

The Under Secretary (Medical Services),
Department of Health and Family Welfare,
Ministry of Health and Family Welfare,
Govt. of India, Room No. 508, D-Wing,
Nirman Bhawan, New Delhi.-110011.
(sunil.kumar20@gov.in)

Subject: - **CLINICAL ESTABLISHMENT ACT, 2010- NOTIFICATION
DATED 5TH MAY, 2017-REGARDING.**

Sir,

This is with reference to Notification No. G.S.R. 441 (E) issued in the Gazette of India: Extraordinary on dated 5th May, 2017 regarding the subject captioned above.

I wish to submit my following objections and suggestions for the kind consideration of Ministry of Health and Family Welfare, Govt. of India, New Delhi.

1. That I have no objection as far as the Govt. of India has prescribed minimum standards for every Clinical Establishment offering services and facilities requiring diagnosis, treatment or care of illness, injury, etc. and with regard to infrastructure, maximum fee and charges, etc. under Rule 8 A in CEA Amended Rules, 2017 (herein after 'Amended Rules' in short) by virtue of powers conferred by section 52 of the Clinical Establishments (Registration and Regulation) Act, 2010 (herein after 'Act' in short).
2. That I have serious objection to draft Schedule proposed to be inserted after Rule 9 to CEA Rules, 2012 (herein after 'Rules' in short), which is illegal, unconstitutional, arbitrary and beyond jurisdiction and in violation of provisions of the Act including section 52 on the following grounds;

- i) **BECAUSE** the Ministry of Health and Family Welfare (herein after 'Ministry' in short) in active connivance with vested interest, inside and outside the Ministry, has been making self styled interpretation of various provisions of Act including section 52. The Ministry wish to suggest that the Act covers each and every establishment including Medical Laboratory Services in and outside a 'Clinical Establishment' where no patient is admitted, no diagnosis is made and no treatment is given or no care of illness is provided.
- ii) **BECAUSE** the futile and overreaching attempt to control and regulate Medical Laboratories by National Council for Clinical Establishment (herein after 'Council' in short) under the Act is a part of bigger conspiracy in continuity of attempts being made by medicos to capture the business and profession of Medical Laboratory Technologists/ Medical Laboratory Scientists under the garb of Indian Medical Council Act, 1956 and State Medical Council Act (s). The Hon'ble Supreme Court is already seized of the matter in Special Leave Petition (Civil) No. 28529 of 2010 titled Association of Self Employed Owners (Para Medical) of Private Pathology Laboratories of Gujarat vs North Gujarat Pathologist Assn. & Ors. **The Hon'ble Supreme Court has been pleased to implead Ministry of Health and Family Welfare, New Delhi and Medical Council of India as necessary parties suo moto vide Orders dated 9.8.2016.** Copy of Interim Orders dated 9.8.2016 is attached as **Annex A-1.**
- iii) **BECAUSE** the word '**Clinical**' in the Clinical Establishment Act, 2010 has been stretched beyond limits by '**Council**' to regulate and control the Allied Health Professionals by medical fraternity with mala fide and bad intentions and with extraneous reasons and consideration to capture business. The ill-move smacks foul play. It is important to know the true meaning of '**Clinical**' before I proceed further to expose

the mala fide and bad intentions by raising the veil, I reproduce the meaning / definition of word ‘ Clinical’ as given in WIKIPEDIA;

“**Clinical** may refer to:

- Clinical (or bedside) medical practice, based on observation and treatment of patients as opposed to theory or basic science.”

I reproduce the meaning / definition of word ‘ Clinical’ as given in OXFORD Living Dictionary;

“Relating to the observation and treatment of actual patients rather than theoretical or laboratory studies.”

I reproduce the meaning / definition of word ‘ Clinical’ as given in MERRIAM WEBSTER;

Definition of CLINICAL for English Language Learners

- : relating to or based on work done with real patients : of or relating to the medical treatment that is given to patients in hospitals, clinics, etc.
- : requiring treatment as a medical problem
- : of or relating to a place where medical treatment is given : of or relating to a clinic”

iv) **BECAUSE** firstly the Allied Health Professionals like Medical Laboratory Technologists / Medical Laboratory Scientists are not authorized and trained to make ‘clinical medical practice’. They neither admit patients, make diagnosis nor provide treatment or care for illness, therefore, no patient is admitted by them or under their control for medical treatment. Therefore, the

establishment of Medical Laboratory is not a 'Clinical Establishment' under the Act.

- v) **BECAUSE** the Medical Laboratory Technologists / Medical Laboratory Scientist are not para-medicals. The work of para-medicals is entirely different. The para-medicals perform pre-hospital emergency services to safely lift or carry immobile patients from homes or accidents sites to hospitals / clinics. The word '**para-medical**' has been defined as under;

“Dictionary Definition

paramedical adj : of or denoting a person who supplements physicians and nurses in their activities; "ambulance drivers are paramedical personnel" n : a person trained to assist medical professionals and to give emergency medical treatment [syn:[paramedic](#)]

Extensive Definition

A paramedic is a medical professional, usually a member of the [emergency medical service](#), who primarily provides [pre-hospital](#) advanced [medical](#) and [trauma](#) care. A paramedic is charged with providing emergent on-scene treatment, crisis intervention, life-saving stabilization and, when appropriate, transport of ill or injured patients to definitive emergency medical and surgical treatment facilities, such as a hospitals and trauma centers.

The use of the specific term paramedic varies by jurisdiction, and in some places is used to refer to any member of an ambulance crew. In countries such as the United States and the United Kingdom, the use of the word paramedic is restricted by law, and the person claiming the title must have passed a specific set of examinations and clinical placements, and hold a valid registration, certification, or license with a governing body. Even in countries where the law restricts the title, popular media has created a culture whereby lay persons may incorrectly refer to all emergency medical personnel as 'paramedics', even if they officially hold a different qualification, such as emergency medical technician-basic.

Places of work

Paramedics are employed by a variety of different organizations. Paramedic can be employed by government agencies as part of a public hospital system, as a separate municipal EMS service, or sometimes, especially in the United States, as part of a fire department. Paramedics are also employed by private sector organizations (private hospitals, private ambulance companies, corporations, mines, air ambulances, racetracks etc.). Paramedics may also work on a volunteer basis, receiving no monetary compensation for their services (i.e. Volunteer Rescue Squad / Volunteer Fire Department and community response units)”

- vi) **BECAUSE** the Medical Laboratory Technologists / Medical Laboratory Scientist belong to category of Allied Health Professional. The word ‘Allied Health Professional has been defined as under;

“**Allied health professionals**, to name a few, include dental hygienists, diagnostic medical sonographers, dietitians, medical technologists, occupational therapists, physical therapists, radiographers, respiratory therapists, and speech language pathologists.”

- vii) **BECAUSE** it is relevant to look at the Statement of Objects and Reasons as placed before Rajyasabha on 3rd February, 2017 with **Bill No. LVIII of 2016.**

STATEMENT OF OBJECTS AND REASONS

The Clinical Establishments (Registration and Regulation) Act, 2010 was enacted to provide for the registration and regulation of the clinical establishments with a view to prescribe minimum standards of facilities and services which may be provided by them so that the mandate of article 47 of Constitution of India for improvement in public health may be achieved.

2. This act was enacted in the year 2010. Certain Rules to operationalise the Act were also issued. **However, there is wide-spread commotion and unrest in the public that certain clinical establishments are (i) subjecting the patients to unnecessary and unwanted diagnostic tests and threatening the patients of dire medical consequences if they do not undergo the tests prescribed to them, (ii) charging the patients with exorbitant prices for**

the diagnostic tests and treatments (iii) prescribing expensive branded medicines ignoring availability of generic medicines, (iv) totally keeping the attendants in dark about the condition of the patient being treated and the treatment extended in the intensive care units and emergency wards and (v) not complying with the conditions imposed by governments after getting concessions and relaxations from the Government.

3. In this context there is a definite need of evolving a proper procedure/ mechanism to streamline these clinical establishments and forcing them to adopt a uniform procedure in charging for diagnostic tests, doctor fees, charges for medical facilities offered by them. There shall be proper check on these clinical establishments and bills charged by them so that they cannot exploit the common people approaching them for treatment of various diseases apart from compelling them to use expensive branded medicines. There are instances wherein these clinical establishments are charging the CGHS/Health Card/ Insurance Patients to the extent of their maximum eligibility by compelling them to undergo various tests, treatments, which may not be necessary for their recovery. The proposed Bill addresses the above concerns to a certain extent.

Hence this Bill.”

The Medical Laboratory Technologists / Medical Laboratory Scientist or Medical Laboratories do not prescribe diagnostic tests, therefore, the question of subjecting the patients to unnecessary and unwanted diagnostic tests and threatening the patients of dire medical consequences if they do not undergo the tests prescribed does not arise. The MLT / MLS do not provide treatment and / or prescribe medicines and have no connection with relatives / attendants about the condition of the patient being treated and the treatment extended in the intensive care units and emergency wards and are not entitled for getting concessions and relaxations from the Government. Therefore, the concerns shown and expressed in Statement of Objects and Reasons with Bill have no nexus with Medical Laboratory Technologists / Medical Laboratory Scientist or Medical Laboratories. Therefore, the Act does not cover the establishment of Medical Laboratory.

- viii) **BECAUSE** it is now very important at this stage to refer to various sections and provisions of Act. The Definitions have been given in Section 2 of Act;

Section 2 (c)

“(c) **“clinical establishment” means**— (i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called **that offers services, facilities** requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy **in any recognised system of medicine** established and administered or

maintained by any person or body of persons, whether incorporated or not; or

(ii) a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases **where** pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not,”

The word ‘medicine’ means the science and practice of the diagnosis, treatment and prevention of disease. The Medical Laboratory Technologists / Medical Laboratory Scientist is not a system of medicine. They do not diagnose and prescribe drugs and medicines for treatment of patients. Therefore, the Medical Laboratory is not a ‘clinical establishment’ in terms of definition under section 2 of Act. The ‘Clinical Establishment’ is a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases **where the support services and facilities of** pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not. The ‘Council’ has been stretching the word ‘clinical establishment’ beyond limits to bring the independent establishment of medical laboratory and Medical

Laboratory Technologists / Medical Laboratory Scientist under its ambit and scope in an illegal and arbitrary manner.

Section 2 (d)

“(d) “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in—

(i) placing the health of the individual or, with respect to a pregnant women, the health of the woman or her unborn child, in serious jeopardy; or

(ii) serious impairment to bodily functions; or

(iii) serious dysfunction of any organ or part of a body;

No such activity is carried out in a Medical Laboratory by Medical Laboratory Technologists / Medical Laboratory Scientist, therefore, the ‘**Council**’ has no power and authority to prescribe minimum standards and educational qualifications and signing powers for the work carried out in Medical Laboratory by highly qualified and trained Medical Laboratory Technologists / Medical Laboratory Scientist.

Section 2 (h)

(h) “recognised system of medicine” means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani System of medicines or any other system of medicine as may be recognised by the Central Government;”

The section 2 (c) (i) talks of “**clinical establishment**” **means**— (i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called **that offers services, facilities** requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy **in any recognised system of medicine** established and administered or maintained by any person or body of persons, whether incorporated or not; or .. *Firstly, the Medical Laboratory Science is not a system of medicine as defined under section 2 (h), and secondly, it falls under the category of Allied Health Profession.*

- ix) **BECAUSE** the ‘Council’ while making categorization of ‘Clinical Establishment’ of different systems under section 13 (1) of Act has included ‘Diagnostic Centers’ and ‘Allied Health Professionals’ at Sr. No. 5 & 6, which is illegal, unconstitutional and arbitrary. It smacks foul play. The Medical Laboratory Science is not a ‘system of medicine’, therefore, it has not been included or mentioned in section 3 (2) (c), (d) & (k) of Act. The ‘Council’ has been acting according to its own whims and fancies by widening and expanding the extent and scope of word ‘clinical’ and ‘different systems of medicine’ in the Act with pure mala fides and under the influence of medicos to capture business and independent profession of Medical Laboratory Technologists / Medical Laboratory Scientist.
- x) **BECAUSE** the ‘Council’ has constituted various Sub-Committees under Section 3 (1) of Act. Since, the Act did not mean to control and regulate the Medical Laboratory Technologist / Medical Laboratory Scientist or their educational qualifications, jobs,

duties and responsibilities, therefore, no Government or private or professional bodies representative of Medical Laboratory Science has been included in these Sub-Committees. Whereas, one representative from DCI, MCI, NCI and PCI have been included. The representatives of other system of medicines have also been included under section 3 (c) & (d). The representative of Indian Medical Association, a professional body, has been included under section 3 (e). The representative of paramedical system has also been added under section 3 (i). Though, the Joint Forum of Medical Technologists of India (JFMT), which is a national registered body of Medical Technologists, exists and is the voice of thousands of Medical Laboratory Technologist but no representation has been given to this professional body. No representative of the Indian Confederation of Medical Laboratory Science (ICMLS) has been included as well.

- xi) **BECAUSE** the Medical Laboratory Technologists / Medical Laboratory Scientist are educated and trained to analyze human fluid samples using techniques available to the clinical laboratory, such as manual white blood cell differentials, analysis by a microscope and advanced analytical equipment. They perform a full range of laboratory tests – from simple blood and urine tests to more complex tests, and report laboratory findings to pathologists and other physicians.

- xii) **BECAUSE** under the prevailing law anyone can own a laboratory and there is nothing which restricts setting up of a medical laboratory to a medical practitioner whose name has been entered in the register maintained under the Indian Medical Council Act or State Council. A

laboratory can be set up even by a Company or be run by qualified professionals.

- xiii) **BECAUSE** there is no law in the States nor there is any Central legislation which insists on additional qualification in Pathology as a pre-condition for owning or running a private laboratory or independently working in a Government Medical Laboratory. A laboratory, under the existing laws, can be set up by any person.
- xiv) **BECAUSE** the Medical Laboratory Technologists / Medical Laboratory Scientist do not fall within the purview of the Indian Medical Council Act, 1956 and, therefore, the provisions of the said IMC Act, 1956 are not applicable to them. The IMC Act, 1956 prohibits a person other than a medical practitioner enrolled in the register maintained under the IMC Act, 1956 from practicing medicine. It does not prohibit running a medical laboratory by a highly trained and qualified Medical Laboratory Technologist.
- xv) **BECAUSE** the work of Medical Laboratory Technologists / Medical Laboratory Scientist cannot be termed as practicing modern scientific medicine. Their work is restricted to examine the specimen samples and reporting the data observed on analyzing the said sample. The said report is then carried to a person who would read the report, interpret the analytical values in the context of other visible symptoms of the patient, his history and then prescribe medicine or advise therapy/treatment. Thus, the work being done by Medical Laboratory Technologists / Medical Laboratory Scientist is essentially a pre-diagnosis work and the report prepared by them works an aid in diagnosis and treatment of the patient. Therefore, it cannot be said that the Laboratory Technologists / Medical

Laboratory Scientist are practicing modern scientific medicine, and therefore the Act or Rules are not be attracted to the work being done by the Medical Laboratory Technologists / Medical Laboratory Scientist.

- xvi) **BECAUSE** it is an irony that the establishment of Medical Laboratory run by trained and qualified medical technologists is ‘not any recognized system of medicine’ and cannot be registered with ‘Council’ yet the ‘Council’ wish to control and regulate the establishment of Medical Laboratory and its human resource.

- xvii) **BECAUSE** the ‘Ministry’ has proposed and placed a number of Bills for constituting Central Regulatory Authority with different nomenclatures for Medical Laboratory Technologists / Medical Laboratory Sciences before the august Parliament since the year 2004, like “Paramedical and Physiotherapy Central Council Bill-2007”, “National commission for human resources in health (NCHRH) Bill -2011”, Most recently, the ‘Ministry’ has placed the Bill with following Statement of Objects and Reason titled as ‘Allied Health Professionals Council Bill, 2017 . It is clearly evident that the “Ministry’ has separate proposal to control and regulate ‘Allied Health Professions’ by an independent Bill even after the Act came into existence in the year 2010.

- xviii) **BECAUSE** the ‘Ministry’ has recently issued Model Curriculum for Medical Laboratory Sciences, the cadre hierarchy, jobs, duties and responsibilities of Medical Laboratory Technologists along with the list of categories of Allied Health Professionals, in 2017 which includes Medical Laboratory Technologists. It will be observed that the “Council” has been acting contrary to the document released by Ministry of H&FW. The copy of chapter 5: Job description for all levels

(page 162-189) can be seen in “Govt. of India Model Curriculum Handbook of Medical Laboratory Science”, which is relevant, is being attached as **Annex- AII**

- xix) **BECAUSE** the MLS Technocrats only perform a full range of clinical laboratory tests and should be able to extrapolate data acquired while MBBS medico Diagnose and manage common health problems and practice evidence based medicine. Bachelor of Medical Laboratory Science is absolutely laboratory oriented intensive workout whereas in MBBS it is more of superficial laboratory practical and more of medicine based patient preparation. Therefore, it is wrong and incorrect on the part of ‘Council’ to authorize a MBBS doctor to validate and sign the work of clinical laboratory independently done by Allied Health Professionals. It is an indirect attempt to capture the business of highly trained and qualified professionals without logic and justifications.
- xx) **BECAUSE** in all Semesters of curriculum BMLS, MLT/MLS are given intensive orienting workout in different subjects i.e Bacteriology, Haematology, Biochemistry and Histopathology and are applied aspects, whereas in MBBS, it is carry over brief practical in one subject only i.e Microbiology, Pathology etc. The semester wise comparative chart of BMLS and MBBS showing duration of Courses, ethics of courses, eligibility for admission to courses and practical based Semester wise course contents, which had the due approval of ‘Ministry’ is being attached for your kind perusal and due consideration. It is clearly evident from the comparative chart that the Medical Laboratory Technologists or Laboratory Scientists are well trained and highly qualified professionals in their field and are competent to perform pre-analytical, analytical, and post-analytical processes to generate a test report based on laboratory Standard

Operating Procedures (SOP) and statistical calculations, thus are legally authorized for the laboratory work done by them. Copy of semester wise comparative chart is being attached as **Annex-III** and Syllabus of MBBS AIIMS New Delhi is as **Annex-IV**

xxi) **BECAUSE** though, the object and purpose to control and regulate the establishment of Medical Laboratory under the Act is mala fide and mischievous yet it is well known that the present strength of MBBS and Pathologists in the country will not be able to handle the huge task and work spread over across the country as proposed under the 'Schedule'. The MCI has been facing severe shortage crisis even to manage qualified Physicians / Surgeons / Pathologists, etc. to run MBBS and MD courses in Government and private medical colleges / universities and these Colleges / Universities indulge in unfair practices by showing fake recruitment to fulfill the minimum standards fixed for by the MCI. The illegal and arbitrary proposals of '**Council**' will not only cause delay in diagnosis and treatment by withholding results and reports of medical laboratory but it will further create shortage. Besides, the proposed 'Schedule' to control and regulate the establishment of Medical Laboratory under the Act is illegal, unconstitutional, arbitrary and there is total non-application of mind. It may create kiosk and sheer mess, and will breed corruption, having no nexus with object and reasons given by legislature.

xxii) **BECAUSE** the Hon'ble Supreme Court in Special Leave Petition (Civil) No. 28529 of 2010 titled Association of Self Employed Owners (Para Medical) of Private Pathology Laboratories of Gujarat vs North Gujarat Pathologist Assn. & Ors is already seized of the identical issue and has been pleased to implead Ministry of Health and Family Welfare, New Delhi and Medical Council of India as necessary parties suo moto vide Orders dated 9.8.2016.

In view of the above facts and submissions, it is, therefore, respectfully prayed that the move of 'Council' to expand and widen the scope and meaning of word 'clinical establishment' to bring Medical Laboratory or Medical Technologists under the ambit of Act is illegal, unconstitutional and arbitrary and in violation of Statement of Objects and Reasons of basic Clinical Establishment (Registration and Regulation) Bill, 2007, which has no legislative intent to control and regulate medical laboratories, where no diagnosis is made no treatment is provided or care for illness is given and no medication to control emergency situations is administered. Therefore, the Medical Laboratory is not a 'Clinical Establishment' under the Act.

It is hoped that the proposal and move by 'Council' to treat the medical laboratory as 'clinical establishment' will be dropped and withdrawn more so when the Ministry is already considering to bring a fresh Central Regulatory Mechanism as Bill / Act for Allied Health Profession and Professionals.

Thanking you in anticipation,

Yours faithfully,

Dated: .06.2017