



# भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग I—खण्ड 1

PART I—Section 1

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं. 82]

नई दिल्ली, सोमवार, मार्च 19, 2018/फाल्गुन 28, 1939

No. 82]

NEW DELHI, MONDAY, MARCH 19, 2018/PHALGUNA 28, 1939

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

### NOTIFICATION

New Delhi, the 16th March, 2018

F.No. Z-28015/2/2012-TB.—Whereas, the Central Government is satisfied, that tuberculosis is a dangerous epidemic disease, threat to life and is a major public health problem accounting for substantial morbidity and mortality in the country. Early diagnosis and complete treatment of tuberculosis is the corner-stone of tuberculosis prevention and control strategy. Further, inappropriate diagnosis and irregular or incomplete treatment with anti-tubercular drugs may contribute to complications, disease spread and emergence of drug resistant tuberculosis.

2. Whereas, to ensure proper tuberculosis diagnosis and its management in patients and their contacts and to reduce tuberculosis transmission and further to address the problems of emergence and spread of Drug Resistant-Tuberculosis, it is essential to collect complete information of all tuberculosis patients.
3. Now, therefore, in the interest of public health to control and prevent the tuberculosis disease, the Central Government, specify the following measures, namely:-
  - (1) The Healthcare Providers, termed as Clinical Establishment henceforth; shall notify every tuberculosis patient to local Public Health Authority, namely, District Health Officer or Chief Medical Officer of a District and Municipal Health Officer of urban local bodies in whatever way they are known; or their designated District Tuberculosis Officers in a format as specified in, -
    - (i) Annexure-I by the Medical Laboratories;
    - (ii) Annexure-II by the Medical Practitioners.
  - (2) All Pharmacy, Chemist and Druggist dispensing anti-tubercular medicines, shall notify respective tuberculosis patients along with details of medicines as per Annexure-III and maintain a copy of prescription - Annexure IV, the treating Medical Practitioner as per Schedule H1 of the Drugs and Cosmetics Rules, 1945; and shall furnish the same either electronically or in hard copy, to the Nodal Officer of the District or any Officer authorised by Nodal Officer.
  - (3) Considering the importance of patient support needed for complete and appropriate treatment of all tuberculosis patients are encouraged to self-notify themselves with their own details and that of treating medical practitioners.
4. **Definitions:** For the purpose of this notification, unless the context otherwise requires, the expressions -
  - (i) 'Tuberculosis patient' means a patient diagnosed with at least one clinical specimen positive for acid fast bacilli, or culture-positive for *Mycobacterium tuberculosis* or rapid diagnostic molecular test positive for tuberculosis, or any other tests recommended by Ministry of Health and Family Welfare, Government of India or a patient diagnosed clinically as a case of tuberculosis, without microbiologic confirmation, and initiated on anti-tubercular drugs.
  - (ii) 'clinical establishment' shall have the meaning assigned to it, clause (c) of Section 2 of the Clinical Establishment Registration and Regulation Act, 2010, (23 of 2010).
5. List and contact details of the concerned State Tuberculosis Officers and District Tuberculosis Officers, shall be regularly updated by the Central Tuberculosis Division, in the Ministry of Health and Family Welfare, Government of India and made available on [www.tbcindia.gov.in](http://www.tbcindia.gov.in) and <https://nikshay.gov.in>; who are responsible for implementation of tuberculosis notification in their respective areas of jurisdiction and shall ensure that following action is taken by local public health staff of general health system of rural or urban local bodies, on receipt of information on tuberculosis patient notification through hard copy or through online application named Nikshay:
  - (1) patient home visit as per convenience of patient;
  - (2) counselling of tuberculosis patient and family members;

- (3) treatment adherence and follow up support ensure treatment completion;
- (4) contact tracing, symptoms screening, evaluation of tuberculosis symptomatics and offering isoniazid chemoprophylaxis to eligible contacts;
- (5) offering HIV counselling and testing, drug susceptibility testing;
- (6) linking with available social welfare and support schemes.

6. Secured web portal like <https://nikshay.gov.in> shall be made available by the Central Tuberculosis Division to all practitioners, clinical establishments, pharmacies, chemists, druggists and patients for online submission of information.

7. The information on tuberculosis notification received by Public Health Staff, shall be used only for extending the care and support, take appropriate public health action as mentioned in paragraph 5 above; including financial and non-financial incentives to patients, like free drugs and diagnostics, screening for co-morbidities, drug susceptibility testing, information technology based treatment adherence support system for improving quality care, etc., and providing feedback to the respective treating medical practitioner: provided that the confidentiality of the individual identity of the tuberculosis patients shall be maintained.

8. Tuberculosis patients notified from Pharmacies, Chemists and Druggists and those patients self-notified, shall be contacted and verified by Public Health Authority or their authorized representative.

9. For tuberculosis patients notified from Medical Laboratory, Chemist and self-notification by tuberculosis patient, staff of public health system will gather information to complete notification which include basis of diagnosis, site of disease, history of anti-tubercular treatment and classify type of tuberculosis patient.

10. These measures shall prevail over the earlier measures issued vide order F.No. Z-28015/2/2012-TB, dated the 7<sup>th</sup> May 2012 and its amendment dated the 23<sup>th</sup> July 2015.

11. The Clinical Establishment, Pharmacy, Chemist and Druggist, failing to notify a tuberculosis patient to the nodal officer, as mentioned in paragraph 3 above and local public health staff of general health system of rural or urban local bodies, not taking appropriate public health action on receiving tuberculosis patient notification as per paragraph 5 above, may attract the provisions of sections 269 and 270 of the Indian Penal Code (45 of 1860), as the case may be, which are reproduced below:

**“269. Negligent act likely to spread infection of disease dangerous to life.** - Whoever unlawfully or negligently does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both.

**270. Malignant act likely to spread infection of disease dangerous to life.** - Whoever maliciously does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both.”

ARUN KUMAR JHA, Economic Adviser

### TB Notification reporting format for Medical Laboratory

Period of reporting: From ...../...../..... To ...../...../.....

Name of the Laboratory : .....

Health Establishment code for TB Notification

Registration Number:..... Telephone (with STD):..... /.....

Mobile number:.....

Complete Address: .....

Sr. No.	Name of TB Patient (surname first)	Father / Husband's name	Age (yrs)	Sex (M/F/O)	GoI issued identification number	Complete residential address	PIN number	Patient Phone number	Date of TB Diagnosis*	Date of sputum collection	Date of result	Type of Test result (smear microscopy positive / culture positive / MTB on LPA / MTB on Xpert / MTB in FNAC / TB on Histopath/ DST	DST results for each drug tested (R=resistant / S=sensitive/NA=not available) Rif, INH, SM, EMB, Ofx, Km, Eto, Cipro, Capr, etc.							
													Rif	INH	SM	EMB	Ofx	Km	—	—

\* Mandatory Laboratories include those Health Establishments carrying out any of the RNTCP endorsed TB diagnostics

Signature:.....

Date: ...../...../.....

**Annexure II**

**TB Notification reporting format for  
Medical practitioners/Clinics/Hospitals/Nursing homes**

Period of reporting: From ...../...../..... To ...../...../.....

Name of the health facility / practitioner :.....(single/Multi) Health Establishment code for TB Notification  
 Registration Number:..... Telephone (with STD):.....  
 Mobile number:.....  
 Complete Address: .....

Sr. No.	Name of TB Patient (surname first)	Father/ Husband's name	Age (yrs)	Sex (M/ F/O)	GoI issued identification number *	Complete residential address	PIN no.	Patient Phone number	Date of TB Diagnosis *	Date of TB treatment initiation*	Site of Disease (P/EP)*	Patient Type (New TB case/ Recurrent TB case/ Treatment change) *	Basis of diagnosis (Smear microscopy/ culture / PCR/ LPA/ FNAC/Histopathology/Clinical exam/X-Ray)	Weight in Kg.	Drugs and dosages (in mg) H/R/Z/E/S/ O/K/Cs/Eto/ Levo/Mx/Cpr/ Other (specify)

\* Mandatory

**Private practitioner / Clinic (single)** will include any Health Establishments where TB cases are treated or diagnosed clinically / radiologically and the medical services are provided by single medical practitioner.

**Hospital / Clinic / Nursing Home (multi-practitioners)** will include any Health Establishments where TB cases are treated or diagnosed clinically/radiologically & medical services are provided by more than one practitioner.

**Signature:..... Date: ...../...../.....**

**Annexure II**

**TB Notification reporting format for  
Medical practitioners / Clinics/Hospitals/Nursing homes**

Period of reporting: From ...../...../..... To ...../...../.....

Name of the health facility / practitioner :.....(single/Multi)      Health Establishment code for TB Notification

Registration Number:..... Telephone (with STD):..... /.....

Mobile number:.....

Complete Address: .....

Patient ID	Patient home visit Done (Y/N)	If Yes, done by	Patient counseling Done (Y/N)	Type of treatment adherence (DOT/SMS/Phone/99 DOT/Video DOT/Pill box/SAT)	Status of patient (regular/ Not regular)	Month at which FU examination done	Status at FU examination (SM/Cult) (Pos/Neg)	Clinical improvement (Yes/No)	No. of contacts	No. of contact symptomatic	No. found to have TB among contact	No. of contacts initiated on anti-TB treatment	No. of contacts offered chemoprophylaxis	HIV testing offered (No/Neg/Pos)	DST offered (No/RIF resistance /RIF sensitive/ Indeterminate)	Treatment Outcome (C/TC/F/D/LTFU/TO/RC)

C=Cured, TC=Treatment Completed F=Failure D=Died LTFU=Lost to FollowUp TO=Transferred Out RC =Regimen Change.

This information on page 2 is to be submitted during treatment and after treatment completion with sos updation in Nikshay with public health action support by local public health staff.

Signature:.....

Date: ...../...../.....

**Annexure III**

**TB Notification reporting format for Pharmacy, Chemist & Druggist**

Period of reporting: From ...../...../..... To ...../...../.....

Name of the Reporting (pharmacy) :..... Telephone (with STD):.....

Mobile number:.....Complete Address:.....

Sr. No.	Name of TB Patient (surname first) *	Father / Husband's name	Age (yrs)*	Sex (Male/Female /Transgender) **	GoI issued identification number *	Complete residential address	PIN no*	Patient Phone number	Date of TB Diagnosis**	Date of TB treatment initiation **	Date of prescription*	Date of Dispensing Medicines*	Number of Days for which Medicines dispensed*	Name of treating medical practitioner (Prescriber) *	Address & Registration no. of treating medical practitioner

\* Mandatory

\*\* Not mandatory

Signature:..... Date: ...../...../.....

**Annexure-IV**

For each notified patient the prescription details on drugs prescribed and drugs dispensed should be mentioned with dosages, formations and duration