

Frequently Asked Question on Gazette on Mandatory TB Notification for Chemists/ Pharmacies.

1. The patient or his relative does not want to disclose their name & identity. How to notify such TB patients?

As per the Gazette on mandatory notification of Tuberculosis (TB), it is the duty of the registered pharmacies to divulge the information to the authorized notification official as regards TB which is a notifiable disease in the country. It is estimated that a TB patient can spread the infection to atleast 10-15 persons in a year, if untreated. Hence, in case of TB, the concerned public health authorities should be informed immediately.

Moreover, the information remains secured within the TB Notification system – NIKSHAY of the Government of India. Only authorized user of Nikshay on behalf of 'Revised National TB Control Programme' (RNTCP) will have access to the information on patient for ensuring public health measures (to support TB patients in ensuring cure from the disease and prevent spread of the disease) as mentioned in the section 5 of this Gazette. The information will not be shared outside the RNTCP and health officials. Confidentiality of the data gathered will be ensured as per EHR/EMR standards and IT Act 2000 of Govt of India & its amendment 2008.

2. Patient and their relatives are not ready to provide detailed residential address, their ID & Mobile or Telephone Number. How to provide this information in such instances?

TB is a communicable disease and it is estimated that a TB patient can spread the infection to atleast 10-15 persons in a year, if untreated. The infection spreads through air droplets while coughing, sneezing by TB patients. Hence, TB patients should be treated at the earliest and certain public health measures like contact investigation, chemoprophylaxis for the households, treatment support (if required), nutrition support, comorbidity testing and drug susceptibility testing need to be undertaken in order to ensure complete cure. To deliver this, the public health system need at least mobile number and residential address of the patient. Moreover, Government of India has recently initiated the scheme for TB patients in which, TB patients are provided Rs. 500/- per month through Direct Benefit Transfer (DBT) till the duration of treatment for nutrition support. To provide this support, contact details of TB patients are essential. Mobile number is particularly useful to contact person and inform them before reaching to them.

3. Chemists can ask them for the information but cannot compel for ID proof and their mobile number, matter of secrecy about illness and information of disease arises. How to provide this information in such instances?

All services including treatment will continue without interruption even on non-availability of ID proof at time of dispensing medicine. However, in pursuance of the provisions of the section 7 of the Aadhaar (Targeted Delivery of Financial and Other

Subsidies, Benefits and Services) Act, 2016 (18 of 2016) (hereinafter referred to as the said Act), a TB patient to receive the benefit under the RNTCP is, required to furnish proof of possession of Aadhaar number (vide number S.O. 1935(E), published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (ii) date 16th June 2017). Financial incentives to eligible individuals will still be extended if the individual produces any of the government issued valid proof of identity. This will help to provide Direct Benefit Transfer to TB patients at Rs. 500/- per month till duration of treatment. Mobile number is particularly useful to contact person for communication of various benefits, counselling, follow up reminders and ensure all treatment support to ensure cure.

4. Patient from rural or far flung area are sometimes not bringing fresh prescription from their doctor and ask for the medicines to be continued for a certain period. How to maintain record in such instances?

As per Drugs and Cosmetic Act, Rule 1945, anti-TB drugs are specified under the Schedule H1. Substances specified in Schedule H and Schedule H1 shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner.

5. In case of young TB patients, they themselves and their families don't want to disclose their name and in particular in case of female they don't bring her in front and hence it is very difficult to tackle them. How to get information in such instances?

Name, Age, Sex, Contact details of a patients are required for medical records and notification of TB, in particular. Notification of disease is not merely collecting number of TB patients, but to understand its distribution among various age and gender groups. Similarly, public health measures following notification is an important purpose to notify every TB patient to adequately support TB patients to complete the treatment and ensure public health measures. Mobile number is particularly useful to contact and inform patients before reaching to them. This is even more relevant to young TB patients.

6. If a TB patient did not bring photo id, then, will a chemist not dispense anti-TB drug, as he/she will not be able to notify?

If a TB patient did not bring photo id, the photo id can be collected later on by the public health staff or chemists themselves. It is not mandatory to provide photo id at time of notification only. in pursuance of the provisions of the section 7 of the Aadhaar (Targeted Delivery of Financial and Other Subsidies, Benefits and Services) Act, 2016 (18 of 2016) (hereinafter referred to as the said Act), a TB patient to receive the benefit under the RNTCP is, required to furnish proof of possession of Aadhaar number (vide number S.O. 1935(E), published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (ii) date 16th June 2017). Financial incentives to eligible individuals will still be extended if the individual produces any of the government issued valid proof of identity. This will help to provide Direct Benefit Transfer to TB patients at Rs. 500/- per

month till duration of treatment. Mobile number is particularly useful to contact patients and inform them before reaching to them.

7. It is difficult to do photocopy of every anti-TB prescription, when electricity is not regular in villages. How to get records of such patients who even bring prescription?

As per the Drug and Cosmetic Rule, 1945, the supply of a drug specified in Schedule H1 shall be recorded in a separate register. Anti-TB drugs have been specified under the Schedule H1. Photograph of prescription can also be taken which later on can be printed or preserved as electronic copy.

8. How to report on monthly basis from remote villages where there are issues related to internet availability, courier or post services?

Reporting of anti-TB drug sale is desirable to be sent from pharmacies on monthly basis to DTO and Drug Inspector. In case of unavailability of communication measures, public health staff can support collection of such reports in consultation with DTO / Drug inspector.

9. If Doctor notifies TB patient at time of prescribing medicine, why pharmacies are asked to provide information?

The Gazette mandates health facility, pharmacy and laboratories to notify each TB patient at the earliest. Accordingly, the health facility/doctor will notify TB patients. But, in case it does not happen the Government cannot afford to lose any TB patients from being notified, as it is a public health responsibility to prevent the spread of disease in the community. Those health facilities/ doctors who are not notifying TB patients will attract the Gazette provisions and it will be ensured that health facility notifies at diagnosis. Moreover, there are now incentives for notification of TB patient, which will be provided to the provider (doctor / chemist / laboratory) whoever notifies the TB patient.

10. Do pharmacies have to or don't have to retain the original, or a photocopy of the prescription of the doctor?

As per the Drugs and Cosmetic Act, 1940, it is mandatory for pharmacies to keep a copy of prescription of drugs covered under Schedule H1 in a separate record and such record should be maintained for three years and be available for inspection. As per Drugs and Cosmetic Rules, 1945, the supply of a drug specified under schedule H1 shall be recorded in a separate register at the time of supply giving name and address of prescriber, the name of patient, the name of drug and the quantity supplied and such record shall be maintained for three years and be open for inspection.

11. What is the exact format of Annexure IV ?

Annexure IV will be as per the requirement of keeping information as per Schedule H1 of Drugs and Cosmetic Rules, 1945. The same is enclosed for reference.

12. What all information need to be furnished or to be maintained in regards to TB, by the pharmacies?

Annexure III is the TB notification format for pharmacies. It includes information of medical practitioner who prescribed the anti-TB drugs in addition to TB patients information, diagnosis and drug dispensing information.

Details of the drugs prescribed to be furnished or maintained as per annexure IV in line with Schedule H1 of Drugs and Cosmetic Rules, 1945. This includes dosages, formations (to be read as formulation) and duration of anti-TB drug dispensed for.

13. Who is the nodal officer for submission of information?

District TB Officer is the nodal officer for notification of TB patients and related to anti-TB drug sale information. The list of Nodal Officers is available on <http://tbcindia.gov.in/>. In States/UTs or districts where the bilateral understanding is established between the Health Establishments and the local public health authorities for convenient local TB notification, the information on TB Notification can be submitted to the local public health authorities (e.g. Medical Officer of the Primary Health Center) as designated by the district nodal authority for TB notification. However, this should be done only in consultation with the concerned district nodal officer for TB notification. In case, health care provider is not aware about the contact details of the nodal officer for TB Notification in the district the same may be obtained from the respective District TB Officer / State TB Officer for the updated contact.

Submission of information is mandatory; either electronically (online) or in hard copy (paper based). Modalities of reporting of information can be any of the following.

- Hard copy by post, courier or by hand to the nodal officer
- Electronic copy by email from persons / institutes authorized for this purpose to the nodal officer
- Uploading of information directly on to the Nikshay portal <http://nikshay.gov.in>
- Using authorized mobile numbers by phone call on 1800 11 6666
- Direct online information transmission from laboratory or hospital MIS to NIKSHAY

14. Should the Annexure III and IV be sent to the state FDA also ? Or not ?

If annexure III & IV is submitted to the District TB Officer & Drug Inspector. The onwards transmission is secured by them to the State FDA.

15. Is online submission of information mandatory for pharmacies/chemists & druggists?

Submission of information is mandatory; either electronically (online) or in hard copy (paper based). Modalities of reporting of information can be any of the following.

- Hard copy by post, courier or by hand to the nodal officer
- Electronic copy by email from persons / institutes authorized for this purpose to the nodal officer
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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

