1. **Background**

IMA has raised various issues such as the capping-off of the compensation for alleged medical negligence, assault on doctors, amendment in PC&PNDT Act and the Clinical Establishments Act. It has also put forth its demand that non-MBBS and non-BDS doctors may not be allowed to prescribe medicines under modern system of medicine. Consequent to the meeting of National President and Secretary General of IMA with Hon'ble Union Minister for Health & Family Welfare, a Committee was constituted under the chairmanship of Additional Secretary (Health), Union Ministry of Health and Family Welfare to examine the issues raised by Indian Medical Association (IMA). The constitution of the Committee is as under:-

i) Joint Secretary (dealing with the subject), Ministry of Health & Family Welfare;

ii) Joint Secretary, Ministry of Law & Justice;

iii) Joint Secretary, Department of Consumer Affairs;

iv) Joint Secretary, Ministry of Home Affairs;

v) A representative from MCI;

vi) A maximum of three representatives from IMA

2. As per the Terms of Reference, the Committee was to examine the following issues raised by the IMA and on the points impinging on these issues.

a. Frequent instances of assault on doctors and clinical establishments across the country and the need for a Central Legislation for providing protection to the same.

b. Urgent amendments in the PC & PNDT Act to ensure that strict penalties are imposed only on actual act of sex determination or female feticide and not for clerical errors in the maintenance of registers etc. The IMA is also of the view that registration should be of ultrasound machine and not of doctors not doing pelvic ultrasound.

c. Single doctor establishments should be exempted from the purview of the Clinical Establishments Act and the need for pre-registration inspection may not be there for those clinical establishments which already have entry level NABH accreditation and above.

d. Suitable amendments should be made in the Consumer Protection Act for capping the compensation amount as the current compensation practice, apart from being very high at times, was also tilted in favour of the persons with higher income.

e. The non-MBBS and non-BDS doctors should not be allowed to prescribe medicines under modern system and the other stream practitioners like AYUSH doctors etc. should not be allowed to practice though bridge courses and through government orders.
Secretary, M/o Home Affairs, Secretary, D/o Consumer Affairs, Secretary, M/o Law & Justice of the Government of India were requested to depute Joint Secretary level officers as Members of the Committee. Secretary, Medical Council of India (MCI) deputed a nominee to the committee. National President, Secretary General and past National President of IMA, were informed to be the part of the Committee and to attend the meetings as scheduled.

All the issues were discussed in detail and the stakeholders were asked to submit their comments. IMA also gave its comments. The comments of Medical Education Division, RCH Division and the Division dealing with Clinical Establishments Act, Drugs and Regulations in MoHFW inter-alia were also sought and considered. The comments from Ministry of Home Affairs, Department of Consumer Affairs and Ministry of Legal Affairs were also sought.

2. Discussions and Recommendations

The Committee examined all the submissions made by different stakeholders. It took all the comments and facts on record. On the basis of facts, records and submissions, the Committee decided to make the following recommendations:-

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<th>Sl. No.</th>
<th>Terms of Reference</th>
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<td>1.</td>
<td>Frequent instances of assault on doctors and Clinical Establishments across the country and the need for a Central Legislation for providing protection to the same.</td>
<td>The issue was discussed in detail in the meetings on 8/12/2015 and 5/1/2016. Thereafter, comments were also sought from different stakeholders. M/o Home Affairs commented that Indian Penal Code (IPC) is a general comprehensive code intended to cover all substantive aspects of criminal law and code; criminal procedure is the main legislation or procedure for administration of substantive criminal law in India irrespective of category of work etc. The IPC does not provide punishment for offences committed against any specific category of professionals. The offence which is otherwise covered in the IPC/Cr.PC committed against a doctor/clinical employee would automatically get covered under IPC/Cr.PC. IMA in its last submission indicated that States have enacted laws or issued ordinances to protect medical practitioners. Both Law &amp; Order and Health are State subjects and the conditions differ across the county on these matters. The provisions of IPC and Cr.PC are sufficient as far as the protection of property or life of any professional in India is concerned. The Committee maintained that essentially the enforcement of these provisions was most crucial.</td>
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Committee accordingly recommends as follows:

(i) Ministry of Health & Family Welfare will suggest to all State Governments which do not have a specific legislation to protect doctors/health professionals to consider enacting one.

(ii) Ministry of Health & Family Welfare will write to all State Governments to strictly enforce the provisions of special legislation wherever they exists and/or enforce the IPC/Cr.PC provisions with vigour.

2. Urgent amendments in the PC & PNDT Act to ensure that strict penalties are imposed only on actual act of sex determination or female feticide and not for clerical errors in the maintenance of registers etc. The IMA is also of the view that registration should be of ultrasound machine and not of doctors not doing pelvic ultrasound.

IMA’s suggestions regarding various provisions of PC & PNDT Act were discussed in detail. The comments of the concerned Divisions of the Ministry of Health & FW were also considered. The Committee recommends as follows:

(i) Ministry of Health & Family Welfare will consider methods of protecting bonafide clerical errors and also provide for graded punishments.

(ii) Ministry of Health & Family Welfare will examine the demand in relation to ensuring that these doctors not doing pelvic ultrasound are not subject to provisions of PC&PNDT Act, in view of the Delhi High Court Orders in this regard.

3. Single doctors’ establishments should be exempted from the purview of the Clinical Establishments Act and the need for pre-registration inspection may not be there for those clinical establishments which already have entry level NABH accreditation and above.

a. IMA also raised the demand of deletion of the City Police Commissioner/SSP/SP or his nominee from the District Registering Authority (DRA). IMA also wanted the inclusion of a representative each from the professional associations of modern system of medicines and AYUSH in DRA. These demands were discussed and comments were obtained from the relevant stakeholders.

The Committee recommends the suitable amendment in the Central Rules to reconstitute the District Registration Authority so as to delete the provision of membership of City police commissioner/SSP/SP or his nominee in the DRA and the inclusion of a representative
from the professional associations of modern medicine as well as AYUSH.

b. As regards the concerns of the Indian Medical Association about inclusion of single doctor establishments in the definition of clinical establishments, the Committee noted that minimum standards will need to be specified for and adhered to even by clinical establishments owned and operated by single doctors. However, such standards cannot be the same as for larger establishments. The Committee, therefore, recommends that the standards for single doctor establishments may be finalised by the National Council of Clinical Establishments after deliberations with all concerned including the Indian Medical Association.

c. The Committee noted that the Indian Medical Association does not have any objection to the registration of NABH accredited clinical establishments under the Clinical Establishments Act. However, the association is of the strong view that NABH accredited establishments may not be subjected to inspection. The Committee, after detailed deliberations, noted that in terms of Section 25 of the Act, clinical establishments are required to submit evidence of having complied with the prescribed minimum standards in a manner as may be prescribed. The Committee considers that the fact that a clinical establishment is NABH accredited, could be taken as an evidence of complying with the prescribed standards. Further, Section 33 (1) of the Act vests a discretion to cause an inspection or, or enquiry in respect of any registered clinical establishment, its buildings, etc. The Committee, therefore recommends that exercise of discretion in respect of clinical establishments with NABH accreditation need not be insisted upon in each case and the rules may be amended accordingly. As per Section 45 of the Act, if any clinical establishment is
registered under any other existing law requiring registration such as PC&PNDT Act, the clinical establishments are also required to apply for registration under the Clinical Establishments Act. While there can be no exemption from registration under the CEA, it is recommended that concerned Divisions of MoHFW can explore the possibilities of bringing in legislative changes for single window registration.

d. The Clinical Establishments Act provides for provisional and permanent registration. At the time of provisional registration, there is no inquiry or inspection. As per Section 14(4) of the Act existing clinical establishments can apply for permanent registration within a period of two years after notification of minimum standards. Thus, the clinical establishments have sufficient time to upgrade the facilities, if required, to meet the minimum standards. The registration, with the government increases consumers confidence and brand value of the clinical establishments. In so far as the penalty for non-registration is concerned, it is applicable to the one running the clinical establishment and not necessarily to a doctor as per Section 41(1). As far as penalty for running a clinical establishment without registration is concerned, Section 41(5) clearly stipulates that while determining the quantum of monetary penalty, the authority shall take into account the category, size and type of the clinical establishment and local condition of the area in which the establishment is situated.

e. The committee recommends that IMA may set up a Committee which would periodically suggest changes in the Standard Treatment Guidelines under the Clinical Establishments Act with justification. These suggestions would be examined by the Central Government in consultation with the other stakeholders viz. State Governments (health being a state subject) and Standard Treatment guidelines would be revised periodically.
whenever required.

f. The Committee recommends that the position of the Rule 9(2) of the Clinical Establishments Rules can be considered to be changed to the extent that Central Government should specify the list of procedures and costing templates while actual determination of the range of rates could be left to the State Governments who can take into consideration the relevant facts while deciding upon the range of rates for their respective States in consultation with relevant stake-holders including Indian Medical Association.

| 4. | Suitable amendments should be made in the Consumer Protection Act for capping the compensation amount as the current compensation practice, apart from being very high at times, was also tilted in favour of the persons with higher income. | The suggestions given by IMA were discussed and comments were also sought from different stakeholders. During the discussion it was felt that reasonable fee should be charged by the doctors, and accordingly the compensation should be reasonable. The IMA proposed that a formula mentioned in Rule 122(B) for Drugs and Cosmetics Rules may be used to ascertain the quantum of compensation. In case of medical negligence, the compensation is decided on the basis of Consumers Protection Act, which is under the Ministry of Consumers Affairs. Hence, any change would be carried out by them. The Committee recommends that that the proposal submitted by IMA will be forwarded to the Ministry of Consumer Affairs for an appropriate decision in the matter. |
| 5. | The non-MBBS and non-BDS doctors should not be allowed to prescribe medicines under modern system and the other stream practitioners like AYUSH doctors etc. orders. | The representatives of IMA stated that certain State Governments have allowed AYUSH doctors to prescribe certain allopathic drugs/medicines. Health is a State subject. As far as the existing legal position is concerned, as per IMC Act, only those who are in the IMC/SMC register can prescribe allopathic drugs/medicines. Further, as per section 2-C(l) of the Clinical Establishments Act, only clinical establishment of a recognised system of medicines can be registered. This Act also seeks to register and regulate the clinical establishments which have been set up and managed by the qualified professionals only. |