had frequent episodes of pain, fever, bedsores, frequent X-rays etc.
- Held-National Consumer Disputes Redressal Commission (NCDRC): It made NIMS vicarious liability and awarded 15.4 lakhs. The honorable national commission deliberated on important issues such as what constitutes medical negligence, duty of a hospital to engage a specialist when a specialist is available, vicarious liability of a hospital for omissions and commissions of doctors and staff, compensation for mental and physical torture etc.
- Lesson: There is no substitute for proper preoperative investigations, written informed voluntary consent, involvement of specialists, and adequate and proper postoperative care.

Dr Adarsh Kumar and ORS versus Jagjeet Kaur – NCDRC

- Facts: Lab reported blood group AB+ and blood bank confirmed A –ve before BT
- Held: Rs 25,000/- awarded by national forum. The commission reiterated the fact that no damage need not be the deciding factor. The fact that the blood group testing and reporting was wrong is enough to constitute negligence in accordance with the following two maxims Ubi Jus Ibi Remedium(where there is a right here is a remedy), Injuria sine damno(injury without damage)
- Lesson: Legal inury arising out of a right is punishable even if there is no damage.

Smt. Archana and ORS vs Chaudhari Chest Hospital and 1998(1) CPR 556, State of Maharashtra

- Facts: Deceased husband of complainant was operated for hip bone fracture and he passed away in same evening. Complainant alleged no proper postoperative care and patient had excessive bleeding. Negligence attributed to massive outflow of blood to the extent of 2500 mL.
- Evidence: Evidence and Panchanama did not supported that conclusion. Pathological report showed that deceased had no diabetes mellitus, ischemic heart disease, and therefore, no blood clotting test was required under such circumstances. As per medical literature, in case of hip fracture, risk of embolism could develop at the time

of fracture and not at surgery. Unexpected death could occur on account of pulmonary embolism.

- Held: In postmortem report, doctors were unable to arrive at definite opinion regarding cause of death. Possibility of pulmonary embolism being cause of cardiac shock leading to death could not be ruled out which does not make any case of negligence on the part of doctor.
- Lesson: Unexpected death and unable to come to conclusion is not construed as medical negligence.

Bolam versus Frien Barner Hospital Management Committee (1957) 1 WLR 582

- Facts: Electroconvulsive therapy given for mania without scoline. This caused multiple fractures to the patient. Negligence was alleged.
- Held: Doctor was not found to be because he followed standard practice usually done by his peers "Bolam Test", a test to determine the liability of a doctor. The test is the standard of the ordinary skilled man exercising and professing to have that special skill.
- Lesson: It is expected of a professional man that he should show a fair, reasonable competent degree of skill. Neither, he is expected of a higher degree of skill of a person who has higher education and greater advantages, nor is he expected to guarantee cure.

Medical men would not be found negligent simply because one of the risks inherent occurs or because in a matter of opinion he legitimately took a view which unfortunately happened to produce an adverse result in particular circumstances.

Laxman Balkrishna Joshi versus Trimbhak Bapu Godbole; AIR 1969 SC 128

- Facts: Fracture femur in a young boy due to road traffic accident. Fracture reduced without general anesthesia which produced shock and death.
- Held: Liable as duty of care not fulfilled and awarded Rs 5000/- compensation (First medicolegal case in SC from Pune). Supreme Court inter alia held as follows: The duties, which a doctor owes to his patient, are clear. A person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill or knowledge for the purpose. Such a person, when consulted by a patient, owes him certain duties, namely a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or a duty of care in administration of that treatment. A breach of any of these duties gives a right of action for negligence to the patient.
- Lesson: The doctor must bring to his task a reasonable degree of skill and knowledge and must exercise reasonable degree of care.

TWO IMPORTANT LEGAL CONCEPTS

Negligence Per Se

Homeopathic doctor prescribing allopathic medicine in crosspathy is "Negligence Per se"- neither damage nor any further proof required. Absence of a basic qualification for a homeopathic doctor to practice a system of medicine (allopathy) in Poonam Verma vurses Ashwin Patel and Ors., (1996) CPS, SC. Supreme Court held that a person who does not have knowledge of a particular system of medicine but practices in that system is a quack. Where a person is guilty of negligence per se, no further proof is needed.

Res ipsa Loquitur–the Thing Speaks for Itself

In Nihal Kaur v/s Director, P.G.I.M.S.R. III (1996) CPJ 112

- Facts: A patient died a day after surgery and the relatives found a pair of scissors utilized by the surgeon while collecting the last remains.
- Held: Compensation of Rs 1.20 lakhs was awarded by the state commission, Chandigarh on the grounds that negligence was writ large on record in handling the case though, it was argued that arterial forceps and sponges were left behind in an attempt to save the life of the patient and (the said things were to be later removed, but could not be done as the patient died) the same did not contribute to patient's death.

CONCLUSION

The relationship between doctor/hospital and patients is a relationship of trust; doctors are still known as healers.

Consumer Protection Act provide for better protection of the interests of consumer and for that purpose to make provision for the establishment of consumer councils and other authorities for settlement on consumers disputes and for matters connected therewith.

CPA is applicable to the medical profession. Valid consent, adequate, and appropriate preoperative investigations, due care during treatment/surgery, proper documentation, expert opinion, employing qualified staff, and avoiding crosspathy are some tips to avert the dreaded liability in day to day practice.

Formation of local level medicolegal cells is not a luxury but a necessity.

Apt to conclude that it's better to prepare and prevent than repair and repent.

SUGGESTED READINGS

1. Rao YV. Commentary on The Consumer Protection Act, 1986. 3rd edition. Asia law house: 2013.
2. The Consumer Protection Act, 1986 (bare act). Available from:

11

CHAPTER

Consent: Does it Concern?

Lata K Trivedi

INTRODUCTION

Voluntary agreement, compliance or permission. It is defined in section 13 of Indian Contract Act as, two or more persons are said to consent, when they agree upon the same thing in same sense i.e., "Parties AD IDEM".

If a medical practitioner attempts to treat a person without valid consent, he/she can be liable under both – tort (civil wrong) as well as criminal law. Ignorance of law is not a defense in legal cases. Thus, all medical practitioners should be aware of their duties in regard to consent in clinical practice.

Consent is not an event of merely obtaining signatures on paper before patient submits to particular treatment, but it is process of communication. It is proactive process of making sufficient disclosure, and empowerment the patient to consciously decide on what he or she considers best after understanding pros and cons involved.

Before deliberating the term consent, let us review one landmark judgement of Samira Kohli versus Dr Prabha Manchanda, in which 3 judges bench (BN Aggarwal, PP Naolekar, and RV Ravendran) finally defined consent in context of medical negligence in Indian scenario.

Samira Kohli versus Dr Prabha Manchanda.

- Fact: A 44 years old, unmarried woman complains of bleeding from vagina with ultrasound evidence of chocolate cyst of ovary and fibroids, that was posted for laparoscopy
  - Consent was taken for admission, laparoscopy, and if needed, operative steps for endometriosis
  - It was explained to be a minor surgery
  - Laparotomy may be required
  - Not explained about alternative treatment
  - There was no mention of hysterectomy in consent
  - On table, however, hysterectomy was performed after taking consent of old mother of the patient sitting outside the operation theater
  - The boyfriend of patient created a scene in the hospital and took away patient without paying bill, for which police complaint was lodged
- Patient's Allegations:
  - Hysterectomy was done without parent's consent
  - No preoperative information about alternative modalities were given
  - Lead her to premature menopause for which she has to take hormone replacement therapy for a long period of time.

Judgement

- Judges agreed to well fought argument that Total abdominal hysterectomy with bilateral salpingo-oophorectomy (TAH + BSO), in this case is not a negligence. This fact was well supported by book references and expert witness.
- She was considered to be acted in good faith, in the interest of the patient. However, it was done without consent of patient and that amounts to tortuous act of assault and betrayal.
- Patient was allowed Rs 25,000 + bill + 5,000 legal cost.
- In this case, the term "consent" was discussed in detail.

Following questions were raised and answered in relation to medical context of "consent":

Question 1. Whether informed consent is necessary for surgical removal of reproductive organs?

Answer: Yes

Question 2. What should be the nature of consent?

Answer: Consent should be voluntary and free. Patient should have capacity and competence to consent. Consent should be based on knowledge, which means patient should have adequate information about:

- Nature and procedure of treatment
- Purpose of treatment
- Benefits and effects of treatment
- Alternatives available

- Possible risks
- Consequences of refusal of treatment

Question 3. Does supreme court expect to explain about all possible complications?

Answer: The doctors are to expected to anticipate certain complications or requirements depending on the condition of patient. No need to explain about theoretical risks involved which can frighten or confuse patient resulting in either refusal of consent for treatment or lead the patient to undergo fanciful treatment. A balance should be achieved.

Question 4. Can there be a common consent for diagnostic and operative procedures when they are Contemplated?

Answer: Yes

Question 5. Can we do additional surgery either as a conservative or as a radical treatment, without specific consent for the same?

Answer: Big 'no'

Question 6. Can consent be taken by assistant doctor?

Answer: Yes

This case has been referred to and cited several times, subsequently.

TYPES OF CONSENT

1) Implied Consent
2) Expressed Consent
3) Informed Consent.

Implied consent: Implied consent is a consent which is not expressly granted by person, but rather implicitly granted by a person's actions, facts, and circumstances of particular situation.

For example, once patient enters in to a dentist's clinic and sits on dental chair and opens his mouth, it implies that he agrees to a simple general examination. Then he cannot complain that the dentist depressed his tongue with spatula

Expressed consent: The terms of which are stated in distinct and explicit language. It may be oral or written. Oral consent is also equally valid

Informed consent: Patient should be informed about diagnosis, nature of treatment, procedure, risks involved, prospects of success, prognosis if not treated, and alternative methods of treatment.

Informed consent was practically nonexistent till the time Consumer Protection Act (COPRA/CPA) came in to existence.

- Consent in case of minor or mentally challenged person: Patient should have capacity and competence to consent. That means patient should be an adult and of sound mind. If these conditions are not fulfilled, the guardian's consent is valid.
- Proxy Consent: When person himself is incapable of giving expressed consent, consent of near relatives and lawful guardian can be taken
- Loco Parentis: Consent of teacher or head master can be taken, if parents are not available
- If arrested person refuses to get examined, it will be lawful resource management plan, to examine the alleged person at the request of police subinspector
- Blanket Consent: Blanket consent has no legal value. This is what most of the doctors practice routinely. They have routine stereo-typed printed consent forms for all surgical procedures whether, it is hysterectomy or medical termination of pregnancy (MTP). But "I authorize Dr So and so, to carry out any test, procedure or surgery in the course of my treatment…" is not valid in court of law. Consent should be procedure specific. There should be different consent forms for different surgical procedures, which should included explanation of possible risks and complications involved in that particular surgery
- "GHOST Surgeon"
  Services of expert surgeon in particular disciplinary, for example, laparoscopic surgeon should be routinely sought for in fraternity. It is advisable to incorporate the name of visiting operating surgeon in the consent form, to reduce own's liability in case of future litigations. To extent, the best thing would be to inform the patient about it, "I am calling Dr name for his expertise in that particular surgery"
- Can we do additional surgery?
  No. An argument that it was beneficial, it would save the time or would relieve the patient from pain or suffering in future, does not hold the grounds if defense is in court of law
  The only exception to this rule is, where an additional procedure, though unauthorized, is mandatory, in order to preserve the health of patient then it would be unreasonable to delay such procedure, until the patient regains consciousness and takes decision
- Informed Refusal: After being informed about procedure, its side effects and other related facts, if patient refuses to undergo treatment, informed refusal consent should be taken, to protect ourselves for litigations in future. In case of informed refusal of treatment, signature of witness should also be taken
- Consent is invalid:
  - If act itself is unlawful
  - Consent is given by minor or mentally ill person
  - If it is not informed consent.
- Consent is must in all cases of medical examination and treatment, in all medicolegal cases, and criminal cases like rape etc.
- Examination without consent:
  - Section 53[I] allows examination without consent, at the request of police (not below the rank of police subinspector)
  - Section 53[2] deals with examination of accused female
- Consent and age:
  - Section 87 Indian Penal code (IPC) – A person under the age of 18 years cannot give valid consent for the act that may harm him grievously i.e., wrestling

  - Section 89 IPC – A child under 12 cannot give consent for operation
  - Section 375 IPC – Sexual intercourse by man with girl below 15 years even if she is his wife, contributes to offence of rape
  - Minimum age of blood donation is 18 years.
- Consent for blood transfusion should be taken separately
- Fresh consent should be taken for repeating procedure
- Surgical consent is not sufficient to cover anesthesia care
- Unilaterally executed consents are void. Consent paper should be signed by doctor, too
- Patient is free to withdraw consent any time during procedure
- Consent should be taken in relation to publication, presentation, when the identity of patient is to be disclosed
- For MTP, consent of husband is not required. As such, MTP is privilege of patient in regards to secrecy
- For sterilization operation, consent of spouse is required
- Consent for examining or observing patient for educational purpose is must
- Counseling before female sterilization is necessary
- Explain the couple about availability of sterilization whether, temporary or permanent
- Informed voluntary consent should be taken in understandable local language
- Explain all the complications of sterilization including failure
- Clients must be encouraged to ask questions to clarify doubts
- Consent of spouse us must for sterilization.

A FEW LANDMARK JUDGMENTS IN CONTEXT OF CONSENT

- Mr. C. Jayapal Reddy versus Dr. Padmini Valluri, Yashoda Hospital, Secundarabad.
  - Jayapal Reddy's wife Kusuma was patient of gynecologist since 2006. She was diagnosed with fibroid uterus and endometriosis
  - She was admitted on July, 2010. Jayapal later learnt that Dr Valluri had operated on Kusuma and performed TAH + BSO + adhesiolysis
  - Jayapal said that informed consent was not taken. Signature was taken on blank form. He also claimed that related documents including occupational therapy notes were not given
  - He also accused that ovaries were removed unnecessarily leading to loss of ability to have child through surrogacy
  - Opponents were directed to pay Rs 10 lakhs with 9% interest.
- M. Chinniyan versus Gokulam Hospital
  - Patient was posted for hysterectomy
  - Blood transfusion was asked for excessive bleeding
  - Consent for blood transfusion was not taken
  - Patient developed acquired immunodeficiency syndrome, later
  - Compensation of Rs 4 lakhs with 6% interest was awarded.
- Zeba Hamid versus Hajela Hospital
  - Patient of primary infertility was posted for diagnostic laparoscopy.
  - Ovarian drilling and salpingectomy was performed without consent.
  - Rs 25,000 plus 2,000 was awarded.
- Dr. Janki versus Sarafunnisa
  - During lower segment cesarian section, tubectomy was performed without prior consent
  - Defense: During operation, surgeon found that future pregnancy could be dangerous
  - Doctor was liable to pay compensation.
- Ram Gopal Varshney versus Laser Sight India Pvt Ltd.
  - Cataract surgery was done on 76 years old patient. But consent of grand son was taken
  - Case of loss of vision was very well fought and no negligence was found
  - Rs 25,000 + 10,000 was awarded because patient's consent was not taken.
- Mrs Chandoke versus Sir Ganga Ram Hospital
  - Patient of dysfunctional uterine bleeding, with previous 2 cesarean sections, was posted for TAH
  - On table, doctor decided to do vaginal hysterectomy
  - Laparotomy had to be done for bleeding from ovarian stump
  - Subsequently, patient ended up with nephrectomy
  - Judgement: Bleeding was not negligence. Deviation from routine is not acceptable, unless lifesaving
  - Rs 5 lakhs was awarded.

12

CHAPTER

Facilities and Charges

Girish R Mane, Vrishali G Mane

INTRODUCTION

The health care sector in India comprises both of private sector and public sector. Health care service is gradually emerging as one of the largest service sectors in India. The private health care sector comprises organizations with 'nonprofit motive' and also others with 'profit motive. 'The "non- profit" health sector consists of various service providers such as "Non-Government Organizations (NGO's), charitable institutions, trusts, etc. Health care services in "for-profit" segment consist of various types of practitioners and institutions in private sector. Most of the critical health care services are provided by the private sector. The increased purchasing power of the Indian Society is providing growth opportunities to health care providers.

Publicly-funded government hospitals provide all desirable care but often lack adequate infrastructure and facilities. We may witness the crowded public funded government hospitals with long waiting time. Further, the Government hospitals are often understaffed; however the cost of care is significantly less as compared to private hospitals. On the other hand, the private hospitals offer a high standard of health care and are well equipped with modern technology, the doctors are highly qualified and well trained, and therefore the cost of care is significantly more. Furthermore, the private sector in India has a dominant presence in medical education and training, hospital infrastructure and ancillary service areas such as medical technology and diagnostics.

Pharmaceutical health care costing is one of the least analyzed topics in India. This is mainly on account of the uncertainty and nontransparency which was associated with health care delivery systems in India. In addition, the concept of corporate or trust hospitals came much later in the last three to four decades only. The individual nature of health care delivery was also one of the reasons where there was a close relationship between the Doctor and patient through the "family doctor" concept.

OBJECTIVES OF HEALTH CARE

The proper goal of a health care delivery system is to "touch and enriching billion Lives with creating certain set of value" i.e., patient centricity, ownership, and integrity to patients. Objective in health care is measured in terms of the patient outcomes achieved per rupee expended. It is not the number of different services provided or the volume of services delivered.

ACHIEVING THE OBJECTIVE WITH OPTIMUM COST

To manage proper cost, both outcomes and cost must be measured at each patient level. Measured outcomes and cost must include the whole cycle of patient care in particular medical condition. A medical condition is an interrelated set of patient circumstances that should be best addressed and defined to include common complication and symptoms. For example, The cost of treating a patient with diabetes, must include not only the cost associated with pregnancy care but also the cost of endocrinological care, the cost of managing and treating associated condition such as retinal disease and renal disease and educating the patient about the life style changes in order to contain the ill effects.

ESSENTIALITY OF COST MANAGEMENT IN HEALTH CARE SECTOR

Most health care organizations continue to struggle with identifying the costs of products and services provided by them, capturing the full cost of products and services, including inter-entity and department costs as part of full costs. The hospital usually feels difficulties to allocate the cost of stand-by facilities such as generator backup, operation theatre, and extra trained staff and many more hidden expenses. They have to charge these cost to each patient,

which is overloading the price. Poor costing system have adverse influence on pricing and on its own sustainability and quality of service rendered. It is a well-known management axiom that what is not measured cannot be managed or improved.

Without a correct understanding of cost it is difficult to make out the sound pricing system. It is unable to link cost to process improvements or outcomes, preventing them from making systemic and sustainable cost reductions and services. Hence, it becomes imperative to hold the sound cost management strategies and technique.

Cost management can be a useful tool for hospital managers to:

- Estimate the reasonable cost of health care resources used in patient care
- Performance measurement of all the cost and revenue drivers
- Lower health care cost without compromising on quality of services rendered or extended
- Define the health care delivery value chain
- Determine the fees or tariffs for goods and services
- Estimate the capacity of each resources and comparison with actual utilization
- Authorize, modify, or discontinue a programme or activity
- Manage materials and its storage and associated costs in terms of consumables, drugs, etc.

HEALTH CARE PRICING

Pricing of health care services requires a balance between the patient's concern for affordability and the industry's concern for adequate returns on investment for growth and sustainability. The pricing strategy in health care is the most critical component of managing hospitals irrespective of whether they are for-profit or not-for-profit. While a variety of factors influence pricing strategies, it is important to keep the process simple and uncomplicated. Pricing is dependent on a variety of factors like competition, demand for the Services in the community, affordability by the community, and quality of services rendered by hospital. Therefore, the beginning of pricing process has to start with understanding the activities involved in such health care service. The cost of medicines which we use are governed by National Pharmaceutical and Pricing Authority (NPPA). However, an approach would be justifiable for price determination with regard to a list of essential diagnostics, equipments and for certain critical health procedures as well.

Alan Sager, a professor of health policy and management at the Boston University School of Public Health said in a recent Wall Street Journal that facility charges "are the latest gimmick to generate additional revenue for hospitals." On the other hand, hospitals that charge these fees say they are necessary to offset overhead, including higher staffing, equipment, and utility costs.

Physicians that practice in free-standing non-hospital-based settings usually include these overhead costs into a single office visit bill. The practice depends on the hospital's ownership structure, choice of approach, and contracts with insurers. In part because of lawsuits and new laws in some states about transparency of these fees, more providers are prominently displaying signs in their offices if they charge a facility fee.

Facility fees have been a hot legal topic and remain controversial. Consumers have increasingly complained about unexpected provider-based billing, which allows a health care organization to bill patients for physician care in addition to a service charge for the patient's use of hospital facilities and equipment. The practice has spurred federal regulators to examine the procedures in place for hospital service charges and pricing transparency. Federal regulators, concerned with rising care costs and consumer complaints, plan to review the impacts of provider-based billing this year.

The government setups costs 4 to 10 times lesser than private to the patient. But the actual expenses behind each management are much higher in government setups too, which are bare by Indian government. For example according to one study the cost of one normal delivery in a government hospital or pricing health care is around Rs. 50,000.00 (fifty thousand). There are conspicuous reasons for higher costs in the private health care setups like cost of land, construction, equipment, higher salaries, extra facilities, government taxes and miscellaneous expenses. Also every service borrowed for the maintenance and running of the system costs much more. The quality of facilities in the private setups are said to be better than government setups comparatively. Also the number of per day patients visiting in private and government setup are different. These all factors indirectly rise the facility charges in the private hospitals more in comparison to government setups.

WHY IS HOSPITAL COST MANAGEMENT IMPORTANT?

Hospital cost information is derived by relating the inputs of resource in monetary term to the output service provided by the hospital. Cost information is part of the basic information needed by the manager, policy maker and government for making decision about how to improve the performance of a hospital, where to allocate the resources within or among hospitals, or to compare the performance of different hospitals to one another. In addition, some of the other reasons wanting for cost information are to improve efficiency, increase effectiveness, enhance sustainability, improve quality and vital factors that are needed for pricing.

WHAT ARE THE USES OF COST DATA?

Cost data can be used for two primary purposes, for the present situations and for the future. It can be used to assess the current situation of a hospital, such as for assessing its efficiency, determining the effectiveness of the hospital, reviewing its priorities, and setting of prices. Cost information may also be used for the future i.e., for making cost projections, budgeting, and scenario planning with

"what if ?" situations. The information can be used to assess the internal operations and performance of a single hospital and to make comparisons of the operations and efficiency of different hospitals.

Some of the specific potential uses of cost information for a health care administrator are:

- Comparison of costs across different facilities and to identify efficient from not efficient facilities
- Comparison of costs with revenue
- Evaluation of financial feasibility of a new program, or activity, or any other future planning
- Analysis of the effect of changes in resources used.

HEALTH CARE SYSTEM IN INDIA

India has traditionally been a rural, agrarian economy. From health care perspective, it is geographically divided into rural, semi-urban, and urban areas. In India, only 65 doctors are available per 100,000 populations whereas 230 doctors are needed per 100,000 populations. This was the status in 2009. In rural areas, about 58% of all hospitalization cases go to private hospitals. This is up from about 56% in 1995–96. In urban areas, 68% cases go to private hospitals, up from 57% twenty years ago, according to the report.

On an average a hospital admission cost would be 4 to 10 times more in a private hospital as in a government facility. Some cases, like childbirth costs eight and a half times more in private hospitals compared to government ones. These findings are part of the latest survey report put out by the National Sample Survey Organization (NSSO).

Health care is one of India's largest service sectors. It is the second largest employer in the country. The challenges faced by this sector are substantial such as from the need to reduce mortality rates, improve physical infrastructure, necessity to provide health insurance, ensuring availability of trained medical personnel, etc.

Following are the major weaknesses of Indian health care system:

- Availability of health care service, public, and private sectors taken together is quantitatively very less
- Quality of health care services varies considerably in both public and private sector. Regulatory standards for public and private hospitals are not adequately defined and ineffectively enforced
- Affordability of health care is a serious problem for the vast majority of the population, especially in tertiary care. The lack of extensive and adequately funded public health services pushes large number of people to services rendered by private sector. Out of pocket expenditure arises even in public sector hospitals many times, because of insufficient supply of medicines and equipments, means that patients have to buy them from medical shops. This result in a very high financial burden on families in case of severe illness. The problem outlined above is likely to worsen in future due to ever-growing population and diseases
- Health care costs are expected to rise, with rising life expectancy which typically requires extensive treatment and demand of latest facilities by patients too for example, air conditioners, elevators, standard quality rooms, toilets, etc.
- The above weakness can be overcome by implementing the following reforms that are needed in the hospital administration
  - Making health care facility affordable by common man
  - Availability of emergency care
  - Identifying well trained and qualified doctors
  - Providing all facilities under one roof
  - Providing/enabling quick service
  - Ensuring cleanliness and hygiene
  - Availability of latest technical medical equipment
  - Providing adequate infrastructure
  - Good post hospitalization services
  - Friendly attitude towards patients
  - Training of paramedical staff
  - Providing all types of medicines
  - Simplified administrative process
  - Timely repair of faulty medical instruments
  - Faster appointment of skilled doctors
  - All employees of hospital to have adequate technical/ medical knowledge.

REASONS FOR RISING HEALTH CARE COSTS IN INDIA

- One of the main reasons for rising health care costs in India is use of latest sophisticated technology and equipment by the doctors and hospitals. Earlier, over dependence on technology has become the norm instead of dependency on the skill of the doctors. Earlier doctors prescribed tests only if the patient's illness was of serious nature. However, a bunch of complex tests are advised now by the same doctor for various needed reasons
- Medical negligence cases are being experienced nowadays and are being viewed seriously by consumer courts. So doctors practices defensive strategies and ask for test reports even before prescribing the treatments. This has also lead to the over recommendation of diagnostic services. So there is need of correction or review of laws
- The opening up of the corporate hospitals in providing health care has also contributed to the rise in costs. In private hospitals all things are commercial, be it land, professional fees to doctors, salary to nurses, staff etc. So while fixing the charges for treatments/ procedures by the private hospitals, the costs are to be loaded and the patients have to pay for diagnostic, hospital stay, doctor fees, nursing charges, and planned diet while seeking treatment from private hospitals
- As per the World health organisation (WHO) data 2016, higher average life expectancy of 71.5 years and lower

infant mortality rate of 34 per 1,000 live births have also played its role and more people are seeking health care putting a demand on its availability and hence pushing the cost upwards
- Higher purchasing power due to rising income levels and rising literacy levels has boosted awareness on preventive and curative health care and, in turn, increase the hospitalization rate
- The sustained expansion of health care insurance coverage also push the hospitalization costs
- Demand for health care from patients from abroad in the form of medical tourism.

Physical boundaries no longer restrict people to get the best services at most competitive prices from any part of the earth. Medical treatment is one such service for which patients frequently travel to countries where they can get the best values, for money. This medical tourism is a worldwide phenomenon that is expected to grow substantially in the coming decade. The primary reason for foreign patients flocking to India is a huge cost saving in medical treatment. The rule of thumb shows that the treatment cost in India is about 20% of the cost in United States.

BROAD BUSINESS MODEL OF HOSPITALS IN INDIA

Charitable Hospital

These hospitals are usually formed by a group of philanthropists, societies and groups of people with charity as the primary motive. Charity means, a certain percentage of cases are treated free, some on concessional/subsidized basis. These hospitals are mostly not-for-profit organizations. Not-for-profit does not necessarily mean that the hospitals do not generate surplus, but the surplus are ploughed back into the operations for upgrading/improving the technical base of the hospitals. These hospitals do not attract taxes in the form of Income Tax on the revenue generated but necessarily need to prove that the income so generated is used for treating the weaker section of the society. In most hospitals, the money collected for treatment would be very nominal. These hospitals usually undertake promotional programs to create awareness among the community. Usually Research Institutes are associated with such hospitals. Such hospitals look towards the trust/society for capital requirements and for funding the day to day operations. Viability is not the criteria at all.

Private/Corporate Hospital

The basic difference between this hospital and all the others as discussed above is the motive. In this case the motives are rendering the best health care services as well as the profit making. These institutions usually hire money in the form of loans to establish the setup. Hence, the charges are usually on the higher side as they need to service the loan component toward the institution.

REVENUE STREAMS IN HOSPITAL SECTOR

The source of income in a typical hospital would be from direct medical services and from medical support services such as from blood bank, radiology department, pharmacy etc. Each of the above source is further classified as, from outpatient channel or serving inpatient channel. Whatever be the source, each source is influenced by a variety of complex qualitative and quantitative factors as follows:

Qualitative factors	Quantitative factors
Usage of advanced medial equipments	Number of patient
Complexities of critical cases	Number of beds
Types of services hospital offers	Capacity occupancy level
Frequency of services	Infrastructure availability
Quality of employees (such as doctors, nurses)	Number of back up facilities

REVENUE GENERATION STREAM CHART

Outpatient Revenue

Medical services: Consultation fee, injection and immunization charges, casualty, day care, master health checkup, ambulatory care, endoscopy, medical support services, OP registration charges, lab services, radiology services, blood bank services, diet counseling, physiotherapy, ambulance services.

Inpatient Revenue

Medical services: Doctor's fee, surgeon fee's, surgeon charges, operation theatre charges, anesthesia charges, intensive care unit charges, room rent charges, special nursing charges, nursing charges,

Medical support services: Admission and documentation, lab services, radiology services, medical counseling, medical legal charges, blood bank charge, oxygen charges, mortuary charges, surgery/procedure charges, medical and surgical consumables.

Other Operational Income

Pharmacy income, admission charges, outsourced pharmacy, outsourced lab, infrastructure charges, telemedicine consultancy, research and development income on assignment basis.

EXPENDITURE STREAMS IN A HEALTH CARE SECTOR

The expenditure stream refers to consumption of resources (cash or kind) that is charged to expenses as soon as resources are consumed. By doing so, a hospital uses the matching principal to link the expenses incurred to revenue generated

in the same period. In hospitals, expenses incurred in following departments:

- Medical department
- Medical support department
- Service departments.

Doctor's fees, surgeon's fees, clinical expenses, operation theatre, implants expenses, nursing expenses, emergency expenses, casualty expenses, medical support service department, pharmacy expenses, general lab expenses, referral lab. Charges, radiology expenses, pathology expenses, blood bank expenses, ambulance services expenses, mortuary expenses, research and development expenses, CSSD (central sterile services division), service department, help desk, stores, food and beverage, housekeeping, medical record expenses, equipment maintenances expenses, training expenses, call center expenses, oxygen and gas charges, power and fuel expenses, biomedical wastage, administrative staff salary, other maintenances expenses, transportation expenses, traveling expenses, telecommunication expenses, office expenses, books and periodicals expenses, rent charges, others finance expenses, legal expenses, advertisement and sales promotion, insurance, audit fees, capital expenditure patent, copyright, and trademark charges, surgical equipments, medical tools, medical furniture, operational expenditure, and nonoperational expenditure.

Some of the terminologies used in above expenditure stream:

- Ambulance expenses: These are incurred in providing ambulatory care to outpatient
- Blood bank charges: These are incurred in purchase of blood from outside bank or in house blood bank running expenses and billed the patient as per protocol
- Call center services: These are provided as a one stop solution to patient and generally call center diagnoses and consult patient through telecommunication. Such services are also known as "telemedicine" in modern science. The expenses involved in providing such services are call center expenses
- Central sterile services division: In this division used and contaminated articles, equipments are sent from various departments. These are collected at one place, cleaned, sterilized, stored in sterile condition till it is supplied to user department. In this division, all medical devices/instruments and usable shall undergo sterile treatment. This is one of the vital departments in hospital. It caters to the sterilization needs of wards, operation theatre, and a host of other units. This CSSD is equipped with auto claves, gas sterilizers, hot air ovens, and other sterilizing equipments. Steam from central boiler section is supplied to this CSSD for sterilization purpose. One fourth of steam generated in a hospital will be consumed in this CSSD and also the steam cost is the major cost element in this department
- Consumables: General store which are used by the hospital staff in ward and various department It also includes material common to all patients but not billable. Surgical consumable used and billed to the patient are also grouped under consumables. This does not includes and material received on consignment basis like stents, catheters, and implants
- Housekeeping expenses: This can be done either by outsourcing only labor activities without consumable or entire service with consumables through any agency. Then housekeeping department costs are reimbursed to such outside contractor and the entire expenses incurred for housekeeping is booked under respective outsourcing account head
- Implants charges: These are the charges incurred for the purchase of implant or implants material used in hospitals
- Medical record and scanning charges: These are incurred to take soft copy of medical reports and other related documents of the patients as part of maintaining electronic medical records or medical case histories
- Oxygen and other medical gases expenses: These are incurred in purchase of such gases used for patient in Operation theatre or wards
- Research and development expenses: These are spent by hospital in either medical science or engineering or the social sciences for humanities development with primarily "patient care" objectives
- Referral laboratory charges: These are incurred in few unavailable lab tests to be send to outside labs or as per the doctor's instruction. Laboratory charges paid to such lab as per agreement are called referral lab charges
- Repair and maintenance of building, plant and machinery, medical equipment, vehicles, nonmedical assets, this includes amount paid for Annual maintenance contract for asset mentioned above.

It is therefore imperative to identify the cost of each activity/procedure to have efficient cost accounting and profitability analysis systems in a hospital. Capacity percent used in the context of service industry like health care is expressed as the amount of time that the resources are kept occupied , say number of beds kept occupied in given period. No of hours employees render service against the available period, time usage of each resource as against its total availability period. Capacity used percent can be worked out for each resource. However, overall capacity used percent is expressed as the quantum of services rendered as against the overall capacity available in the hospital.

The type of cost model practiced will vary from hospital to hospital depending on the size of such hospital and the extent of the capacity being used. Typically the department of cost model is made according to the size of the hospital such as small, medium and large ones. For small hospitals where the number of services rendered are minimal, variable cost approach would be an ideal one since the fixed overhead shall be kept at minimal level. However for medium and large hospitals total cost approach would be appropriate since there is a large overhead portion involved in nonmedical services department. Following cost models can be practiced depending on the size and policy:

- Variable cost approach
- Total cost approach
- Health care package cost approach
- Activity based cost approach.

Variable Cost Approach

Doctor consultation fees + direct medicines and consumables + direct labor + variable overhead + profit margin = price.

Total Cost Approach

Direct costs + indirect costs + all fixed cost + profit margin = price.

Health Care Package Cost Approach

Direct medicines and consumables + direct labor + variable overhead + apportioned fixed overhead + profit margin = price.

Activity Based Cost Approach

All direct costs + activity costs + profit margin = price.

Costing Approach

Each approach is explained as follows:

- Direct/variable cost approach: Here all variable costs are traced to respective procedures/operations via accounting process namely cost center model. This is for both medical and medical support department. Mark up is added to such variable cost to arrive at the billing costs. This is because the cost of nonmedical support services would be kept minimal due to direct interaction of management on day to day activities. This is applicable for small hospitals.
- Total cost approach: Here the direct costs are traced to respective procedures/services (including medical support services department) and then nonmedical support services costs usually called as overhead costs are identified to activities are then added on to the respective services. In addition the cost of fixed resources in the form of fixed cost has to be clubbed with the above cost to arrive at total cost.
- Health care package cost approach: Here the patient is advised with estimated costs/price for a procedure/for a list of services needed for the patient after the completion of the procedure he will be provided with actual price with cost details. In this approach, all costs that are incurred exclusively for a patient is assigned and then end to end cost is computed after adding a portion of apportioned fixed overhead in the name of administrative charges, as applicable to respective patient. Some of the examples of medical packages are delivery package, diagnostic lap, hospital master health checkup, *in vitro* fertilization package.
- Activity based cost method: Here the resources costs are assigned through activities:
  - Direct cost collected through respective cost center
  - Activities are identified for each of the services rendered
  - Cost drivers for each of the activity are determined
  - Cost is accumulated for each activity according to the cost drivers
  - Assignment of cost to the activities is done based on cost drive.

The final cost object decides the matrix of cost collection and final costs. Following are few suggested cost objects that can be used as final cost object:

- Cost per bed/day
- Cost per patient
- Cost of each department (cost collectible from respective cost center bookings)
- Cost per standard procedure/treatment/package
- Cost for a service activity (cost workable based on ABC method).

Health Care Services Cost Pool and Allocation Practices

Cost pooling means classification, collection of costs/resources used in respective department and then allocated, apportioned to respective activities. Health care services are broadly classified into the following groups and hence cost pools are also classified in the same manner:

- Medical departments
- Medical support departments
- Nonmedical (service) departments.

Medical Departments

Department which generates income directly from the patients are called medical departments. These are also called as profit centers. e.g., general medicine, gynecology, cardiology, orthopedic, neurology, nephrology etc. Income from lower segment cesarean section) surgery will be an example of income of gynecology department. Medical departments are further classified into outpatient (OP) and Inpatient (IP). Of course, day care unit is considered as separate medical department.

Medical Support Departments

These departments generally support medical departments. These also generate revenue from patients directly and hence these are also called as profit centers. However, in addition to revenue generation since these departments render support to main medical departments, resources are expended in these departments and hence will remain as cost centers also. e.g., operation theater, laboratory, radiology, physiotherapy, blood bank, pharmacy, and wards.

Nonmedical Departments

Department which do not generate income directly but supports the medical and medical support departments to do their services effectively are known as nonmedical (service)

departments. e.g., medical records, business operations and admin, finance and accounts, information technology, biomedical engineering, maintenance, housekeeping, admission, human resource, purchase and stores department etc.

Profit Centers Cost Driver

- Wards: Intensive care unit, class patient suite, deluxe rooms, semi private (twin sharing room), common class patient rooms/beds
- Operation theater (OT): Supra major OT, major OT, minor OT, labor room
- Physiotherapy: Total hours utilized and standard hours required for each
- Radiology/imaging: Number of tests done in computed tomography scan, magnetic resonance imaging, two-dimensional echocardiography, stress tests, sonography, X-ray, ECG.
- Health checkup
- Pathology
- Casualty/day care: Number of patients (IPD and OPD separately)
- Outpatient department consultation: Category wise number of patients.

Integrating Finance and Cost Accounting System in Hospitals

The financial accounting info system module deals with cash/bank, receipt/payments, journal voucher and general ledger etc. books like cashbook, bankbook, and ledger book can be generated. This module generates reports like trail balance, balance sheet and profit and loss statement. The financial accounting screens describe about the account payable, account receivable, and general ledger. Also describe the activities related to IP, OP, bank related activities and provision to clearing the supplier invoice and keep track of the account receivable and revenue related activities. The services that are covered by the sponsor companies, insurance agencies, family accounts, individual accounts, sponsorship details of the patient, health care insurance are recorded in the system. In a hospital, the data flows are seamless and shall remain connected in a crisscross way among all departments. Hence, the design of books of accounts shall be in such a way that the data's shall be made available in all directions for an individual cost object or group of cost object and cost centers.

Performance Appraisal System in a Hospital

The performance of a hospital can be done by analyzing the income streams and expenditure streams separately and also in comparison to each other (i.e.,) the performance of each medical and medical support services are related to each other and hence performance of a hospital are dependent on several interdependent variables. This chapter discusses uses of cost data within a hospital and therefore aims to show managers and hospital administrators how costing can help improve their performance. This chapter is structured around profitability level, strategic level, and efficiency levels performance.

At Profitability Level

- Departmental profitability: Cost and revenue should be split by different departments like labs, radiology, OT, blood bank, wards, emergency
- Service level profitability: Cost should be ascertained for each lab test, radiology investigation, room type etc. And the departmental costs should be further split for each service
- Patient level profitability: The revenue from each patient should be broken down to the service elements like individual lab tests etc. and the costs of each service should be matched and aggregated at the patient level
- Patient segment wise profitability: The profitability of each patient segment like cash, insurance. corporate can be analyzed, once the hospital is ready with patient level costing
- Specialty wise, doctor wise profitability: The patient level profitability can be summed up by primary consultant and then by the medical specialty. This will help us in understanding the profit generated by each specialty and the relative performance of each doctor.
- Diagnosis wise profitability
- Measurement using current cost accounting and imputed costs
- Cost reduction—Comparing best practices across locations, implementing uniform protocols to optimize costs are other few cost reduction and performance measurement areas. For e.g., the standard material requirements can be formalized by comparing the procedure material requirement of various leading consultants and their clinical outcomes regarding Theatre consumables, pharmacy pre- and postoperation, diagnostic tests, stay duration etc.

At Strategic Level

- Budgeting perspective: The cost to the patient should be measured in full, which includes the doctor's fees and pharmacy supplies. This will help in quoting for Insurance, corporate customers, as well as offering package products for common diseases to cash patients.
- Standard vs. actual perspective (i.e.,) variance assessment perspective: Developing clinical pathways for all the diagnosis related group (DRG) codes will help in determining the standard treatment costs for a given disease, severity and associated complications or co-morbidities. This data can be used to compare the actual cost of treatment done for patients falling into the corresponding DRG code. Variances can be analyzed and controlled, wherever there is a significant deviation.
- Cost of entire care cycle: Normally, system captures the cost of the patient per admission/episode. It should be

extended to data capturing for every inpatient to the OP visits prior to and after the admission using the ID reference for a span of say 1 year, so that the full cost of treatment spanning across the entire cycle can be correctly understood for each DRG type.

- Cost control perspective:
  - Identifying areas of waste /rework that can be corrected, periodic replacement of consumables, Expansion or contraction of services, grouping or regrouping of services
  - Rendering in-house service or subcontracting the same
  - Enhancing cost-effectiveness in hospitals (e.g., comparing alternative approaches such as engaging a resident doctor on full time employment or engaging doctors on call, in house ambulatory vs. outsourced ones).

At Efficiency Level

Performances are measured not only in terms of money, but also to be measured in terms of effectiveness of resource utilized.

- Measuring effectiveness of treatment: With suitable parameters like patient survival rate, treatment effectiveness, back to normal life, re-admission for same disease.
- Cost of quality: Perceived by patient. Quality is contributed by two factors (a) Clinical efficiency, which is measured by various parameters such as hospital acquired infections, patient fall, wrong medication, wrong diagnosis are examples of factors affecting clinical efficiency, and (b) operational efficiency which is measured by 'patient satisfaction index'. Delay in discharges, billing disputes, food quality, nursing attention, noise level, room ambience, air conditioner problems are examples of factors affecting operational efficiency.

Other suggested indices for measuring the effectiveness of a hospital are referral index, bed occupancy ratio, turn over interval, average duration of illness, average daily outpatient admissions, the average outpatient attendances per day, Average cost of medicines for a patient, cost of daily diet, fatality rate, anesthesia death rate, postoperative death rate.

ROLE OF GOVERNMENT IN PLANNING THE COSTS IN PRIVATE HOSPITALS

Many allegations and litigations are faced by private as well as corporate hospitals for huge health care charges. There is no clear cut Law for deciding the costs of Hospital services in India. Mamata Banerjee government in West Bengal is working on a Bill for regulation and fixation of service charges in private health care. But at present there is no practical enforcement of any law. Karnataka government also tried to make laws for fixation of charges in medical services, but Indian Medical Association and Karnataka Medical Associations did not accept this law.

CONCLUSION

The idea behind this chapter is to guide the health care providers to design the costs of hospital facilities, which should be suitable and affordable to the hospital as well as to the patients. Instead of haphazard charging system, one should adapt either of the above mentioned cost approaches as per the setups. This will surely please your patients as well as will save the hospital from litigations.....!!!

13

CHAPTER

Billing and Payments

Ajay S Mane, Megha M Jogdand

INTRODUCTION

As of today, the hospitals are becoming up to date with today's era of medical information system (MIS).In western countries the system is named as health information system (HIS).

We will be elaborating Billing and Payment section of MIS in this chapter.

The patients are of two types: (i) OPD, outpatient department (ii) IPD, inpatient department. In both groups we need to maintain the medical record and financial record. As the patient may come for revisit or follow-up visit, the charges are less than new patient. There can be multiple slabs of consulting fees for different consultants and super consultants. The OPD patient needs investigations as advised by treating doctor for which payments are to be accepted from patient at different department or central payment collection place of hospital.

In IPD patients, for each investigation the patient may not pay on the spot and that bill may be stored as pending with the patient's identity document (ID) number and can be collected at the time of final billing.

For all these purposes a systematic billing department which can be either traditional hand written bill section or an ideal computerized billing unit is required. Nowadays, many options are present in hospital management system software. These systems are more over equally compatible and good to maintain billing and payment history of patients.

TYPES OF HOSPITALS

Indoor Hospitals (OPD + IPD)

In these hospitals the patient is admitted for more than 24 hours and assigned a bed and 24 hours nursing services in respective categories.

- Government hospitals/semi government hospitals: In this sector, the charges are very much less compared with other category of hospitals. Moreover, for certain group of people like below poverty line (BPL), the charges are totally zero or completely free.
  For others except BPL & above poverty line (APL) the charges are less. The charges paid in Govt. hospital are 100% reimbursed in systems. Reimbursement system do not pay certain charges of private hospitals (e.g., disposables etc.). The corporation hospitals are also considered in this category (they fall in semi government category)
- Private hospitals of individual owners: These kinds of hospitals are owned by individual persons (Medico or nonmedico).The charges may be moderate to high compared with government set-ups. These hospitals are liable for the income tax payments of the owner's income.
- Private Hospitals–Corporate/Group ownership/limited liability partnership Company/private limited companies: These kind of hospitals are owned by group of persons (Medico or nonmedico). The charges may be moderate to very high compared with government set ups as these hospitals render services of consultants/super consultants (which may not be available at other set up) and they provide superior quality of hospital services like staying, assistants, nursing, operation theatre, latest world class equipments. These hospitals are liable for the income tax payments of the owner's income
- Public charitable trust owned hospitals: These kinds of hospitals are owned by group of people (medico or nonmedico) under the Public charitable Trust Act. The charges may be low to very high compared with government set ups as these hospitals render all types (category wise) of services from free to highly paid

treatments. These hospitals are exempted for the income tax under sections 80 G of Income Tax Act, 1961. (Under this section the donation to these hospitals will be 50% exempted from donors tax liabilities)

These hospitals are also exempted for Income Tax only when they are registered under section 12 A and provided that they perform audit every year by authorized auditors and submit it to the commissioner of public charitable trust office regularly.

These hospitals are liable to give 100% free treatment to 10% of total patients and subsidized rate treatment to another 10% of total patients of that hospital for the BPL category.

Only Outpatient Department (OPD) Clinics

- Private/Govt./Corporation/Trust/ESIC
- In these kinds of clinics the charges are of OPD services only, and no indoor facilities can be availed
- Charges are applied as shown in above category.

CONTENTS OF HOSPITAL BILLS

There are two parts of bills.

A. Patient Information section
B. Proper bill with headings and charges.

Patient Information Section

This section of bill carries complete information and photograph (in certain software this facility is given) of the patient with patient's ID number, OPD number, IPD number, bill number, date of bill, date of admission, date of discharge, category of patient's stay etc. For example:

Nowadays, "adhar card number" can be made compulsory to avoid fraud bills and fake patients. As it contains unique ID number and the person's (patient's) photograph.

Bill of OPD: Once a Patient comes to OPD, his/her registration is done either in register or in computerized system with unique ID number (that will be stored forever in record). All treatments & procedures are recorded for the same ID by the treating doctors, and total bill is generated at counter for payment. The patient has to pay for various services at various departments and get the receipt of those payments. Compilation of bills is a big headache for hospital management on daily basis & cash collection management at many places is a difficult task.

Ideal bill is as follows:

OPD BILL RECEIPT				
ID no. : 2256		Bill no. : OPB0016152		
Patient name : xxxxxxxxx		Age : 38 years 5 months 1 day		
Aadhar card no. :				
Doctor's name : yyyyyyyyy		Date : 12/01/2018 4:20 PM		
Reference document :		Category : Self		
Serial No.	Service Name	Qty.	Rate	Net Amount
1	Follow-up Consultation	1	200.00	200.00
			Total :	200.00
			Payment :	200.00
Amount in words : RUPEES TWO HUNDRED ONLY				
Remark : 0				
Receipt no. : OPR0013651				
Cash Pay : 200.00				
04:42 PM, 12/01/2018				Received By : zzzz

In above bill there is only follow-up consultation charges.

Proper Bill with Headings and Charges

Ideally, this section of bills should contain details about the treatment, investigations, and advice. It can be as follows:

OPD Bills: If a new patient comes to OPD, the bill will look as shown below.

Sr.No	*Heads / Iteams*	*Charges*
1	Consultation	Rs……
2	Pathology Lab Investigation Charges	Rs……
3	Physiotherapy/ Rehabilitation charges	Rs……
4	Minor Procedure charges (OPD procedure only)	Rs……
5	Radiological Investigation charges	Rs……
6	Transportaion charges	Rs……
7	Total	Rs……

These heads are given certain numbers in software system but many systems do not give item code.

IPD Bills: In indoor hospitals there are some additional headings as follows.

Sr.No	*Heads / Iteams*	*Net Amount*
1	Consultation before admission (if any)	Rs……
2	Pathology lab investigation charges	Rs……
3	Physiotherapy/rehabilitation charges	Rs……
4	Procedure charges—Major/Minor	Rs……
5	Radiological investigation charges	Rs……
6	Stay (accomodation)—Patient category	Rs…..
7	Transportaion charges	Rs……
8	Pharmacy bill (total)	Rs…..
9	Total	Rs……

In these bills first page will display total bill against each head and the subsequent pages carries the details about them.

For example, the investigation of pathology shows Rs. 5,000/- then details of head under pathology will be on separate page with code and name of investigation, charges, number of times of investigations etc.

Once patient is admitted his/her ID number is created and every bill is attached to that ID no. If the patient pays any amount either as advance or as a part payment or against any bill (say like pharmacy or investigations etc.) it is recorded with same ID (this is real advantage of computerized hospital management system) and deducted from final amount bill.

An Ideal indoor bill of a Gyecology set up is shown below:

HOSPITAL NAME			
IPD FINAL BILL CUM CASH RECEIPT			
Bill no.	: IPB0003284	BILL DATE : 16-DEC-2017	
ID no.	: 20912	ADMISSION DATE : 15-DEC2017 03:14PM	
Patient name	: xxxxx	Discharge Date : 16-Dec2017 11:32AM	
Aadhar card no.	:		
Admiting doctor	: yyyyy	Admission No. : 20197562	
Patient category	: Self	Bed Class : Special Room	
Patient address	: zzzzzzzzzzzzzzzzzz		
Particulars		Qty.	Rate	Net Amount
Hospital charges		2		**4,200.00**
Anesthesia charges		1		3,000.00
Stay charges		1		1,200.00
Operation theatre charges		2		**25,000.00**
Operation theatre charges		1		9,000.00
Surgeon's charges		1		1,60,000.00
Advance Details & Settlement Details : IPA00001292 DATE = 15DEC2017=12000.00				
		Gross amount		**29,200.00**
		Cash advance used		12,000.00
		Paid amount		17,200.00
		Final bill amount		29,200.00
		Refund amount		0.00
Amount in words : TWENTY-NINE THOUSAND TWO HUNDRED RUPEES AND ZERO PAISE, ONLY.				

We received Rs 29,200 towards hospital against above bill.

Payment details: Complete bill is given at the time of discharge, as shown below.

Payment Type	Bank Name	Cheque/DD/ Credit/Debit Card No	Amount	Cheque Date
Cash Payment			17,200.00	
Advance Used			12,000.00	

Cashier Adminstrator Prepared By

Some hospitals give bill in very much detailed manner and confuse the patients, which is not advisable. See table shown below:

Sr.No.	Item	Quantity	Rate	Total amount
01	Room charges	05 days	700	3,500
02	Nursing Charges	05 days	200	1,000
03	DMO charges	05 days	200	1,000
04	Injection charges	10	50	500
05	I.V. charges	20	20	400
			Total	Rs 6400/-

The details should be written in a simple manner that may not confuse the patient. The charges can be rounded off. As shown below:

Sr.No.	Item	Quantity	Rate	Total amount
01	Room charges	05 days	1,000	5,000

In a previous table, Rs 6,400 is given, instead in the above table total of Rs. 5,000 is shown.

Nowadays, it is mandatory to display all the charges, thus, if it is decided to display it is not possible.

As suggested, package charges for complete procedure category wise so that it includes all heads except pharmacy bills should be given. Let us see an example.

Type	Category	Quantity	Rate
A	(Procedure name) in general ward	01	3,000/-
B	(Procedure name) in special room	01	5,000/-
C	(Procedure name) in deluxe room (airconditioned)	01	6,500/-

Likewise, it should be so that patient's confusion and query with quarrels at payment counter can be reduced. Moreover, it will be easy for us to give the quotations for procedures. This is for the patients who pay from their pockets, mediclaims, and reimbursements from government departments.

If the payment is from cashless system of mediclaims then we have to provide them complete planned bills which includes 100% expenses and all services from admission till discharge.

Additional emergency charges can be intimated to companies at times, if unfortunately, the patient needs treatment in intensive care unit etc. and get the approval.

For reimbursement purpose the pharmacy bills are to be approved by treating doctor with signature and hospital stamp on each bill.

PAYMENT

Payment of bills are made in various forms:

- Individual payments by cash/cheque/demand draft/ cards/net banking: Most of the payments are in cash but, nowadays digital method of fund transfer is increasing which is good for record keeping and for information technology (IT) purpose
- Company/Organization payments: There can be a contract between company or an organization and the employees in which all expenses are given by organization directly to hospital. Most of the payments are by NEFT or RTGS or cheques, at times
- Insurance/Mediclaims: Most of them are cashless and needs approval before planned treatment.In emergency, the intimation should be given online and should get the approval during treatment
- Government schemes like Rajiv Gandhi Jivandayee Yojna (RGJY) (now name changed) in Maharashtra and likewise, in various states and by central government, all are package charges and reimbursed to hospital directly by government by real time gross settlement systems (RTGS)/national electronic funds transfer (NEFT)/public financial management system (PFMS)
- Donations or mass patient camp by organizations or individuals as charity: In this category any organization or any person may arrange certain number of procedures in the memory of their relatives (say 100 cataract surgeries done by XYZ in a hospital) and the payment is done in bulk by them as again above mentioned methods.

Receipts of Rs 5,000 and above amount is needed to be signed with a revenue stamp affixed. It is mandatory for mediclaims and reimbursement purposes. But for general purpose the simple computer print with cashier's signature and hospital stamp is sufficient.

CONCLUSION

The system is changing fast. Patients are not only smart but they can be over-smart at times. Therefore, to avoid complications in billing and payments one should be systematic and up to date. There are various software of billing system which can be used for easy handling. It is beneficial for both. Bill is a legal document.

14

CHAPTER

Prescription and Generic Medicines

Sudesh M Doshi

INTRODUCTION

Prescription writing is an integral part of any kind of medical practice. It is both science and art. Prescriptions also form apart of legal document in treating patients. Medication errors form a large segment of various factors causing damage to public health and life. In the era of consumer protection act and anything done by doctors coming under scrutiny from media to bollywood stars to lay public we have to cautious about our prescription writing. Any error in prescription suddenly becomes an object of media attention. Unfortunately we doctors as a community are known to write in illegible script and such prescriptions are a subject of mockery in our colleauges, pharmacists, and general public.

Most of the countries have various laws rules regulations and guidelines about prescription writing.

In India, governing bodies like Government of India, various state governments and Medical Council of India have from time to time issued guidelines for prescription writing in India.

There are various laws which govern the prescription writing

1. The Indian Medical Council Act 1956
2. The Indian Medical Council (Professional conduct Etiquette and Ethics) regulations 2002
3. The Drugs and Cosmetics Act 1940 and Rules 1945
4. The Pharmacy Act 1948
5. The Narcotic Drugs and Psychotropic Drugs Act 1985 and rules 1987
6. The Drugs and Magic Remedies Objectionable Advertisement Act 1954 and Rules 1955.

The various guidelines mainly deal with four aspects of prescription:

1. The doctor
2. The medicine
3. The patient
4. The pharmacist.

Prescription has various parts some of them mandatory which is a legal necessity under various acts and rules and some though not mandatory but help better understanding of prescription to pharmacist and patient.

WHO CAN PRESCRIBE?

- Registered medical practitioner/pertaining to that pathy
- Dentist/veterinary physician.

WHO CANNOT PRESCRIBE?

- A nurse or midwife
- A pharmacist
- A medical student who has not yet registered in state or national medical register.

The prescription should have following particulars pertaining to doctor, patient, and medicines as indicated below:

- D – About doctor/prescriber
- P – About patient
- M – About medicine
- Act means - Drugs and Cosmetics Act 1940
- Rules means - Drugs and Cosmetics Rules 1945

Doctor's (Prescriber's) Full Name **D1**

Qualification (e.g., MBBS, MD) **D2**

Reg. No.: (specify alphabets specifying pathy)/Reg. No. **D3**

Full Address, **D4** Contacts: (telephone no, email etc.) **D5**

Prescription Serial Number **D9** Date: dd/mm/yy **D6**

Rx **D10**

Doctor's signature and date **D7** Doctor's stamp **D8**

D1 – Doctor's Full Name

It is statutory requirement to mention name of the prescriber on cash or credit memo of the drugs under Rule 65(3) and it is also necessary to authenticate prescription. Therefore, the prescription shall bear doctor's full name as mentioned in her/his registration certificate.

D2 – Doctor's Qualifications

To know competency and genuineness of prescriber, the prescription shall bear Doctor's primary qualification such as MBBS/BAMS followed by subsequent qualifications. For example MBBS MD or BAMS MD.

D3 – Registration No.

Prescription shall bear the registration number of doctor's registration with their respective council. The registration number should be prefixed with letters indicating the council in which doctor has registered her/his name.

For example: Allo. (allopathic), Intgrtd. (integrated medicine), Homeo. (homeopathic), Dental (dentist), Vet. (veterinary), etc.

D4 – Address of Doctor

It is statutory requirement to mention the address of the prescriber on the cash or credit memo of the drugs under Rule 65 (3) and the patient and pharmacist should know where the prescriber is practicing and, therefore, prescription shall bear complete address of clinic/hospital where the prescriber is practicing.

D5 – Contacts

The prescription shall have telephone number (landline/ mobile) and e-mail of the prescriber. These details will help patient as well as pharmacist to contact doctor, if required.

D6 – Date of Prescription

As per the Rule 65 (10) prescription shall be dated. The date of prescription is also essential to know the validity of prescription and to avoid misuse of such prescription.

D7 – Doctor's Signature and Date

As per Rule 65 (10) prescription shall be signed by the person issuing it with her/his usual signature and, therefore, the prescription shall have full signature of prescriber with date.

D8 – Doctor's Stamp

To authenticate prescription and also to avoid misuse of blank prescription and to protect patient from quacks and un-qualified doctors, the prescription should have doctor's rubber stamp containing his/her full name, qualifications, and registration number below his signature.

D9 – Prescription Serial Number

For traceability and purposes of record the prescriptions must be serially numbered.

D10 – Rx-Superscription

As a matter of practice the prescription may bear Rx-superscription.

Patient

Patient's full Name **P1**

Patient's address and phone number **P2**

Sex **P3**..... Age **P4** ..... Weight **P5**

P1 – Patient's Full Name

As per Rule 65 (10), prescription shall specify the name and address of the person for whose treatment it is given or name and address of the owner of the animal if the drug is meant for veterinary use. Therefore, prescription shall bear patient's/ animal owner's full name.

P2 – Patient's Full Address

As per Rule 65 (10), prescription shall specify the name and address of the person for whose treatment it is given. It is also essential for follow up of patient, or to get in touch with patient in case of dispensing or prescribing errors and also essential for recall of medicines, if required. Therefore, the prescription shall bear patient's full address.

P3 – Patient's Sex

As certain drugs are gender specific, sex of the patient should be mentioned on prescription.

P4 – Patient's Age

The drug dosages may differ with age of patient and, therefore, prescription must bear patient's age.

P5 – Patient's Weight

The drug dosages may vary with weight of the patient, therefore, prescription may bear patient's weight.

MEDICINE

- Name of the medicine* **M1**, As far as possible, generic name in capital letters
- Strength **M2**
- Dosage form **M3**
- Dosage instruction **M4**
- Duration and total quantity **M5**

*Or any other cheaper generic medicine as per choice of patient.

M 1 – Name of the Medicine

a. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 under Indian Medical Council Act 1956 under Code of Medical Ethics at 1.5 prescribes as "every physician should as far as possible prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and rational use of drugs". Therefore, prescription shall bear the name of medicine as generic name.

   The name of medicine should be in capital letters in legible manner.

b. If the prescriber is not sure about generic name he shall add following instructions on the prescription above her/his signature or any other cheaper generic medicine as per choice of patient.

M2 – Strength of Drug

Prescription shall invariably bear strength of the medicine.
For example, paracetamol tablets 500 mg, amoxycillin capsules 250 mg.

M3 – Dosage Form

Prescription shall bear a proper dosage form of medicine prescribed.
For example, tablets, capsules, syrups, creams, etc.

M4 – Dosing Instructions

Prescription shall bear proper dosing instructions that could be easily understood by patient or owner of animal in case of veterinary drugs. Preferably in marathi or any other language easily understood by the patient or owner of animal.
For example, 1 (after breakfast)------0------1 (after dinner) 1 (empty stomach)----0.

M5 – Total Quantity of Medicine and Duration of Medication

Prescription shall specify duration of the treatment and total quantity of the medicine for that duration.
For example,

- Medicine 1 ----- 1 tab × 2 times a day for 7 days = 14 tablets
- Medicine 2 ----- 1 tab per day for 3 months = 90 tablets.

Dispensed By

Name and address of medical store. If entire prescription is not dispensed, specify name or number of medicine and quantity dispensed.

Date of dispensing:

Minimum size of the prescription blank should be:

- 14 × 21cm (A5 size)

SUGGESTIONS

- Changes in prescription: If any changes are warranted in prescription please issue fresh prescriptionDo not use prescription pad with the name of medical store
- Doctors should not use prescription pads, with pre-printed messages, like "available at XYZ medical stores"
- Do not print names of more than one doctor on the prescription
  One should avoid having names of two or more doctors on the same prescription pad (even if it is a husband and wife team)
- Do not use prescription pad of another doctor: A doctor should not use another doctor's prescription pad, even with her/his consent. Conversely a doctor should not allow other doctor to use her/his prescription pad
- Precaution about computer generated prescription: If the doctor types or generates her/his prescription on a computer, she/he must ensure that he/she issue it with her/his full, recognizable dated signature in ink. She/he must sign as close as possible to the last drug listed in the prescription
- Prescription of certain medicines by specialist: Certain medicines can be supplied on the prescription by specific specialist only.

For example, sildenafil citrate can be prescribed only by an urologist, psychiatrist, endocrinologist, dermatologist, or venerologist.

Prescribing should be part of a logical deductive process, based on comprehensive and objective information. It should not be a knee jerk reflex, a recipe from a cookbook, or a response to commercial pressure.

It is better to generate prescriptions using computer software as they are less likely to commit errors of incorrect spellings and illegibility.

Common Errors in Prescription Writing

- Illegibility—this can be overcome by either writing in capital letters or generating on computers
- Prescribing two preparations containing same medicine. For example, prescribing iron containing liquid as well as capsule at the same time
- Error due to similar spellings of two different medicines. For example, keterolac and ketamin
- Error in writing the correct dose
- Error in writing incomplete name of the patient
- Irrational prescriptions.

Copy of all prescriptions should be kept with doctor as an integral part of medical records of the patient.

If computerization of records is done it is easy to reproduce it as and when necessary.

Medical Council of India recommends computerization of records.

GENERIC MEDICINES

Generic medicines are medicines which are available in market by their generic name and not by brand name. They are generally cheaper than branded medicines.

Medical Council of India has recommended writing generic names of the drugs in prescription along with brand names.

The Indian Medical Council (Professional Conduct, Etiquette and Ethics)

Regulation, 2002 under Indian Medical Council Act 1956 under Code of Medical Ethics at 1.5 prescribes as "Every physician should as far as possible prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and rational use of drugs". Therefore, prescription shall bear the name of medicine as generic name government guidelines insist on generic names.

Hypocratic attitude of society and government towards doctors has flared this issue out of proportion. Patients want all the rights of a consumer but deny all the rights of a doctor as a service provider.

Actually if government wants doctors to prescribe only generic medicines then it should abolish brands from the market. It has enough constitutional powers to do so but is unwilling to do so.

Why Doctors Prefer to Prescribe Branded Medicines?

- Brand name is catchy and easier to remember
- Every brand is established in market with years of efforts and marketing skills. Brands have earned confidence of doctors as doctors have been using them for years together
- Doctors are also human beings and they are also likely to get influenced by market forces
- Many generic medicines are not available in the pharmacy as they earn fewer profits
- Patients psychology that cheaper medicines are not effective and costly medicines are more effective has to be kept in mind
- A deep rooted belief amongst doctors that branded medicines are more effective.

15

CHAPTER

Paperless Hospital Management System

Mahesh Jariwala

INTRODUCTION

Doctors are having lots of privileges in society or to be more broad term in a world. Simultaneously they are loaded with lots of responsibilities to prove them self. They are expected to have knowledge of everything includes laws, business, and social sciences. Doctors are highly criticized "not because of the treatment and medical management of the patients" but because of the poor understanding of laws, unethical business practices, and poor record maintenance. There are so many jokes for hand writings of doctors and they cannot read their own hand writings.

- All doctors are agreed that to come out of these menace of manual record keepings, digitalization of office is mandatory
- Doctors agreed that the digitalization is a transparent, effective and flawless record management system
- Author's responsibility in this article is to explain the technology, related laws, and importance to understand the digital data management system for our individualized clinical practice
- Technology: It is pertinent to note that the technological advancement is last decade is at the glance. We hardly find a person without a mobile device. There are so many commercial devices are available for entertainment and day to day livings. If we consider our practice of medicine there are list of gadgets available like computers, mobile devices, multipara monitors, hand held domestic medical devices like blood pressure measurement, blood sugar monitoring, portable cardiac devices etc.

The author would like to limit the discussion of technology for patient data management system. If an individual doctor wants to manage day to day activity of hospital by electronic data management system a computer with basic features are more than enough.

Hardware:

1. Computer with basic features (computer on stick)
2. Tablet or good quality smart phones
3. Camera with closed circuit television (CCTV) 8 port.
4. Finger print scanner and reader
5. Attendance system
6. Internet ready wifi modem

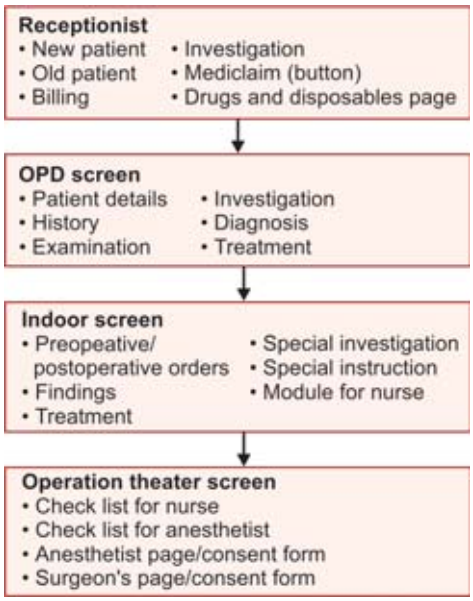
Software.

1. Good quality with post sale services program
2. CCTV monitoring application

7. Working of technology: The commercially available CCTV with DVR will record each activity of our hospital and maintain the footage with predefined timings. Usually the 8 port digital recording device are managed like:
   - Consulting room without examination room (with audio recordings)
   - Waiting room
   - Operation theater (to monitor staff activity and patient monitoring device view)
   - Recovery room camera to monitor patients vitals
   - Entry at hospital
   - Corridors
   - Sonography output (available in all machines)
   - Endoscopy camera output.

   With this basic requirement will cost you not more than one lac rupees and it will give you excellent management at your fingertips with your basic smart phones.
8. The CCTV and digital video recorder (DVR) will record each and every activity of your hospital and the violent people will afraid of doing any mischief's at your premises. We can apply a board depicting that the "you are under CCTV surveillance". Simultaneously we can record the endoscopic surgeries and we can analyze the video after the completion of surgery for future reference and to improve our technique. There are footages of ultrasound also to take videos and photographs for academic purpose and useful during the Pre-natal Diagnostic Techniques (PNDT) raids to prove our self-innocent. If any violence occurs at hospital premises, the video footages are always available for court proceedings as strong evidence against the individuals. The CCTV –DVR can be connected by internet so our

vigilance to our hospital premises are on finger tips with smartphones.



Flowchart 1: For the ideal software

9. Software: Softwares are the heart of the digital data management system. Choosing the right software is very much important because it will remain for whole life of the health care institute.
10. Very important laws related with digitalization IT ACT 2000.
    - An Act to provide legal recognition for transactions carried out by means of electronic data interchange and other means of electronic communication, commonly referred to as "electronic commerce," which involve the use of alternative to paper-based methods of communication and storage of information to facilitate electronic filing of documents with the government agencies and further to amend the Indian Penal Code, the India Evidence Act, 1872, the Banker's Books Evidence Act, 1891 and the Reserve Bank of India Act, 1934 and for matters connected therewith or incidental thereto
    - "Data" means a representation of information, knowledge, facts, concepts or instruction which are being prepared or have been prepared in a formalized manner, and is intended to be processed, is being processed or has been processed in a computer system or computer network, and may be in any form (including computer printouts magnetic or optical storage media, punched cards, punched tapes) or stored internally in the memory of the computer
    - Authentication of electronic records:
        - Subject to the provisions of this section, any subscriber may authenticate an electronic record by affixing his digital signature
        - The authentication of the electronic record shall be effected by the use of asymmetric crypto system and hash function which envelop and transform the initial electronic record into another authenticated tamper proof electronic record
        - Any person by the use of a public key of the subscriber can verify the electronic record
        - The private key and the public key are unique to the subscriber and constitute a functioning key pair
    - "Digital signature" means authentication of any electronic record by a subscriber by means of an electronic method or procedure in accordance with the provisions of section 3. There are government recognized firms to issue digital signature to individuals. These digital signatures are of various types and can be used to authenticate any electronic documents
    - "Electronic signature certificate" means an electronic signature certificate issued under section 35 and includes digital signature certificate
    - Legal recognition of 1 [electronic signatures]: Where any law provides that information or any other matter shall be authenticated by affixing the signature or any document shall be signed or bear the signature of any person, then, notwithstanding anything contained in such law, such requirement shall be deemed to have been satisfied, if such information or matter is authenticated by means of 1 [electronic signature] affixed in such manner as may be prescribed by the central government
    - Legal recognition of electronic records: Where any law provides that information or any other matter shall be in writing or in the typewritten or printed form, then, notwithstanding anything contained in such law, such requirement shall be deemed to have been satisfied if such information or matter is, (a) rendered or made available in an electronic form; and (b) accessible so as to be usable for a subsequent reference
    - Use of electronic records and 1 [electronic signatures] in government and its agencies: (1) Where any law provides for, (a) the filing of any form, application or any other document with any office, authority, body or agency owned or controlled by the appropriate government in a particular manner; (b) the issue or grant of any license, permit, sanction or approval by whatever name called in a particular manner; (c) the receipt or payment of money in a particular manner, then, notwithstanding anything contained in any other law for the time being in force, such requirement shall be deemed to have been satisfied if such filing, issue, grant, receipt or payment, as the case may be, is effected by means of such electronic form as may be prescribed by the appropriate government

- Retention of electronic records: (1) Where any law provides that documents, records or information shall be retained for any specific period, then, that requirement shall be deemed to have been satisfied if such documents, records or information are retained in the electronic form, if: (a) the information contained therein remains accessible so as to be usable for a subsequent reference; (b) the electronic record is retained in the format in which it was originally generated, sent or received or in a format which can be demonstrated to represent accurately the information originally generated, sent or received; (c) the details which will facilitate the identification of the origin, destination, date, and time of dispatch or receipt of such electronic record are available in the electronic record
- Tampering with computer source documents.– Whoever knowingly or intentionally conceals, destroys or alters or intentionally or knowingly causes another to conceal, destroy, or alter any computer source code used for a computer, computer programme, computer system or computer network, when the computer source code is required to be kept or maintained by law for the time being in force, shall be punishable with imprisonment up to three years, or with fine which may extend up to two lakh rupees, or with both. Explanation. For the purposes of this section, "computer source code" means the listing of programmes, computer commands, design and layout and programme analysis of computer resource in any form
- Punishment for publishing or transmitting obscene material in electronic form. Whoever publishes or transmits or causes to be published or transmitted in the electronic form, any material which is lascivious or appeals to the prurient interest or if its effect is such as to tend to deprave and corrupt persons who are likely, having regard to all relevant circumstances, to read, see, or hear the matter contained or embodied in it, shall be punished on first conviction with imprisonment of either description for a term which may extend to three years and with fine which may extend to five lakh rupees and in the event of second or subsequent conviction with imprisonment of either description for a term which may extend to five years and also with fine which may extend to ten lakh rupees
- Pre-natal Diagnostic Techniques act 1996: Maintainance and preservatoins of record:
    - In case the genetic counseling center or genetic laboratory or genetic clinic maintains records on computer or other electronic equipment, a printed copy of the record shall be taken and preserved after authentication by a person responsible for such record.

  There is practically PNDT laws has accepted the use of digital data management system.

  The honorable Gujarat high court has given land mark judgement in 2006 in case of
    - It is observed that the doctors will make necessary efforts, say within a period of one year from now, to ensure that the duly filled in Form F is sent to the concerned health authority, both physically as also 'on-line'
    - However, while doing so, care should be taken that details, if any, which may fall under the category of 'privacy' of the patient concerned, are not disclosed while transferring the data 'on-line' but, at the same time, such details should, in any case, be reflected in the Form F, which shall be filled in physically.
    - The concerned department, in collaboration with other departments/agencies, shall work for developing a computer software, which would help in achieving the object of transferring the data pertaining to Form F online safely and speedily in future.

"The requirement of maintaining the records was itself an effective check against commission of other offences, according to the submission. *Per contra*, it was submitted that the provisions of sub-section (3) of section 4 were procedural and any lapse in maintaining the record could not be equated with substantive offences of contravention of the provisions of section 5 or 6. It was submitted that even a minor, formal, technical or accidental slip in filling the forms or keeping the record cannot be the basis of allegation of inaccuracy or deficiency and should not be allowed to expose the person conducting ultrasonography on a pregnant woman to prosecution for serious offences and cast upon him an impossible burden of proving all the ingredients of sections 5 and 6 of the act.

Another land mark judgement on 1212-10 of ahmedabad metropolitan court, "during the raid by appropriate authority of Ahmedabad city, he found that the Form F are maintained in computer and on demand all the required Form F were printed and submitted to raiding authority" the argument by appropriate authority under section 9/7 of PNDT law does not maintained for punishment.

CONCLUSION

The digitalization of hospital management system should be started. Initially, it is difficult to get habitual with key-board and mouse, but once started it would be helpful for flawless documentation of day to day activity of hospital. Digitalized records last long and are tamperproof, making them easily retrievable without much effort. The video recordings of rare and important cases can be saved for future references, teaching, and for self-improvement purposes. The clinical data can be fetched very easily from the digital records for the research activity and academic purpose. Digitalization shall further decrease the litigation and keep the goons away as the video surveillance evidence is valid in the court of law. In prenatal diagnostic technique cases, the Form F would be easily filled up by a few clicks and without any errors.

16

CHAPTER

Receptionist

SK Bhasin

Anger and it's elimination are triggered by face and behavior of the person in front of them. There comes the importance of receptionist in the hospital. With the increasing impatience, misbehavior, dissatisfication, hooglism by the patients and their attendants the role of person on the reception of the hospital has become more important. Receptionist itself can be cause of dissatisfaction of the person coming to the hospital because of much trivial mismanagement at the desk.

Receptionist must have following qualities to suite his or her worth for medical institution:

- Looks: The personality should be good, pleasant and should have a smiling face. Everybody likes this and definitely this helps receptionist to influence the visitor. Smart dressing and simple make up add to the personality of person on reception
- Memory: Sharp memory helps in completing tasks in satisfactory manner. Remembering the visitor and its purpose of visit gives good impression on them. It is also very necessary for receptionist to do her designated work such as appointments, messages, phone calls, instructions, referral, and many more
- Multitasking: She should be well versed with many tasks which may be expected of her at times. Many a times any other staff may not be available such as accountant, thus, she should be able to make and check bills of the patients. She should be good at computer
- Leadership: Receptionist must be able to delegate work to others and to lead in hour of demand so that efficieny is maintained. She should also be in good relations with other staff
- Concern: Receptionist must be concerned to the needs of visitor specially the patient. This the main point in the satisfaction of the patient and their attendants. Promptly asking the purpose of visit, attending the immediate need of patient, trying to make the things move. Consoling and communicating will win the heart of the person and patient
- Empathy: It should be there and visible in her deeds. All visitors are having problem and pain and thus, must be sympathetically handled. Just few kind words and promptness will have immense soothing effect. Unnecessary and unexplained delay will generate anger and dissatisfaction
- Cleanliness: Her desk should be matriculate. It helps in smooth working and is also liked by visitors. She must also take care of whole reception in regard to cleanliness
- Behavior: It is the most important part of any good receptionist. Good behavior will immensely increase the business of the hospital. It will reduce and remove almost all moments of anger. It will also help removing anger due to the act of any other staff. Good behavior will mask many dis qualities and misdeeds.

  There are many things which will count as good behavior of the receptionist such as:
  - Patience: Patient or their attendants are not supposed to have patience as they are worried and in problem. The same is not expected from receptionist. First she should without delay must listen to the visitor. Giving full attention and hearing the visitor to the end before answering or acting will be very effective. Impatience on part of receptionist is the beginning of dissatisfaction. There may be some unimportant or irritating things in their statement but receptionist must not counter them in between.
  - Politeness: It is the key to win the visitor specially in anger. Many a times, it should include “Sorry” even if there is no fault of her’s or the hospital’s. Do not try to prove the arguer wrong at the outset. Always, sir or madam should be for the visitor. It should be told to him that you are very important to hospital and hospital will take care of your problem very seriously. They should be told that the staff is there to help him or her and will leave no stone unturned in doing so.

- Promptness: Delaying irks in everybody at the reception and more so at the hospital as there is a person in agony. Delay might be genuine but even then it is to be promptly explained to the visitor. Attending the person at his or her arrival is utmost important for receptionist. A healing statement and first-aid for a patient in pain is very much required. No delay is condonable. Asking ward staff and doctor to see the new entrant is first job expected from receptionist. Paper work or depositing of money should not be made as excuse in the way.
- Assurance: Offering reassurance to patient and attendants is must and very much needed from the receptionist. It is more effective than the whole complicated and exhaustive treatment to follow. It may be needed to assure again and should be done repeatedly.
- Keeping promise: Receptionist have to make many a time promises to the patients attendants or visiting doctors etc. It is important to remember what has been promised and for that has to be penned down. Anybody would be disappointed on the unfulfillment of the promise.
- Phone: Please note that more than 80% of the calls at hospital reception turn out to be for business of hospital. Good handling is very important and it includes, prompt phone pick up on 2nd or 3rd ring, no long hold ups, no light background talks or disturbances, no jokes among staff, noting every call, sympathetic and correct answer, call back if promised, patient hearing, offering regretted sorry and thanks when required, greeting with pleasantries, saying sir or madam, correct transfer of call, no argument, prompt appointment etc. It is the most common way of communication and the receptionist should be perfect in it.
- Calling specialist: Since, many hospitals treat many types of patients they require to call various specialists on-call. It is very important to be respectful, coutious and punctual in it. There is no scope of forgetting or not communicating the message to patient attendants and doctor in charge. It is also the duty of receptionist to call again, remind, and tell attendant the current situation.
- Calling part-time workers: Plumber, electrician, etc. are very much needed and so in urgency. Receptionist must take full responsibility as serious issues may occur out of ignorance.
- Admission and discharge: In many hospitals this responsibility is given to the receptionist. Delay in both gives rise to anger thus, must be executed on preference, specially the admission.
- Tackling complaint: This is a tough and clever job and will determine the outstanding receptionist. Key to it is patient hearing and prompt action to get complaint redressed. Irate attendant or patient may be abusive but receptionist must not be excited or angry. Many will later appreciate and apologize also. Getting into argument will certainly deteriorate the situation. Keep in mind that dissatisfied patient will tell to 11 other individuals and satisfied will tell to only 4. Therefore, more importance and time should be given to complaints.
- Overcharge: This is the most common cause of problems and anguish. It should be given in detail and in writing. Same responsibility is required in taking of charge also. Nothing should be taken for granted and should be made understood, properly.

Please note that RECEPTIONIST is more important than any other staff of the hospital and even doctors. Therefore, invest in it and do not hesitate to give handsome salary to get handsome receptionist. As this investment could give much higher dividends.

17

CHAPTER

Quick Response Team: A Necessity in Indian Healthcare

Sushil K Sinha

INTRODUCTION

"Doctor" is a person who is trained and licensed to treat sick and injured people. They were considered the most dedicated personnel with the utmost feeling of "caring and healing" the sick, hence they were given the highest respect in society and were considered the "next god on earth."

With the urbanization and changes in society, the respect of doctors or clinician has drastically decreased and now in the 21st century, outburst and the mob violence against the hospital is increasing globally after the unsatisfaction or death of the patient.

Almost, 75% of the national healthcare is being managed by the private hospital and nursing homes which are the most susceptible to such mob violence's after incidence of unsatisfaction or death of patient. These small hospital/nursing homes are usually run by single/couple doctor family with limited personal security systems for the doctors and staff members. Many incidences of mob voilences are occurring daily all over the country and usually the police or the local persons remain the silent spectators in such incidence. Around 75% Indian doctors face violence as per Indian Medical Association reports.

The main causes of increasing violence against doctors and hospital are:

- More demanding society
- More availability of knowledge
- More aggression in society
- Increased expectation form doctors expecting for some medical miracle
- Incase of large outstanding bills.

Tips for hospital workers in case of impending violence:

- Watch for signals like anger, frustration or body language such as threatening gestures
- Signs of drug or alcohol intoxications in attendants
- Presence of weapons
- Evaluate the situation for potential violence
- Be vigilant throughout the encounter and try to interact along with your staff
- Always keep an open path for exiting.

Incase the situation cannot be defused then:

- Remove yourself from the situation
- Call security for help
- Call the police with the permission of management
- Call the quick response team (QRT).

WORKING FORMULA FOR THE QUICK RESPONSE TEAM

- Make a group of minimum of 20 hospital or nursing home in a radius of 10 kilometers to form a QRT group security service and engage a good security agency for the services
- Get the QRT approved/informed to the inspector general/senior superintendent of police through your local medical association
- Appoint a security manager who will be posted at one of the group nursing home with proper walky talkie device
- Each shift of group security consist of 3 gunman, 3 bouncers, 1 driver with the bolero jeep which will do the regular patrolling of every hospital daily on 8 hourly shift basis
- Daily patrolling of every hospital with ½ hours flag march in hospital starting from reception to intensive care unit
- In case of emergency, the QRT reaches the affected hospital with in 15 minutes.

DUTY OF THE QUICK RESPONSE TEAM

- To protect and escort doctors/medical staff form vandalizing mob
- To liaison with the local police and administration
- To prevent violence by explaining to the attendants amicably
- To advice security lapses to hospital administration.

Stay united to save our race; Save the doctors to save the patient.

18

CHAPTER

FOGSI, Fogsian, and Fogsianism

Rohit Bhatt, Narendra Malhotra

INTRODUCTION

Every institution or organization has a code of conduct for its members. The prestige and reputation of the organization depends on the conduct and behavior of their members. Therefore, it is very necessary for its members to uphold the dignity and decorum of the organization they represent. FOGSI is no exception. Though obstetric and a gynecological societies had their first meeting in 1936, it has its present status as Federation of Obstetric and Gynecological Society of India from 1950. One of the doctor's (RVB) is associated with FOGSI almost since its inception. The author has seen it grow from a federation of five societies and more than 1,000 members in to the federation of more than 230 societies and above 34,000 members. FOGSI has emerged as a powerful academic body wedded to women health.

Evolution of FOGSI is well depicted in the write up of Nozer Sheriar and Suchitra Pandit. Our pioneers like Shirodkar, Subodh Mitra, Krishna Menon, Kesarnath Das, Jhirad, Purandare brothers and many others have put India in the world map. Chandrakant Saraiya is our first centenarian-living legend (now deceased).

The Contribution of FOGSI in International Events is as follows:

- Three International Federation of Gynecology and Obstetrics presidents. (BN Purandare, Shirish Sheth, CN Purandare)
- Four The Asia and Oceania Federation of Obstetrics & Gynaecology (AOFOG) Presidents presidents (Subodh Mitra, RD Pandit, Dk Tank, Joseph Kurian)
- One International Association of Gynecological EndoscopistsPresident. Nargesh Motashaw
- One Asia-Pacific Initiative on Reproduction president. Jaideep Malhotra
- One International Society of Gynaecological Endoscopy president. Prashant Mangeshkar
- One vice-president. World Association of Perinatal Medicine. DR.Narendra Malhotra
- Two South Asian Federation of Obstetrics and Gynaecology presidents. DK Tank, Alokendu Chatterjee
- One AOFOG vice president Rohit Bhatt
- Magsaysay award to Banoo Coyaji
- Several of our members are the recipients of BC Roy award
- Several members have worked as consultants to international organizations like the World Health Organisation, population council etc.
- Several of our members have edited international textbooks text books
- Several members have written books which are sold not only in India but overseas.

All these achievements prove that FOGSI has emerged as a powerful academic body. We are proud of our achievements. Question may be asked what about developing FOGSI culture? What is FOGSIANISM?

The author would like to stress that membership of FOGSI and FOGSIAN are two different things. One can be a FOGSI member by paying regular fees. But one can be a true FOGSIAN only when inculcates FOGSIAN culture (FOGSIANISM)

WHAT IS FOGSIANISM?

Mahatma Gandhi's favorite song "vaishanav jan to tene re kahia" (qualities of a true noble man). The bhajan summarizes the qualities of a god's men. Similarly, we need to devise guide lines for a true FOGSIAN. Large majority of our members are well disciplined and authority loving. Unfortunately, some of the members do not observe dignity and decorum of our organization.

WHO IS A GOOD FOGSIAN?

The following qualities make a good FOGSIAN

- Who gives 10% of income for poor
- Who gives 10% of time to give free medical help

- Who shows respect and compassion for patients
- Who has ethical practice
- Who does not involve in mal-practice
- Who does not support and do sex determination tests
- Who spends time for communicating with the patient/relatives
- Who maintains cordial relations with other FOGSI members and does not pull down fellow colleagues

HOW A GOOD FOGSIAN SHOULD BEHAVE IN CONFERENCES?

We have four types of people attending the conferences:

- Scholars—who sit sincerely in the hall and attend all scientific sessions
- Stal(I) warts—who go around only in stalls in conference venue
- Outstanding people—they never enter the hall but spend full time in sight seeing
- Spirituals—who wait for evening spirit sessions.

It is often seen that several members coming for spot registration put organizers in difficulty. Some members share food plate with children and spouse. Some spend time in collecting bags and freebees. Some bring children in lecture hall disturbing the audience.

CHARACTERISTICS OF A GOOD FOGSIAN

- Who does not resort to spot registration giving hard times to the organizers? Believes in timely registration which helps organizers
- Who does not bring children in scientific hall disturbing the audience
- Who does not use cell phones during scientific meetings
- Who does not fill the plate with food which he/she is not able to eat and throw in the garbage wasting food
- Who does not share food plate with spouse/children to save money
- Who does not collect only freebees and bags during the conference
- Who does not consider conference only for picnic or holiday with family
- Who sticks to the time limit
- Who respects the chair when told to stop
- Who does not accept registration, travel and accommodation expenses from pharma companies.

FOGSIANS may appear harsh but it is necessary to ensure discipline and help in developing true FOGSIAN Culture

HOW GOOD FOGSIAN SHOULD BEHAVE AS A SPEAKER/CHAIRMAN?

We find most of our speakers observe discipline while giving a talk. But there are some who do not observe the time limit and drag on the talk beyond the permissible time. There are others who accept invitation to be a speaker/chairman and then remain absent at the last moment giving problems to the organizers. We have visited and participated in many international conferences and we find speakers are punctual and time conscious. Good FOGSONIAN is one who does not back out at the last minute putting organizers in difficulty. We need to learn brevity and punctuality from our western colleagues.

SUGGESTED READING

1. Know Your Peers. Editor Rohit Bhatt. Publisher. Medical communication Network. 2014.

APPENDIX 1 FOGSI Social Security Scheme

Jaydeep D Tank, Chandrakant B Narsinghpura

Social Security Scheme

of

The Federation of Obstetric & Gynaecological Societies of India

C-5,6,7,9,12,13, 1st Floor, D-Wing Entrance, Trade World, Kamala City,
Senapati Bapat Marg, Lower Parel West, Mumbai 400013. Maharashtra, India
Tel : +91-022-24951648, 24951654, 24918032
Email : fogsischemes@gmail.com Website : www.fogsi.org

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Member
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Email : krisim007@gmail.com

To,
All Members of
FOGSI

Sub : FOGSI – Social Security Scheme.

Dear Members,

We are glad to inform you that FOGSI has launched a Social Security Scheme (SSS) for its members.

The important feature of this scheme is that each member contributes Rs.100/- for every unfortunate death of the fellow member. On submission of Death Certificate by the nominee to the FOGSI Office, the office will dispatch the cheque to the nominee within 15 days without asking the cause of death. This money will be of great use to the nominee to complete the formalities / rituals after the unfortunate's demise of their beloved.

The fraternity amount will be directly proportional to the strength of SSS Membership. More the members, larger the amount will be available to the nominee.

Thus we request all the FOGSI members to join the scheme, so that a handsome amount is gifted to the nominee upon their sad demise. If you are already a member than motivate others to join the scheme.

With regards,

Thanking you,

Yours sincerely,

Dr.Jaydeep Tank
Secretary General
FOGSI

Encl : Application form + Details.

The Federation of Obstetric & Gynaecological Societies of India
C-5,6,7,12,13, 1st Floor, D-Wing Entrance, Trade World, Kamala City,
Senapati Bapat Marg, Lower Parel West, Mumbai 400013. Maharashtra, India
*Tel : +91-022-24951648, 24951654
*Email : fogsischemes@gmail.com *Website : www.fogsi.org

Membership Form
FOGSI – Social Security Scheme

Personal Details :-

Name : _____

Age : _____ Date of Birth : _____ Sex : _____

Address: _____

_____

City : _____ Pincode : _____ State : _____

Contact Numbers : _____ Email : _____

Name of the Parent Society : _____

Life Member : Yes / No Duration of Membership : _____ years

Nomination Details : -

Name of the Nominee : _____ Relationship : _____
(Full name)

Alternate Nominee : _____ Relationship : _____
(Full name)

Membership Contribution :-

Admission Fees(As recommended): Rs._____ *(Please attached age proof).*
Membership Fee : Rs.100/-
Advance Fraternity Contribution : Rs.1,500/-

Total Amount Paid : Rs. _____ by Cheque / Demand Draft No._____

dated _____ Bank : _____

Signature of Applicant

To be filled by the Member Society (Certificate by the Member Society)

This is to Certify that Dr._____ is a continuous active Member of the Society for the last _____ years.

Seal of the Society

Signature of the President / Secretary

For Office Use Only

FOGSI Membership No. : _____ Application No._____

Recipt No. _____ dated _____

Office Superintendent **Treasurer**

P.T.O.

FOGSI – Social Security Scheme : Salient Features

Membership Criteria

1. Life / Ordinary member of a constituent society of FOGSI for not less than three consecutive years at the time of joining this scheme.
2. Membership of this scheme shall be subject to continuously being an active member of FOGSI, throughout the duration of membership of the FOGSI Social Security Scheme.
3. This must be accompanied by an endorsement by the President / Secretary of the member society to which the applicant belongs.

Age Criteria

1. The age will be considered as age in completed years on the date of encashment of the draft / cheque received.
2. Proof of age must be attached with application.

Admission Fee

Age	Rate
At or below 30 years	Rs.1,000/-
Between 31 and 40 years	Rs.2,000/-
Between 41 and 50 years	Rs.3,000/-
Between 51 and 60 years	Rs.5,000/-
Above 60 years	Rs.10,000/-

Membership Fee

Every member of this scheme shall pay Rs.100/- as membership fees. The membership fee is non-refundable.

Advance Fraternity Contribution

Every member has to pay initially Rs.1,500/- as A.F.C. along with the admission fee and membership fee, which will be adjusted as Rs.100/- (Death Fraternity Contribution) per death of member during the year.

Fraternity Benefit

1. Benefit of fraternity contribution of the scheme is available to nominees of scheme members after completion of two years of membership of FOGSI S.S.S. An exception is made to this clause in the first two years of this scheme.
2. If the death of a member occurs in an accident after joining the scheme, the nominee has to present the police file number and post mortem report.
3. On receipt of information from a nominee about the death of the member, his/her nominee shall be paid the fraternity contribution as per entitlement under this scheme and the balance if any lying in A.F.C. account of member.

Death Fraternity Contribution (D.F.C.)

1. Every member of the scheme shall contribute D.F.C. of Rs.100/- in the event of death of a member.
2. This amount shall be adjusted against the A.F.C. during the year.
3. Out of the above amount, Rs. 90/- shall be paid to the nominee of deceased member, with Rs. 10/- being retained by this scheme, for utilization for administrative expenses and to bridge any problem shortfall in overall D.F.C. collection.

Mode of Payment

The payment is to be made by cheque / draft payable in Mumbai, drawn in favour of **"FOGSI–S.S.S."**.

Details about the Payment

Age	Admission Fee	Membership Fee	Advance Fraternity Contribution	Total Amount
At or below 30 years	Rs.1,000/-	Rs.100/-	Rs.1,500/-	Rs.2,600/-
31 and 40 years	Rs.2,000/-	Rs.100/-	Rs.1,500/-	Rs.3,600/-
41 and 50 years	Rs.3,000/-	Rs.100/-	Rs.1,500/-	Rs.4,600/-
51 and 60 years	Rs.5,000/-	Rs.100/-	Rs.1,500/-	Rs.6,600/-
Above 60 years	Rs.10,000/-	Rs.100/-	Rs.1,500/-	Rs.11,600/-

Every member of the scheme shall contribute D.F.C. of Rs.100/- in the event of death of a member.

** If a member furnishes any wrongful information in the application form or at any time during the membership term, the Managing Committee of this scheme shall have the right to terminate the membership of the member concerned without any benefit.*

FOGSI Social Security Scheme True Fellowship and Fraternity in Distress

When tragedy strikes, families can be lost and distressed particularly in a situation where the support or protection of organized social security is lacking as in our country. This is even more acute with professionals who have to look out for themselves.

The FOGSI Social Security Scheme (SSS) is a fellowship scheme that in the true sense engenders a spirit of fraternity and togetherness among our members by encouraging their participation in a common cause and creating a reliable financial and emotional safety net for their loved ones in case of tragedy.

The FOGSI SSS is the only national scheme for our specialty, specially formulated for the mutual benefit of the large family of FOGSI members. Financial support and solace in their time of need is available at a very short notice. It is your support to your colleague's family!!

FOGSI Indemnity Insurance Existing for your Protection by Safety in Numbers

There is no doubt that of all the medical specialties, our branch of obstetrics, gynecology, infertility management, and gynecological endoscopy is considered to be at the highest medicolegal risk, with anything less than an optimal outcome being considered unacceptable by our patients and their families.

It was to address specific concerns brought on by the currently charged medicolegal climate we now have to cope with as medical specialist professionals, that FOGSI devised and launched this tailor made scheme, which was made possible by negotiating with insurance companies as a national professional organization to protect member interests.

This policy offers coverage to all participating FOGSI members as well as the medical establishments owned by members. It can also club the standard policy with an errors and omission policy for medical establishments. An important feature is the in built coverage of unqualified staff. Recently we have increased the cover till around Rs 3 crores.

For further details

FOGSI, C-5,6,7,9,12,13, 1st Floor, D-Wing Entrance, Trade World, Kamala City, Senapati Bapat Marg, Lower Parel West, Mumbai 400013. Maharashtra, India

Contact Numbers : (022)24951648 / 24951654 / 24918032

Email : fogsischemes@gmail.com Website : www.fogsi.org

APPENDIX 2 FOGSI Indeminity Scheme

Jaydeep D Tank, Chandrakant B Narsinghpura

The Federation of Obstetric & Gynaecological Societies of India
C-5,6,7,9,12,13, 1st Floor, D-Wing Entrance, Trade World, Kamala City,
Senapati Bapat Marg, Lower Parel West, Mumbai 400013. Maharashtra, India
Tel : +91-022-24951648, 24951654, 24918032
Email : fogsischemes@gmail.com Website : www.fogsi.org

Dear Colleagues,

Re: FOGSI-Indemnity Policy : Own Establishments Covered For Ob-Gyn. Practice & Procedures , Not For Other Faculties.

FOGSI has evolved a dedicated Medical Indemnity Policy prolonged negotiation with Insurance Companies to protect and defend our members and their hospitals against litigation's. It has always been a difficult task dealing with day to day practice and worry about litigation most of the times frivolous, taking valuable time in legal advice and courts. FOGSI decided to take this on and share your responsibility with policy and we hope all of you will avail of this facility.

The salient features of the policy are:

a. As soon as you are served a notice you have to forward it to FOGSI office along with case papers. FOGSI will then forward it to the Insurance Company.

b. Committee of seven people comprising of three from FOGSI, one solicitor and three from Insurance Company will decide how to deal with it and the best of lawyers appointed by Committee will represent you at your court with medical support from Zonal Committee of FOGSI. The Committee can also decide whether to contest or settle the claim.

c. All litigation including criminal will be dealt with. If a member is found criminally guilty and liable for a fine, then the fine alongwith the legal bill will have to paid by the member. If not found guilty criminally all the expenses will be borne by the Insurance Company.

d. The polices are designed for **20 lacs, 40 lacs, 60 lacs, 80 Lacs, 1 Crore, 2 Crores and 3 Crores** cover. You can choose whichever as per your needs.

e. There are various categories of policy:
   1. Individual FOGSI members operating at different hospitals.
   2. Resident doctors.
   3. Individual FOGSI members working in **their own hospitals** along with Hospital Indemnity covers.
   4. Individual FOGSI members **who render Medical Services in other hospital plus own hospital** indemnity for 10, 20, 30, 40 beds.

THE IMPORTANT FEATURES OF THIS POLICY IS THAT UNLIKE IN THE PAST THIS POLICY WILL COVER ALL YOUR UNTRAINED STAFF UNDER YOU.

f. Your **Cheque /Demand Draft will have to be paid to "FOGSI – Indemnity"** alongwith the form marking which category you are opting for.
   1. The policy will then be sent to you by the Insurance Company.
   2. **THIS IS AVAILABLE ONLY TO FOGSI MEMBERS.**
   3. All queries and correspondence regarding this be addressed to FOGSI Office or to Mr.Chandrakant Narsingpura.

AN OPPORTUNITY HAS ALSO BEEN NEGOTIATED FOR BACK DATING PROTECTION FOR 3 YEARS FOR THOSE WHO ARE ALREADY INSURED. THIS RETORACTIVE PROTECTION IS AVAILABLE WITH A PAYMENT OF JUST 30% LOADING AMOUNT ONCE.

I hope this will take care of the long required need of our members.

Hoping for an early response.

Thanking you,

With warm regards,

Yours Sincerely,

Dr.Jaydeep Tank
Secretary General, FOGSI

PLEASE SEND YOUR DEMAND DRAFT IN FAVOUR OF **"FOGSI INDEMNITY"** PAYABLE AT MUMBAI OR LOCAL MUMBAI CHEQUES.

P.T.O.

Limits of FOGSI – Indemnity Policy
(FOR OBST & GYN PRACTICE & PROCEDURES ONLY)

Premium Sheet for Different Categories of Doctors

Categories of Doctors ↓		Limits of Indemnity: Rs.20 Lacs anyone year (multiple incidents aggregating to 20 Lacs) Rs.20 Lacs incident	Rs.40 Lacs anyone year (multiple incidents aggregating to 40 Lacs) Rs.40 Lacs incident	Rs.60 Lacs anyone year (multiple incidents aggregating to 60 Lacs) Rs.60 Lacs incident	Rs.80 Lacs anyone year (multiple incidents aggregating to 80 Lacs) Rs.80 Lacs incident	Rs.1 Crore anyone year (multiple incidents aggregating to 1 Crore) Rs.1 Crore incident	Rs.2 Crore anyone year (multiple incidents aggregating to 2 Crore) Rs.2 Crore incident	Rs.3 Crore anyone year (multiple incidents aggregating to 3 Crore) Rs.3 Crore incident
		Total Premium	Total Premium	Total Premium	Total Premium	Total Premium	Total Premium	Total Premium
Individual Doctors [A] →		Category : A : Rs.3,776/-	Category : A1 : Rs.7,552/-	Category : A2 : Rs.11,328/-	Category : A3 : Rs.15,406/-	Category : A4 : Rs.19,258/-	Category : A5 Rs.38,515/-	Category : A6 Rs.57,773/-
Resident Doctors without any Private Practice / Consultancy [B] →		Category : B : Rs.944/-	Category : B1 : Rs.1,888/-	Category : B2 : Rs.2,832/-	Category : B3 : Rs.3,852/-	Category : B4 : Rs.4,814/-	Category : B5 Rs.9,629/-	Category : B6 Rs.14,443/-
Doctors who own Medical Establishment, do not Render Medical Service Elsewhere.								
Hospitals with beds upto (For Obst & Gyn practice & procedures) [C] →	10 Beds	Category : C1 : Rs.7,033/-	Category : C11 : Rs.13,122/-	Category : C21 : Rs.20,154/-	Category : C31 : Rs.26,768/-	Category : C41 : Rs.33,942/-	Category : C51 Rs.67,883/-	Category : C61 Rs.1,01,789/-
	20 Beds	Category : C2 : Rs.7,977/-	Category : C12 : Rs.14,066/-	Category : C22 : Rs.22,042/-	Category : C32 : Rs.28,694/-	Category : C42 : Rs.36,073/-	Category : C52 Rs.72,145/-	Category : C62 Rs.1,08,218/-
	30 Beds	Category : C3 : Rs.8,921/-	Category : C13 : Rs.15,010/-	Category : C23 : Rs.23,930/-	Category : C33 : Rs.30,620/-	Category : C43 : Rs.39,719/-	Category : C53 Rs.79,438/-	Category : C63 Rs.1,19,156/-
	40 Beds	Category : C4 : Rs.9,865/-	Category : C14 : Rs.15,954/-	Category : C24 : Rs.25,818/-	Category : C34 : Rs.32,546/-	Category : C44 : Rs.42,607/-	Category : C54 Rs.85,215/-	Category : C64 Rs.1,27,822/-
Doctors who own Medical Establishments, Render Medical Service in any other Hospitals also								
Hospitals with beds upto (For Obst & Gyn practice & procedures) [D] →	10 Beds	Category : D1 : Rs.10,809/-	Category : D11 : Rs.20,674/-	Category : D21 : Rs.31,482/-	Category : D31 : Rs.42,173/-	Category : D41 : Rs.53,199/-	Category : D51 Rs.1,06,398/-	Category : D61 Rs.1,59,597/-
	20 Beds	Category : D2 : Rs.11,753/-	Category : D12 : Rs.21,618/-	Category : D22 : Rs.33,370/-	Category : D32 : Rs.44,100/-	Category : D42 : Rs.56,088/-	Category : D52 Rs.1,12,176/-	Category : D62 Rs.1,68,263/-
	30 Beds	Category : D3 : Rs.12,697/-	Category : D13 : Rs.22,562/-	Category : D23 : Rs.35,258/-	Category : D33 : Rs.46,026/-	Category : D43 : Rs.58,976/-	Category : D53 Rs.1,17,953/-	Category : D63 Rs.1,76,929 /-
	40 Beds	Category : D4 : Rs.13,641/-	Category : D14 : Rs.23,506/-	Category : D24 : Rs.37,146/-	Category : D34 : Rs.47,952/-	Category : D44 : Rs.61,865/-	Category : D54 Rs.1,23,730/-	Category : D64 Rs.1,85,595/-

Payment : At par Cheque / Demand Draft in favour of **"FOGSI-Indemnity"**. It includes 18% GST.

Correspondence Address : FOGSI Office, C-5,6,7,12,13, 1st Floor, D-Wing Entrance, Trade World, Kamala City, Senapati Bapat Marg, Lower Parel, West, Mumbai 400013. Maharashtra

Contact Numbers : (022) 24951648 / 24951654 **Email Id :** fogsischemes@gmail.com

Note : Please send your Contact Numbers and Email ID.

युनाइटेड इंडिया इन्श्योरेन्स कंपनी लिमिटेड

डिवीजनल ऑफिस नं.४ वलकन इन्श्योरेन्स बिल्डींग १ला माला ७७वीर नरीमन रोड चर्चगेट मुंबई ४०००२० .

UNITED INDIA INSURANCE CO. LTD.

Divisional Office No.4,Vulcan Insurance Building,1st Floor, 77,Veer Nariman Road,Churchgate,Mumbai 400020.

Category

PROPOSAL FORM FOR DOCTORS AND MEDICAL PRACTITIONERS GYNAECS & OBSTETRICIANS

INDIVIDUAL DOCTORS

1. Name of the Doctor Member :

2. Address for Correspondence :

3. Email ID :

4. All Contact Numbers :

5. Name of the Affiliated Society :

6. Professional Qualification and the year of such Qualification :

7. Medical Registration Number :

8. Are you a member of any Medical Association / Council, if so, please state Name and Address of such Association / Council with Membership Number :

9. Are you resident doctor without any Private Practice or Consultancy ? :

10. Has any claim been made upon you or Legal Proceedings institute or likely to be instituted against you by patients in respect of your treatment etc. If so, please give details :

11. Have you been previously insured for the subject risk ? If so, please give full details :

12. Limit of Indemnity (liability) required (Please tick the option)
Any One year :
(Multiple incidents aggregating to Rs.3 Crores, Rs.2 Crores, Rs.1 Crore, Rs.80 Lacs, Rs.60 Lacs, Rs.40 Lacs and Rs.20 Lacs respectively as per option chosen)
OR
Any One Incident :

Rs.3 Crores	Rs.2 Crores	Rs.1 Crore
Rs.80 Lacs	Rs.60 Lacs	Rs.40 Lacs
Rs.20 Lacs		

I here declare that the above statement and particulars are true to the best of my knowledge and I have not suppressed or misrepresented any material facts and that at present time. I have no reason to anticipate any claim being brought against me for any negligent act, error or omission on my part and agree that this declaration shall be the basis of contract between me and the Insurer.
I also agree that the Indemnity under the insurance shall not be availed for claim arising out of acts of negligence error or omission or misconduct committed prior to commencement of this insurance.

Date :

Place : Signature of the Proposer

UNDERTAKING :
I hereby undertake to repay entire amount to UIIC (through FOGSI) which was paid by United India Insurance Co.Ltd., towards Defense Costs, etc. if there is a conviction against me on criminal charges.

Signature of the Proposer

Authorised Signatory of FOGSI

युनाइटेड इंडिया UNITED INDIA	**युनाइटेड इंडिया इन्श्योरेन्स कंपनी लिमिटेड** डिवीजनल ऑफिस नं.४, वलकन इन्श्योरेन्स बिल्डींग, १ला माला, ७७,वीर नरीमन रोड, चर्चगेट, मुंबई ४०००२०. **UNITED INDIA INSURANCE CO. LTD.** Divisional Office No.4,Vulcan Insurance Building,1st Floor, 77,Veer Nariman Road,Churchgate,Mumbai 400020.	Category

PROPOSAL FORM FOR OWN MEDICAL ESTABLISHMENTS ERRORS AND OMISSIONS INSURANCE

FOR OBST & GYN PRACTICE & PROCEDURES ONLY

1. Name of the Doctor Member :
2. Name of the Own Medical Establishment & Address :
2. Address for Correspondence :
3. Email ID :
4. All Contact Numbers :
5. Name of the Affiliated Society :
6. Year in which established & Registration Number of Own Hospital :
7. Names and Addresses of Owners. Directors / Partners :
   a)
   b)
   c)
8. Have you complied with all the statutory Rules / Regulations relating to your establishment :
9. Whether the Establishment is meant only for the Purpose of Gynaecological / Obstetric treatment ? If not please specify :
10. Please specify all the facilities available like X-Ray, Scanning, Pathology etc (For Information only) :
11. State number of beds maintained :
12. Please state the number of Unqualified Staff :
13. Give details of Radioative treatment facilities Specify materials used and precautions taken Further for such usage. :

P.T.O.

- 2 -

14. Details of any Claims lodged against the Proposer in the past on account of service rendered by Your Establishment :

15. Details of any event likely to give rise to a liability claims against you a Future date :

16. State Limit of Indemnity (liability) required (Please tick the option) Any One year :
(Multiple incidents aggregating to Rs.3 Crores, Rs.2 Crores, Rs.1 Crore, Rs.80 Lacs, Rs.60 Lacs, Rs.40 Lacs and Rs.20 Lacs respectively as per option chosen)
OR
Any One Incident :

Rs.3 Crores	Rs.2 Crores	Rs.1 Crore
Rs.80 Lacs	Rs.60 Lacs	Rs.40 Lacs
Rs.20 Lacs		

I here declare that the above statement and particulars are true to the best of my knowledge and I have not suppressed or misrepresented any material facts and that at present time. I have no reason to anticipate any claim being brought against me for any negligent act, error or omission on my part and against the company and agree that this declaration shall be the basis of contract between me and the Insurance company.
I also agree that the Indemnity under the insurance shall not be availed for claims arising out of acts of negligence, error or omission or misconduct committed prior to commencement of this insurance.
OR for claims other than Obst & Gyn practice & procedures.

Date :

Place : **Signature of the Proposer**

UNDERTAKING :
I hereby undertake to repay entire amount to UIIC (through FOGSI) which was paid by United India Insurance Co.Ltd., towards Defense Costs, etc. if in case there is a conviction against me on criminal charges.

Signature of the Proposer

Authorised Signatory of FOGSI

This is for members who have Indemnity Policy and want to transfer liability. This consent form has to be filled. You have to attach last 3 years indemnity policy with the proposal form and one time loading or 30% on the premium.

Consent Form

There in no prior on pending litigation and I have no knowledge of any situation which may give rise to a claim.

Name :_____

Address : _____

_____

_____

Contact Numbers : _____

Signature : _____

Date : _____

APPENDIX 3 Posters

RN Goel

PC PNDT ACT

By
Dr. R. N. Goel
Member, NIMC (National Inspection & Monitoring Committee)
President IFUMB (2016)
Secretary Agra Nursing Home Association
Treasurer AICOG 2016
Treasurer IMS
Mob. : 09837037354, E-mail : drngoel@gmail.com

Guidelines to follow PCPNDT Rules

Qualification
a sonologist or imaging specialist or **registered medical practitioner having Post Graduate degree or diploma** or six months training duly imparted in the manner prescribed in the "the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014;. **(Rules 3.(3)1a & b) GSR 13(E) dated 9th January 2014**

Registration
Display a copy of the Registration Certificate (Form B) at a conspicuous place at the US clinic **(Rules 6.(2))**
An enquiry including inspection at the premises of the Genetic Clinic, shall, be carried out only after due notice is Given to the applicant by the Appropriate Authority for initial registration only. **(Rule 6.4)**

Renewal of registration
Renewal of registration should be 30 days before the expiry, in "Form A" in duplicate. **(Rule8.1)**
Renewal Fee is half of fresh registration fee. **(Rule8.4)**
Failure to renew or to communicate rejection for renewal of registration within a period of ninety days from the date of receipt of application for renewal, the certificate of registration shall be deemed to have been renewed. **(Rule8.6)**

Maintenance and preservation of records:
***Genetic Clinic shall maintain a register showing, in serial order, the names and addresses of the women given Genetic counseling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their husbands or fathers and the date on which they first reported for such counselling, procedure or test. (Rule9.1)**
*** For Genetic Counselling Centre: Patient records shall be kept as specified in FORM-D (Rule9.2)**
***For Genetic Laboratory: Patient records shall be kept as specified in FORM-E (Rule9.3)**
***For Genetic/US Clinic Patient records shall be kept as specified in FORM-F (Rule9.4)**
***Every Genetic Clinic/Ultrasound Clinic shall send a complete report in respect of all pre-conception or pregnancy related procedures/ techniques/tests conducted by them in respect of each month by 5th day of the following month to the concerned Appropriate Authority even zero report. (Rule9.8)**

Procedure for search and seizure.-
***The Appropriate Authority or any officer authorized in this behalf may enter and search at all reasonable times** any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, **in the presence of two or more independent and respectable persons** for the purposes of Section 30.**(Rule 12.1)**
*They can check any document, record, register, book, pamphlet, advertisement or any other material object (Machine) found in the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic.**(Rule 12.2)**
*In the case of non-completion of search and seizure operation, the Appropriate Authority or the officer authorized in this behalf may make arrangement, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, for safe keeping, listing and removal of documents, records, book or any other material object to be seized, and to prevent any tampering with such documents, records, books or any other material object.**(Rule 12.5).**

Intimation of changes in employees, place or equipment
Every Genetic Clinic shall intimate every change (Addition/Removal) of employee, place, address and equipment installed, in advance by 30 days of such change and seeking reissuance of Certificate of Registration with the changes duly incorporated by the Appropriate Authority. New Registration not required (Rule 13) GSR 418 (E) dt 4.6.2012

Public Information.-
DISCLOSURE OF THE SEX OF FOETUS IS PROHIBITED UNDER LAW. Display this notice **BOTH in English AND Local language** prominently.**(Rule17.1)**
Keep and make available on request at least **ONE copy of the PCPNDT Act and Rules** to your clientele for perusal.**(Rule17.2)**

Code of Conduct
***Wear NAME TAG yourself and every employee working at the US Clinic. Write full name and designation under signatures. (Rule18-viii & ix)**
***Should not indulge in SEX DETERMINATION & FEMALE FETICIDE and do not commit any other act of professional misconduct. (Rule18-x & xi)**

Appeal
Appeal against charge sheet can be filed to DAC / SAC within 30 days and decision has to be taken within 90 days **(Rule19-1-3).**
Build pressure of the association for early release.

Some GOOD precautions that are NOT specifically mentioned in the PCPNDT Rules:
1. Prominently display the Ultrasonography Timings.
2. Get painted **'ULTRASOUND ROOM/CHAMBER' on the outside of the room** where the equipment is housed.
3. DO NOT let an unauthorized person use the machine. All NON-MBBS doctors are UNAUTHORIZED.
4. Make arrangements that records can be inspected in your absence even if the machine is locked for safety.

THE ASSISTED REPRODUCTIVE TECHNOLOGIES (REGULATION) RULES - 2010

MINISTRY OF HEALTH & FAMILY WELFARE GOVT. OF INDIA, NEW DELHI

INDIAN COUNCIL OF MEDICAL RESEARCH NEW DELHI

By
Dr. R. N. Goel

GUIDELINES

PART 1
1.1 Primary (Level 1) Infertility Clinics
1.2 Secondary (Level 2) Infertility Clinics
1.3 Tertiary (Level 3) Infertility Clinics

PART 2 MINIMUM REQUIREMENT REGARDING STAFF IN INFERTILITY CLINICS
2.1. Gynaecologist
2.2 Andrologist
2.3 Clinical Embryologist
2.4 Counsellor
2.5 Programme Co-ordinator / Director

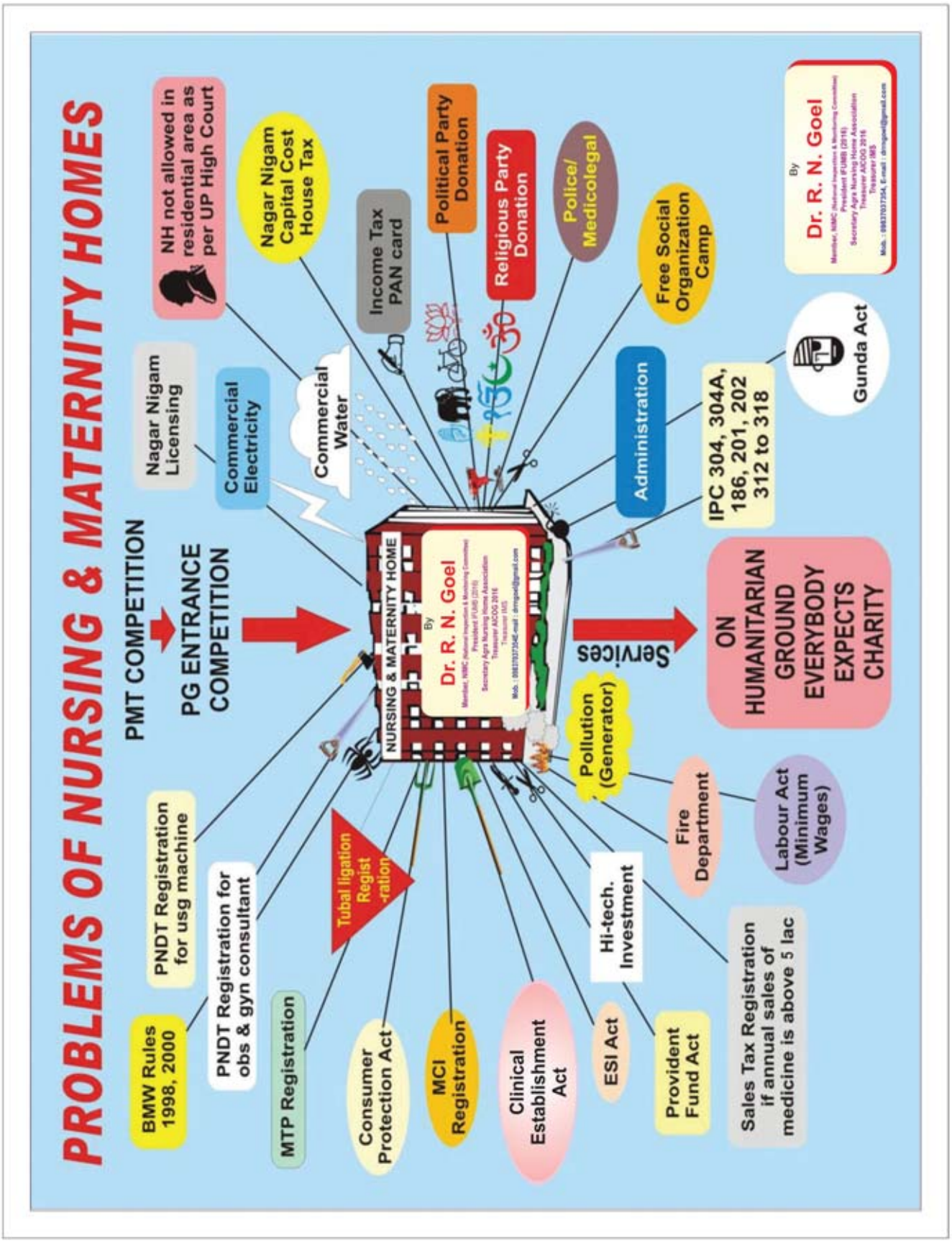
PART 3 MINIMAL PHYSICAL REQUIREMENTS FOR AN ART CLINIC
3.1 The non-sterile area
3.2. A reception and waiting room for patients
3.3 An examination room with privacy
3.4 A general-purpose clinical laboratory
3.5 Store room
3.6 Record room
3.7 Autoclave room
3.8 Steps for vermin proofing
3.9 Semen collection room
3.10 Semen processing laboratory
3.11 Clean room for IUI
3.12 The sterile area
3.13 The operation theatre
3.14 Room for embryo transfer
3.15 The embryology laboratory complex
3.16 Ancillary laboratory facilities
3.17 Hormone and other assays
3.18 Microbiology and histopathology
3.19 Maintenance of the laboratories
3.20 Quality of consumables used in the laboratory
3.21 Back-up power supply

PART 4 ASSISTED REPRODUCTIVE TECHNOLOGY (ART) PROCEDURES:
4.1 Artificial insemination with husband's semen (AIH)
4.2 Artificial insemination with donor semen (AID)
4.3. Intrauterine insemination with either husband's or donor semen (IUI-H or IUI-D)
4.4. In vitro fertilization and embryo transfer (IVF-ET)
4.5 IVF associated techniques
4.6 Intracytoplasmic sperm injection (ICSI) with ejaculated, epididymal or testicular spermatozoa
4.7 Oocyte donation (OD) or embryo donation (ED)
4.8 Cryopreservation
4.9 In vitro culture media

PART 5 PATIENT SELECTION
5.1 Husband
5.2 Wife
5.3 Patient selection for treatment in different infertility care units
5.4 Single defect in one of the partner
5.5 Multiple defects in one or both partners

PART 6 SELECTION CRITERIA FOR ART
6.1 Tubal disease
6.2 Endometriosis
6.3 Unexplained infertility
6.4 Immunological factor
6.5 Cervical factor
6.6 Male factor
6.7 Ovarian disorders
6.8 Uterine disorders
6.9 Use of donor oocytes and donor embryos
6.10 Selection criteria for gamete intra-fallopian transfer (GIFT)
6.11 Choosing between IVF-ET and GIFT
6.12 Micro-manipulation of gametes and embryos (SUZI and ICSI),AH and embryo biopsy
6.13 Complications

PART 7 INFORMATION AND COUNSELLING TO BE GIVEN TO PATIENTS
FORM A - Form of Application for Registration or Renewal of Registration of an Infertility/Art Clinic
FORM A1 - Form of Application for Registration or Renewal of Registration of an ART Bank
FORM A2 - Form of Application for Registration or Renewal of Registration of a Research Centre using Human Embryos
FORM B - Certificate of Registration
FORM C - Rejection of Application for Registration or Renewal of Registration
FORM D - Consent Form to be signed by the Couple for IVF and ICSI
FORM E - Consent for Artificial Insemination or Intrauterine Insemination with Husband's Semen / Sperm
FORM F - Consent for Artificial Insemination or Intrauterine Insemination with Donor Semen
FORM G - Consent for Freezing of Embryos
FORM H - Consent for the Surgical Extraction of Sperm
FORM I - Consent for Oocyte Retrieval / Embryo Transfer
FORM J - Agreement for Surrogacy
FORM K - Consent Form for the Donor of Oocytes
FORM L - Consent Form for the Donor of Sperm
FORM M - Information on Semen Donor
FORM M1 - Information on Oocytes Donor
FORM M2 - Information on Surrogate
FORM N - Results of screening of Semen Donors/Oocyte Donors /Surrogate Mothers
FORM O - Record of use of Donor Gametes and Surrogates
A. For Donor Semen
B. For Oocyte Donors
C. For Surrogate Mother
FORM P - Oocyte-Embryo Record
FORM Q - Semen Analysis Report
FORM R - Contract between the ART Bank and the Semen Donor
FORM R1 - Contract between the ART Bank and the Oocyte Donor
FORM R2 - Contract between the ART Bank and the Surrogate
FORM S - Contract between the ART Bank and the Patient
FORM T - Contract between the ART Bank and the ART Clinic
FORM U - Contract between the Patient and the Surrogate
FORM V - Oath of Secrecy


PROBLEMS OF NURSING & MATERNITY HOMES
PMT COMPETITION
PG ENTRANCE COMPETITION
NURSING & MATERNITY HOME
By
Dr. R. N. Goel
Services
ON HUMANITARIAN GROUND EVERYBODY EXPECTS CHARITY
BMW Rules 1998, 2000
PNDT Registration for usg machine
PNDT Registration for obs & gyn consultant
MTP Registration
Consumer Protection Act
MCI Registration
Clinical Establishment Act
ESI Act
Provident Fund Act
Sales Tax Registration if annual sales of medicine is above 5 lac
Tubal ligation Regist -ration
Hi-tech. Investment
Pollution (Generator)
Fire Department
Labour Act (Minimum Wages)
Nagar Nigam Licensing
Commercial Electricity
Commercial Water
Income Tax PAN card
Nagar Nigam Capital Cost House Tax
NH not allowed in residential area as per UP High Court
Political Party Donation
Religious Party Donation
Police/ Medicolegal
Administration
IPC 304, 304A, 186, 201, 202 312 to 318
Gunda Act
Free Social Organization Camp
By
Dr. R. N. Goel


BIOMEDICAL WASTE RULE 1998 AND AMMENDMENT 2000, 2011
कचरे को निर्धारित कूड़ेदान में ही डालें
By
Dr. R. N. Goel
ट्यूबिंग, कैथेटर, ग्लव्स, ब्लड बैग, प्लास्टिक की बोतलें, सूखी रुई, पट्टियाँ, आई. वी. ट्यूब और अन्य कोई भी दूषित प्लास्टिक सूक्ष्म जैव वैज्ञानिक व अन्य प्रयोगशालाओं का कचरा लाल रंग के डिब्बे में ही डालें।
मानव उत्तक व शरीर के कटे हुये भाग, प्लेसेन्टा, खून में सनी रुईयाँ, गन्दी पट्टियाँ एवं प्लास्टर कास्ट, मूत्र की थैली, खून या मवाद में सने कपड़ें, ब्लड सेट, लैब के बचे सैम्पल
CBWTF के द्वारा अधिकतम 48 घण्टे के अन्दर अस्पताली कचरा उठाना अनिवार्य है।
खाली दवाओं के वाइल्स, काँच की बोतलें, सावूत काँच (नीली बाल्टी में)
सुई, कनूला की निडिल (निडिल डिस्ट्रोयर में नष्ट करने के बाद) टूटा काँच, एम्प्यूल, ब्लेड, स्केलपल आदि (सफेद/ नीले पंचरप्रूफ कन्टेनर में)
कागज व गत्ते, सब्जी व फलों के छिलके या टुकड़े, कीटाणुनाशक व जीवाणु-नाशक, रद्दी कागज, अपशिष्ट पदार्थ एवं अन्य साधारण कचरा
इन्सीनरेटर/CBWTF द्वारा निस्तारण
नगर निगम द्वारा निस्तारण
तरल कचरा
खून, पेशाब, मवाद, लैब के सैम्पल आदि लैटरिन में डालें। लैटरिन को रोज अच्छी तरह से धोऐं।
तरल कचरे को ड्रेन में विसर्जित करने से पूर्व एक प्रतिशत हाइपोक्लोराइट घोल (ब्लीचिंग पाउडर) के द्वारा विसंक्रमण सुनिश्चित करें।


BIO MEDICAL WASTE (MANAGEMENT & HANDLING)
Rule 1998 & Amendment 2000
Through Central Pollution Control Board & State Pollution Control Board (Prescribed Authority)
Authorization for three years including trial period of 1 year than subsequent Renewal for three year by a fee prescribed by state
Authorization for three years including trial period of 1 year than subsequent Renewal for three year by a fee prescribed by state
By
Dr. R. N. Goel
Member, NIMC (National Inspection & Monitoring Committee)
President IFUMB (2016)
Secretary Agra Nursing Home Association
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Treasurer IMS
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OCCUPIERS
Hospital, Nursing Home or Maternity Home, Clinic / Dispensary Pathology Lab./Blood Bank, any establishment generating BMW
Generation (Source)
Dressing Room,
Plaster Room,
Vaccination Room
Patient's Ward,
Patient's Room
OPD Laboratory
Emergency OT
Labour Room
ICU/ICCU/NICU
MTP Room
Blood Banks
Segregation
Schedule 1 : Categories of BMW
1. Human Anatomical Waste — Yellow Bag
2. Animal Waste — Yellow Bag
3. Microbiology & Biotechnology Waste — Red Bag
4. Waste Sharps — Puncture Proof Plastic container PPC
5. Discarded medicine & Cytotoxic Drug — Black Bag
6. Solid Waste contaminated with blood & body fluid — Red Bag
7. Solid Waste disposable item as catheter, tubing etc. — Red Bag
8. Liquid Waste — Chemical disinfection
9. Incinerator Ash — Land Filling
10. Chemical Waste — Black Bag
Reception
Infected dressings Placenta Human tissue Organ Body part Contaminated Cotton; gauge
Contaminated (PVC, PP etc) Soft plastic Blood bags IV Set/catheter Viggo, bottles Gloves/Syringe Resp. equipments
SHARP WASTE
SHARP WASTE
SIMPLE SOLID WASTE
STORAGE
NAGAR NIGAM
LIQUID BMW
LINEN
CHEMICAL TREATMENT
DRAIN
OPERATOR CBWTF
Collection from STORAGE
Transportation from STORAGE to CBWTF
Treatment
Colour coding and type of container for Disposal of BMW
(As per treatment option available at CBWTF as per MOEF rules)
1. Human Anatomical Waste
2. Animal Waste
Incinerator/ Deep Burial
3. Microbiology & Biotechnology Waste
6. Solid Waste contaminated with blood & body fluid
7. Solid Waste disposable item as catheter, tubing etc.
Autoclaving, Microwave, Shredding then recycling
4. Waste Sharps
Autoclaving, Chem. Treatment/ Microwave/ Shredding then recycling
8. Liquid Waste
10. Liquid Chemical Waste
CHEMICAL TREATMENT
DRAIN
5. Discarded medicine & Cytotoxic Drug
Incineration/ destruction
9. Incinerator Ash
10. Solid Chemical Waste
Destruction than secure land filling
DISPOSAL
SECURE LAND FILLING
RECYCLING

MEDICAL TERMINATION OF PREGNANCY ACT, 1971

(Amendment, 2002, Rules & Regulations, 2003)

DEFINITION OF MTP AN ACT TO PROVIDE FOR THE TERMINATION OF CERTAIN PREGNANCIES BY REGISTERED MEDICAL PRACTITIONERS

TERMINATION OF PREGNANCY 1. BY NATURE AS- A. IN EVITABLE ABORTION, B. MISSED ABORTION C. INCOMPLETE ABORTION D. PREMATURE DELIVERY, E. AT TERM DELIVERY DOES NOT COME UNDER MTP ACT

2. BY REGISTERED MEDICAL PRACTITIONERS IT WAS ILLEGAL BEFORE 1971. CERTAIN LIVE PREGNANCY UP TO 20 WEEKS CAN BE TERMINATED BY I. SURGERY OR II. MEDICINE BECOME LEGAL AFTER MTP ACT 1971

MEDICAL ABORTION

Early pregnancy up to 7 weeks using RU-486 with Misoprostol, the same may be prescribed by a Registered Medical Practitioner (RMP) as defined under clause (d) of section 2 of the Act and Section 4 of MTP Rules, at his clinic, provided such a Registered Medical Practitioner has access to a place approved under Section 4 of the MTP Act, 1971 read with MTP Amendment Act, 2002 and Rules 5 of the MTP Rules. For the purpose of access, the RMP should display a Certificate to this effect from the owner of the approved place.

INDICATION FOR MTP

(a) Danger to life of the pregnant woman.
(b) Grave injury to the physical & mental health of the pregnant woman.
(c) Pregnancy caused by rape.
(d) Substantial risk that if the child was born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.
(e) Failure of any contraceptive device or method.

REQUIRED QUALIFICATION OF DOCTORS

(a) In the case of a medical practitioner, *who was registered in a State Medical Register* immediately before the commencement of the Act, experience in the practice of gynecology and obstetrics for a period of not less than three years;
(b) Registered medical practitioner, *who is registered in a State Medical Register*:-
  (i) six months of house surgency in gynaecology and obstetrics; or
  (ii) experience at any hospital for a period of not less than one year in the practice of obstetrics and gynaecology ;
(c) MTP Training, if he has assisted a registered medical practitioner in the performance of twenty-five cases of medical termination of pregnancy of which at least five have been performed independently, in a hospital established or maintained or a training institute approved for this purpose by the government.
  (i) This training would enable the Registered Medical Practitioner (RMP) to do only 1st Trimester terminations (up to 12 weeks of gestation).
  (ii) For terminations up to twenty weeks the experience or training as prescribed under sub rules (a), (b) and (d) shall apply .
(d) In case of a medical practitioner who has been registered in a *State Medical Register* and who holds a post-graduate degree or diploma in gynaecology and obstetrics, the experience or training gained during the course of such degree or diploma.

APPROVAL OF A PLACE

(a) A hospital established or maintained by Government,
(b) A private set up i. e. A place for the time being approved for the purpose of this Act by Government or a ***District Level Committee***

Composition of District level Committee

(1) Chief Medical Officer....Chairman
(2) Gynaecologist/ Surgeon/ Anaesthetist
(3) Member of local medical profession,
(4) Non-governmental organization,
(5) Panchayati Raj Institution of the District.
Provided that one of the members of the Committee shall be a woman.

REQUIREMENT FOR APPROVAL OF A PLACE

(i) Safe and hygienic conditions (ii) Unless the following facilities are provided therein, namely: -

In case of first trimester, that is, up to 12 weeks of pregnancy:-

(a) A gynecology examination (b) Labor table,
(c) Resuscitation and sterilization equipment, (d) Drugs and parental fluid,
(e) Back up facilities for treatment of shock and facilities for transportation;

In case of second trimester, that is, up to 20 weeks of pregnancy:-

(a) an operation table and instruments for performing abdominal or gynecological surgery
(b) anesthetic equipment, resuscitation equipment and sterilization equipment
(c) drugs and parental fluids for emergency use

APPLICATION FOR THE APPROVAL OF A PLACE

FORM A
(See sub-rule (2) of rule 3)

Form of application for the approval of a place under clause (b) of section 4

Category of approved place:
A Pregnancy can be terminated up to 12 weeks.
B Pregnancy can be terminated up to 20 weeks

1. Name of the place (in capital letters)
2. Address in full
3. Non-Government/Private/Nursing Home/Other Institutions
4. State, if the following facilities are available at the place

Category A

i) Gynecological examination / labour table,
ii) Resuscitation equipment,
iii) Sterilization equipment,
iv) Facilities for treatment of shock, including emergency drugs;
v) Facilities for transportation, if required.

Category B

(i) an operation table and instruments for performing abdominal or gynecological surgery;
(ii) Drugs and parental fluid in sufficient supply for emergency cases;
(iii) Anesthetic equipment, resuscitation equipment and sterilization equipment.

Place :
Date :

Signature of the owner of the place

CERTIFICATE OF APPROVAL

FORM B
(See sub-rule (6) of rule 5)

Certificate of approval.

The place described below is hereby approved for the purpose of the Medical termination of Pregnancy Act, 1971 (34 of 1971).

AS READ WITHIN UPTO————WEEKS

Name of the Place

Address and other descriptions

Name of the owner

Place :
Date :

to the Government of the

CONSENT FORM

FORM C
(See rule 6)

I,
daughter/wife of _____ aged about _____ years of _____
(here state the permanent address)
at present residing at
do hereby give my consent to this termination of my pregnancy at
(State the name of place where the pregnancy is to be terminated)

Place :
Date :

Signature

(To be filled in by guardian where the woman is a mentally ill person or minor)
I,
son/daughter/wife of _____
aged about _____ years of _____ at present residing at (Permanent address)
do hereby give my consent to the termination of the pregnancy of my ward _____ who is a mental/minor at _____
(Place of termination of my pregnancy)

Place :
Date :

Signature

OPINION FORM

FORM I
[See Regulation 6(3)]

I,
(Name and qualifications of the Registered Medical practitioner in block letters)
(Full address of the Registered Medical practitioner)

I,
(Name and qualifications of the Registered Medical practitioner in block letters)
(Full address of the Registered Medical practitioner (thereby certify that "I/We partners of opinion, formed in good faith, that it is necessary to terminate the pregnancy of
(Full name of pregnant woman in block letters) resident of
(Full address of pregnant woman in block letters)
for the reasons given below*.
*I/We hereby give information that "I/We terminated the pregnancy of the woman referred to by me/us in the Intimation dated _____ in the Intimation Register of the hospital/nursing home/ place.

Signature of the Registered Medical Practitioner
Signature of the Registered Medical Practitioner

Place :
Date :

*Strike out whichever is not applicable.
** of the reasons specified items (i) to (v) write the one which is appropriate.

(i) In order to save the life of the pregnant woman,
(ii) In order to prevent grave injury to the physical and mental health of the pregnant woman;
(iii) In view of the substantial risk that if the child was born it would suffer from such physical or mental abnormalities as to be seriously handicapped;
(iv) as the pregnancy is alleged by pregnant woman to have been caused by rape,
(v) as the pregnancy has occurred as result of failure of any contraceptive device or methods used by married woman or her husband for the purpose of limiting the number of children. Account may be taken of the pregnant woman's actual or reasonably foreseeable environment in determining whether the continuance of her pregnancy would involve a grave injury to her physical or mental health.

Signature of the Registered Medical Practitioner

Place :
Date :

MONTHLY REPORT TO CMO

FORM II
[See Regulation 6(5)]

1. Name of the State
2. Name of the Hospital/approved place
3. Duration of pregnancy (give total No. only) :
   (a) Up to 12 weeks
   (b) Between 12 - 20 weeks
4. Religion of women
   (a) Hindu
   (b) Muslim
   (c) Christian
   (d) Others
   (e) Total
5. Termination with acceptance of contraception
   (a) Sterilization
   (b) I.U.D
6. Reasons for termination:
   (Give total number under each sub-head)
   (a) Danger to life of the pregnant woman,
   (b) Grave injury to the physical health of the pregnant woman
   (c) Grave injury to the mental health of the pregnant woman,
   (d) Pregnancy caused by rape,
   (e) Substantial risk that if the child was born, it would suffer from such physical or mental abnormalities as to be seriously handicapped,
   (f) Failure of any contraceptive device or method.

Signature of the Official in charge with Date

ADMISSION REGISTER

FORM III
(See Regulation 6)
ADMISSION REGISTER

(To be maintained on the expiry of five years from the date of the last entry to be Register)

1	2	3	4	5	6	7
S. No.	Date of Admission	Name of the Patient	Name, daughter of	Age	Religion	Address

8	9	10	11	12	13	14
Duration of Pregnancy	Reasons on which Pregnancy is terminated	Date of submission of Pregnancy	Date of discharge of patient	Result and Remarks	Name of Registered Medical Practitioner who terminated the pregnancy	Name of Registered Medical Practitioner who refused Pregnancy is terminated

By

Dr. R. N. Goel

Member, NMC (National Inspection & Monitoring Committee)
President IFUMB (2016)
Secretary Agra Nursing Home Association
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EXCLUSION

Rule 5 **(1) The provisions of section 4, and so much of the provisions of sub-section *(2)* of section 3 as relate to the length of the pregnancy and the opinion of not less than two registered medical practitioners, shall not apply to the termination of a pregnancy by a registered medical practitioner in a case where he is of opinion, formed in good faith, that he termination of such pregnancy is immediately necessary to save the life of the pregnant woman.**

PUNISHMENT

Rule 5 : (2) Notwithstanding anything contained in the Indian Penal Code (45 of 1860), the termination of a pregnancy by a person who is not a registered medical practitioner shall be an offence punishable under that Code, and that Code shall, to this extent, stand modified.
(3) Whoever terminates any pregnancy in a place other than that mentioned in section 4, shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years
(4) Any person being owner of a place which is not approved under clause (b) of section 4 shall be punishable with rigorous imprisonment for a term which shall not be less than two years but which may extend to seven years.

PROTECTION OF ACTION TAKEN IN GOOD FAITH

No suit or legal proceedings shall lie against any registered medical practitioner for any damage caused or likely to be caused by anything, which is in good faith done or intended to be done under this Act.

FOGSI FOCUS, 2018

Month	Monthly Theme	FOGSI FOCUS
January	Time for Radical Appraisal—Introspect and Execute	Endometriosis
February	Doctor Patient Relationship	Medicolegal Issues in Obstetrics and Gynecology Practice
March	Noncommunicable Diseases	
April	Labor, Delivery, and Safe Abortion	Surgical Skills
May	Law and Ethics	Multiple Pregnancy
June	Infertility	Infertility
July	Reducing CS Rates	Labor
August	Breast Feeding and Empowerment	Breast Diseases
September	Midlife	Midlife Management
October	Contraception and Adolescents	
November	Preventive Oncology	Preventive Oncology
December	STDs, Communicable Diseases	