

'Medical Geneticist' Not Required To Undertake Competency Based Test Under Pre-natal Diagnostic Techniques Training Rules: JKL High Court

2022 LiveLaw (JKL) 225

HIGH COURT OF JAMMU & KASHMIR AND LADAKH AT JAMMU

SANJEEV KUMAR; J.

WP(C) No. 2199/2022; 25.11.2022

Dr. Kuldeep Chander Sharma and another *versus* Union of India and others

Petitioner(s) Through:- M/s Khawaja Siddiqui & Surjeet Singh Andotra, Advocates

1. The petitioner No.1 is MBBS and M.S. Surgery and claims to possess an extensive professional experience of more than five decades, which includes experience of almost three decades in the field of sonography. Petitioner No.2 is also MBBS and claims to possess an experience of fifteen years in the field of sonography. The petitioners are aggrieved and have called in question notification bearing No.DHS5/PNDT/9288-99 dated 26th September, 2022 issued by respondent No.2 [“the impugned notification”], by virtue of which a decision has been taken by the respondents to conduct an examination as per the Preconception and Pre-natal Diagnostic Techniques (Prevention of Sex Selection) (Six Months Training) Rules, 2014, as amended by (Amendment) Rules, 2020 [“2014 Rules”].

2. The impugned notification has been assailed primarily on the ground that the same is in violation of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition and Sex Selection) Act, 1994 [“1994 Act”] and the Rules framed thereunder. The petitioners essentially seek a direction to the respondents not to put MBBS doctors having experience of two years in the field of sex selection and pre-natal diagnostic techniques to competency based test, as, in terms of Section 2(g) of the 1994 Act, they are exempted and are not required to qualify such test. It is claimed by the petitioners that they are running their ultrasound clinics/imaging centres pursuant to the registration granted by the appropriate authority (Chief Medical Officer) under Section 19(1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994. The Certificates of registration passed on by the learned counsel for the petitioners in the open court, which are taken on record, clearly indicate that right from the year 2012, the petitioners are operating their ultrasound clinics/imaging centres pursuant to valid registration granted by the appropriate authority under the 1994 Act. And, therefore, indisputably, both the petitioners being the persons possessing medical qualification recognized under the Indian Medical Council Act have acquired the experience of more than two years in the field of Pre-natal Diagnostic Techniques. This is evident from the certificates of registration issued in favour of the petitioners, a perusal whereof clearly indicates that the ultrasound clinics/imaging centres of the petitioners were registered in the year 2012 for pre-natal diagnostic procedures approved for genetic clinics.

3. The short point that was raised by the learned counsel for the petitioners for consideration in this petition is that by being MBBS and having more than two years experience in the field of Pre-natal Diagnostic Techniques, the petitioners are medical geneticists, a term that is defined in Section 2(g) of 1994 Act, which came to be extended to the Union Territory of J&K w.e.f. 31.10.2019 when the Jammu & Kashmir Re-organization Act, 2019 was enforced. It is argued that a medical geneticist is not required to undertake any competency based test to be conducted by the respondents under 2014 Rules. The impugned notification, which calls upon all registered medical practitioners

including the petitioners to fill application form accompanied with required documents and examination fee of Rs.10,000/-, is clearly not sustainable in law.

4. On being put on notice, the writ petition is contested by respondent Nos. 2 to 5, who, in their reply affidavit, have sought dismissal of the writ petition on the ground that as under Rule 6(2) of the 2014 Rules, all existing registered medical practitioners, who are conducting ultrasound procedures in a Genetic Clinic or Ultrasound Clinic or Imaging Centre on the basis of one year experience or six months training are exempted from undertaking the training under the 2014 Rules provided they are able to qualify the competency based assessment specified in Schedule-II of the Rules. Strong reliance is also placed by the respondents on the directions of Hon'ble the Supreme Court passed in Writ Petition (Civil) No.349/2006 titled Voluntary Health Association of Punjab v. Union of India and others on 08.11.2016, whereby Hon'ble the Supreme Court has directed all the States and Union Territories to implement the 2014 Rules forthwith considering that the training provided therein is imperative for realizing the object and purpose of the 1994 Act. It is submitted that consequent upon the directions issued by the Supreme Court of India, Directorate Health Services, Jammu amongst others was requested by the Department of Health and Medical Education to take necessary steps for implementing 2014 Rules. As a sequel to the aforesaid steps, the Government Medical College, Jammu was notified as institution for imparting six months training to the registered medical practitioner under the training programme "the Fundamentals in Abdomino-Pelvic Ultra Sonography" vide S.O. 295 dated 20th June, 2022.

5. It is, thus, the stand of the respondents that only a qualified registered medical practitioner can be engaged in genetic clinic, ultrasound clinic or Imaging centre. Such registered medical practitioner, in terms of Rule 3(3)(1) (b) & (c) of the Pre-Conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 [" 1996 Rules"], must have Post Graduate degree or diploma or six months training duly imparted in the manner prescribed under the 2014 Rules or a medical geneticist. It is submitted that in terms of Rule 6(2) of the 2014 Rules, all existing registered medical practitioners who are conducting ultrasound procedures in genetic clinic or Ultrasound Clinic or Imaging Centre on the basis of one year experience or six months training are exempted from undertaking such training under 2014 Rules provided they are able to qualify the competency based assessment test. It is submitted that in the cases of those registered medical practitioners, who fail to clear the test, six months training envisaged under the 2014 Rules would be imperative.

6. Having heard learned counsel for the parties and perused the material on record, I am of the view that a medical geneticist', as defined in Section 2(g) of the 1994 Act, is not required to undertake any training or qualify competency based assessment as specified in Schedule II of the 2014 Rules. The petitioners and those doctors, who possess one of the medical qualifications recognized under the Indian Medical Council Act, 1956 and have experience of not less than two years in the field of sex selection or pre-natal diagnostic techniques, would fall within the ambit of term "medical geneticist" and, therefore, shall not be under an obligation to undergo any training or competency based assessment test. They are exempted from the operation of 2014 Rules. The view I have taken and the conclusions I have drawn herein above are based upon a plain but careful reading of the relevant provisions of 1994 Act and the Rules framed thereunder.

7. The 1994 Act was enacted by the Parliament in the forty-fifth year of the Republic of India to provide for prohibition of sex selection before or after conception and for regulating pre-natal diagnostic techniques for the purpose of detecting genetic

abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex linked disorders and also for prevention of their misuse for sex determination leading to female foeticide. Section 2 of the 1994 Act defines various terms used in the legislation. Some of the relevant terms, which are useful for understanding the issue raised in this petition are set out below:-

“2. Definitions.---In this Act, unless the context otherwise requires,--

(a)

(b)

(c) **“Genetic Counselling Centre”** means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counseling to patients;

(d) **“Genetic Clinic”** means a clinic, institute, hospital, nursing home or any place, by whatever name called, which is sued for conducting pre-natal diagnostic procedures;

[Explanation.---For the purposes of this clause, “Genetic Clinic” includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;]

(e) **“Genetic Laboratory”** means a laboratory and includes a place where facilities are provided for conducting analysis or tests of samples received from Genetic Clinic for pre-natal diagnostic test;

[Explanation.---For the purposes of this clause, “Genetic Laboratory” includes a place where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;]

(g) **“Medical Geneticist”** includes a person who possesses a degree or diploma in genetic science in the fields of sex selection and pre-natal diagnostic techniques or has experience of not less than two years in any of these fields after obtaining----

(i) any one of the medical qualifications recognized under the Indian Medical Council Act, 1956 (102 of 1956); or

(ii) a post-graduate degree in biological sciences;

(i) **“pre-natal diagnostic procedures”** means all gynaecological or obstetrical or medical procedures such as ultrasonography, foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any other tissue or fluid of a man, or of a woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting any type of analysis or pre-natal diagnostic tests for selection of sex before or after conception;

(j) **“pre-natal diagnostic techniques”** includes all pre-natal diagnostic procedures and pre-natal diagnostic tests;

(k) **“pre-natal diagnostic test”** means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, blood or any tissue or fluid of a pregnant woman or conceptus conducted to detect genetic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex-linked diseases;

(l) **“prescribed”** means prescribed by rules made under this Act;

(m) **“registered medical practitioner”** means a medical practitioner who possesses any recognized PNDT Act, 1994 & Amendments medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956, (102 of 1956.) and whose name has been entered in a State Medical Register;

(n)

(o)

(p) **“sonologist or imaging specialist”** means a person who possesses any one of the medical qualifications recognized under the Indian Medical Council Act, 1956 or who possesses a postgraduate qualification in ultrasonography or imaging techniques or radiology;”

8. While, we keep the aforesaid definitions in mind, we advert to Chapter-VI of the 1994 Act, which deals with registration of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics. Section 18 of the 1994 Act unequivocally provides that no person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or centre having ultrasound or imaging machine or scanner or any other technology capable of determining sex of foetus and sex selection unless such Centre, Laboratory or Clinic is duly registered under the Act.

9. Section 19 deals with certificate of registration and Section 20 provides for cancellation or suspension of such registration. Section 21 provides for an appeal against the order of appropriate authority suspending or canceling the registration under Section 20. As is apparent from a reading of Section 18(5), no Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall be registered unless the appropriate authority is satisfied that such centre, laboratory or clinic is in a position to provide such facilities, maintain such equipment and standards as may be prescribed. What should be the facilities, equipments and the standards those are required to be provided by the applicant seeking registration as a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic are elaborately laid down in the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996. It may be pointed out that 1996 Rules have been framed by the Central Government in the exercise of powers conferred by Section 32 of the 1994 Act. Rule 3 of 1996 Rules prescribes and lays down qualification of the employees and the requirement of equipment etc., for a Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic/Ultrasound Clinic/Imaging Centre. It provides different qualifications and different equipments for setting up of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic/Ultrasound Clinic/Imaging Centre. Since this Court is concerned with the registration of Genetic Clinic and the determination of qualification of persons to be employed therein, as such, it would suffice to reproduce hereunder Rule 3 (3)(1), which reads thus:-

“3(3)(1) Any person having adequate space and being or employing-

(a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc., under supervision of an experienced gynaecologist in these fields or

(b) 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; or

(c) A medical geneticist, may set up a genetic clinic/ultrasound clinic/imaging centre.”

10. From a fair and clear reading of Rule 3(3)(1) reproduced herein above, it is abundantly clear that any person having adequate space and being or employing any of the following categories is entitled to set up a Genetic Clinic/Ultrasound clinic/Imaging Centre:-

i) Gynaecologist having experience of performing atleast 20 procedure in the fields indicated in Clause (a); or

- (ii) 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 under 2014 Rules; or
- (iii) A medical geneticist.

It is, thus, beyond any pale of doubt that a medical geneticist, as defined in Section 2(g) of the 1994 Act, is a person qualified to set up Genetic Clinic/Ultrasound Clinic/Imaging Centre and a medical geneticist, as defined in Section 2(g), would include a person, who possesses following qualifications:-

- i) Degree or Diploma in genetic science in the fields of sex selection and pre-natal diagnostic techniques; or
- ii) A person possessing one of the medical qualifications recognized under the Indian Medical Council Act, 1956 and possesses experience of not less than two years in any of these fields i.e. either in sex selection or in pre-natal diagnostic techniques; or iii) A post-graduate degree in biological sciences with experience of not less than two years in the fields of either sex selection or prenatal diagnostic techniques.

11. Viewed thus, this Court has no doubt in mind that the petitioners, who possess MBBS qualification, do possess one of the medical qualifications recognized under the Indian Medical Council Act, 1956. Since both the petitioners have been operating their ultrasound clinics and undertaking, amongst others, pre-natal diagnostic procedures for the last several years, as such, possess the experience of not less than two years in the field of pre-natal diagnostic techniques. The petitioners would, thus, clearly fall within the definition of “medical geneticist as given in Section 2(g) of 1994 Act and, therefore, qualified to set up a genetic clinic/ultrasound clinic/imaging centre in terms of Rule 3 (3)(1)(c) of the 1996 Rules.

12. Having discussed the qualification of a person seeking to register his ultrasound clinic as a genetic clinic under the 1994 Act, it is time to advert to 2014 Rules. 2014 Rules, are framed by the Central Government in the exercise of the powers conferred by Clause (i) of Sub Section (2) of Section 32 of the 1994 Act. For quick reference, Section 32(2)(i) is reproduced hereunder:-

“32. Power to make rules.- 1. The Central Government may make rules for carrying out the provisions of this Act.

2. In particular and without prejudice to the generality of the foregoing power, such rules may provide for—

(i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (2) of section 3;”

13. At this stage, it would be apposite to set out Section 3(2) of the 1994 Act, which reads as under:-

“3. Regulation of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics-----on and from the commencement of this Act,---

(1)

(2) no Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess qualifications as may be prescribed.”

14. 2014 Rules, therefore, prescribe and lay down eligibility for registered medical practitioner to undertake six months training envisaged under 2014 Rules. Rule 6, which has been pressed into service by the respondents to justify the impugned notification, reads thus:-

“6. Eligibility for training.-(1)Any registered medical practitioner shall be eligible for undertaking the said six months training.

(3) The existing registered medical practitioners, who are conducting ultrasound procedures in a Genetic Clinic or Ultrasound Clinic or Imaging Centre on the basis of one year experience or six month training are exempted from undertaking the said training provided they are able to qualify the competency based assessment specified in Schedule II

(3) If a medical practitioner fails to clear the said competency based exam, they shall be required to undertake the complete six months training, as provided under these rules, for the purpose of renewal of registrations.”

15. From a reading of Rule 6 in conjunction with Section 3 of 1994 Act and definition of “medical geneticist” given in Section 2(g) thereof as also Rule 3 of the 1996 Rules, it becomes abundantly clear that six months training under 2014 Rules is required for the registered medical practitioner other than a Medical Geneticist, a Sonologist or Imaging Specialist, and a gynecologist having experience of performing atleast 20 procedures in 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc., under supervision of an experienced gynaecologist in these fields.

16. This is so evident from a bare reading of Rule 3(3)(1) of 1996 Rules. Even a registered medical practitioner except the exempted class aforementioned are exempted from undertaking six months training under the 2014 Rules provided they are able to qualify the competency based assessment as specified in Schedule II. Even such medical practitioners have an option that in case they fail to clear competency based test in three attempts, they shall undertake complete six months training. Viewed from any angle and appreciating the issue in the light of clear picture emerging from reading of various sections of 1994 Act and the Rules framed thereunder, it is crystal clear that a medical geneticist is neither required to undertake any training under the 2014 Rules nor is required to qualify the competency based assessment, as specified in Schedule II of the 2014 Rules. It is also beyond any pale of doubt that a person possessing any of the medical qualifications recognized under the Indian Council Act and having experience of two years or more in the field Pre-natal Diagnostic Techniques falls within the definition of “Medical Geneticist”. On the basis of documents on record and the certificates of registration of their ultrasound clinics with specific approval to carry out pre-natal diagnostic procedures therein issued by the appropriate authority from time to time during the last more than a decade, it can be said with certainty that the petitioners have acquired more than two years experience in the field of pre-natal diagnostic techniques. Pre-natal diagnostic techniques, as defined in Section 2(j) of 1994 Act, include all pre-natal diagnostic procedures and pre-natal diagnostic tests.

17. In the premises, I find merit in this petition and the same is, accordingly, allowed. The impugned notification insofar as it pertains to the petitioners is quashed and a declaration is issued that the petitioners being medical geneticist running their genetic clinics/ultrasound clinics for the last several years are not required to undertake any six months training or to qualify competency based assessment as specified in Schedule II of the 2014 Rules. The respondents shall, accordingly, process the cases of the petitioners for renewal/re-issue of certificate of registration in their favour provided they fulfill and comply with other requirements of the 1994 Act and the Rules framed thereunder.