WORLD BANK GROUP

INDIA: Program Towards Elimination of Tuberculosis (P167523)
(Program-for-Results)

Integrated Fiduciary Systems Assessment (IFSA)

DECEMBER 18, 2018

ABBREVIATIONS AND ACRONYMS

CA	Chartered Accountant
C&AG	Comptroller & Auditor General Office
CGA	Controller General of Accounts
CMHO	Chief Medical and Health Office
CMSS	Central Medical Services Society
CTD	Central TB Division
DLI	Disbursement-Linked Indicator
DOHFW	Departments of Health and Family Welfare
EAC	Externally Aided Component
FM	Financial Management
FMR	Financial Monitoring Report
GC	General Component
GFR	General Financial Rules
GoI	Government of India
IBRD	International Bank of Reconstruction and Development
IDA	International Development Association
IFSA	Integrated Fiduciary System Assessment
INR	Indian National Rupee
LoA	Letter of Acceptance
MoHFW	Ministry of Health and Family Welfare
NGO	Non-Governmental Organization
NHM	National Health Mission
NPV	Net Present Value
NPY	Nikshay Poshan Yojana
PAD	Project Appraisal Document
PAP	Program Action Plan
PFMS	Public Financial Management System
PforR	Program for Results
PIP	Program Implementation Plan
PP	Public Private
PPE	Private Provider Engagement
PPM	Public-Private Mix
PTETB	Program Towards Elimination of TB
RNTCP	Revised National TB Control Program
RoP	Record of Proceedings
SC	Scheduled Castes
SoE	Statement of Expenditure
SHS	State Health Societies
TA	Technical Assistance
TB	Tuberculosis
TSU	Technical Support Unit
WHO	World Health Organization
XDR-TB	Extensively drug-resistant TB

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Section 1: Conclusions

1.1 Reasonable Assurance

1. As part of Program preparation, the World Bank carried out an Integrated Fiduciary System Assessment (IFSA) of the Central Tuberculosis Division (CTD), nine states and the Central Medical Services Society (procurement agency), all of which were involved in the Program implementation. The IFSA was conducted to determine whether the fiduciary systems provide reasonable assurance that funds will be used for the intended purposes and support in achieving the Program results.

2. The conclusion of the IFSA[1] is that the Program's fiduciary systems at the various levels of implementation are sufficient. The assessment provided reasonable assurance that the financing proceeds would be used for intended purposes with due attention to the principles of economy, efficiency, effectiveness, transparency, and accountability. During the IFSA, certain areas in need of improvement have been identified, and recommendations have been made as part of legal agreements and the Program Action Plan (PAP).

1.2 Risk Assessment

3. Based on the IFSA, the fiduciary risk of the Program is assessed as **Substantial**. The Revised National TB Control Program (RNTCP) implementation arrangements are characterized by the proliferation of implementing agencies at multiple levels, with added challenges from disparate arrangements and varying technical capacities across the nine states. The residual fiduciary risks and proposed mitigation measures addressed through the PAP are documented in the table below:

Table 1: Risk and Mitigation Strategy

Risk	Proposed Mitigation	Responsibility
Absence of a unified accounting system: The practice of maintaining accounts at various levels of implementation, varies from using computerized off-the-shelf accounting software to manual accounting. There is no unified accounting system, and reporting is done manually in excel by the states. Until now, the	The Public Financial Management System (PFMS) developed by the Government of India (GoI), is a fund tracking and expenditure filing system that is a viable alternate for unified expenditure reporting. The roll out and usage of PFMS will be mainstreamed during the Program and all Program expenditure will be reported by states through this system.	*CTD and States*

[1] FM assessment under the IFSA was conducted at the national level for the CTD and CMSS; and in a sample of seven out of the nine selected states. Procurement assessment was limited to CMSS and CTD as 90% of program procurement is expected to be done by CMSS & CTD. Procurement is minimal at the states level.

Risk	Proposed Mitigation	Responsibility
implementation of PFMS has been sporadic, limited to the particular nature of expenditures in the RNTCP.	Technical Support Units will be established at the state and central levels to facilitate the roll out of PFMS through capacity building initiatives.	
Scope to improve FM monitoring at the central level by CTD: Regular meetings are organized to review RNTCP progress at the various levels of implementation chaired by National Health Mission (NHM) officials. However, there are no periodic review meetings of the TB finance officials at the state and district level at the central level.	To improve the monitoring and oversight over the FM arrangements of the Program, periodic review meetings of the FM officials from the state and district TB Cells with the CTD FM cell will be established. Such meetings will be organized every six months, with the agenda to review the financial progress, reporting, PFMS roll out, audit findings and compliance, among other FM issues.	*CTD and States*
CMSS sends utilization reports nine months after contract closure.	Six monthly reporting of physical and financial progress by CMSS to the CTD throughout the duration of Program	CTD/CMSS
Inadequate procurement staffing in CMSS	Seven vacant posts at present shall be filled by appointing qualified and experienced staff to fill the gaps. CMSS shall thereafter maintain full staff strength. Conduct tailored training on Government of India procurement systems (General Financial rules (GFR) -2017)) and Contract Management	*CTD/CMSS*
Multiple level approvals of procurement decisions resulting in delays in evaluation of bids and decision making	The system for approval of procurement decision needs to be reviewed with the aim to reduce the time. Ensure that procurements are processed as per the timelines in the procurement plan and within initial bid validity	*CTD/CMSS*
Lack of Contract Management capacity and delays in obtaining test reports from nominated laboratories	CMSS will regularly monitor and follow up with the testing labs and if required, enhance the number of testing laboratories.	*CTD/CMSS*
Risk of substandard quality of drugs and stock out of drugs at the Central Medical Supplies Stores warehouse, as well as at the state Government Medical Stores Depot (GMSD)	A system of quality assurance of drugs is in place. To further mitigate risks of substandard drugs, regular monitoring of quality assurance activities and stocks will be done through the “Nikshay Aushadhi” Software by CTD.	*CTD/CMSS*
Grievances including Procurement related complaints are not independently reviewed	A Grievance redressal system will be developed. The system should state the operating procedures. The complaints would be handled by an independent team.	*CTD/CMSS*

1.3 Key Performance Indicators

4. In addition to the above-mentioned risks mitigated through actions documented in the Program Action Plan (PAP), fiduciary performance will be monitored during Program implementation, through the following indicators:

a. Funds transferred in a timely manner (measured in Days)
b. Timely preparation of annual financial statements within three months from end of FY
c. PFMS rolled out across states
d. Six monthly Financial Reporting submitted by CMSS
e. Timely submission of audit reports within six months from end of FY
f. Average length of procurement processes from receipt of indent to award of contract
g. Time taken for supply of drugs after receipt of award by the supplier and receipt of drugs at CMSS warehouse
h. Time taken for testing of drugs
i. Percentage of procurement complaints addressed

The above will be monitored every six months by CTD and reports shall be shared with the Bank.

1.4 Procurement Exclusions

5. Based on last year's data, it is expected that the procurement of drugs will involve contracts up to a value not larger than the equivalent of US$30 million. Other contracts for medical equipment are expected to be of lower value. Even with the increased funds for drugs and materials (*62.8 percent of the total expenditure as compared to 52.24 percent in FY 2016, 52.71 percent in FY 2017 and 45.33 percent in FY 2018*), the individual contract values are expected to remain within the OPRC thresholds.

6. Contracts for Goods and Consultancies procured under the Program valuing more than the equivalent of US$50 million and US$20 million respectively (OPRC threshold for substantial risk), are excluded from this PforR Program. However, it is expected that there will be no such contracts for goods, drugs, medical equipment, works and consultancies which fall above OPRC thresholds.

Section 2: Institutional Arrangements and Scope of the Program

2.1 Institutional Arrangements

7. The Government of India's (GoI) Revised National Tuberculosis Control Program (RNTCP) is implemented by the Ministry of Family Health and Welfare (MoHFW) under the National Health Mission (NHM), as a Centrally Sponsored Scheme of the Government of India.

8. This is the fourth phase of World Bank support to the TB program in India. Although the earlier phases of the Bank's involvement were investment financing, country systems were followed for Financial Management (FM) arrangements in these earlier projects. The implementation arrangements in the current RNTCP, will be similar to the previous phases to a large extent, allowing the GoI as well as the Bank to draw on past implementation experience. However, it is important to note that the institutional arrangements for RNTCP are characterized by the proliferation of implementing agencies, with added challenges from disparate arrangements across the nine states.

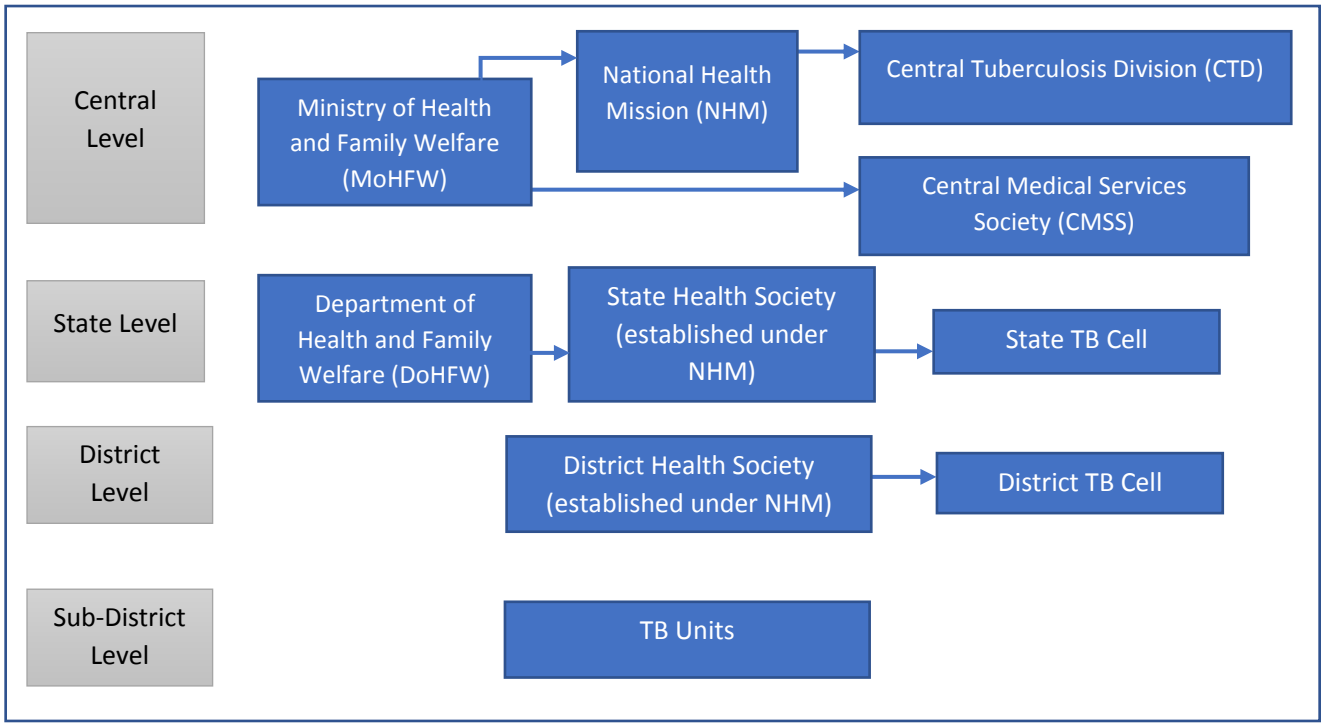
9. *Central level:* At the central level, the overall responsibility for the day to day management of the Program rests with the Central Tuberculosis Division (CTD) at MoHFW. To facilitate quality and uniformity of treatment for the pan-India program, the procurement of anti-TB medicines is done through a Central Procuring Agency (CPA) of MOHFW – Central Medical Services Society (CMSS). CMSS, a legal entity registered under the Societies Registration Act, 1860, was established with the approval of the Cabinet of Ministers on August 24, 2011. It was created as a CPA to streamline the drug procurement and distribution system of the Department of Health & Family Welfare under the Ministry of Health & Family Welfare, Government of India. CMSS is a very lean organization, headed by a Director General & Chief Executive Officer, in the rank equivalent of Joint Secretary to the GoI, with a workforce of 30 employees at their head office in New Delhi, and three employees in each of the 20 warehouses located in some of the state capitals.

10. *State and District level:* At state and district levels, a multi-stakeholder health society, established by NHM, is responsible for RNTCP planning, budgeting and administration. Under the aegis of such State Health Societies (SHS) and the District Health Societies (DHS) of NHM, separate TB cells have been established, headed by the state and district TB officers within state Departments of Health and Family Welfare (DOHFW). Both the SHS and DHS are legal entities, registered under the Societies Registration Act of 1860 (national legislation), or the respective states' equivalent legislation, as applicable.

11. During the earlier years of the RNTCP i.e. in the previous phases of the Bank funded projects, the above-mentioned TB cells were stand-alone legal entities, registered as Societies. During 2005-06, the MoHFW took cognizance of the proliferation of implementing entities and brought a number of health schemes under the aegis of the NHM, implemented through one society at the state level. Over the course of the next few years, this change was executed in the states at different times. It is important to note that even though the merger has been complete, in a few states the RNTCP is still working in a silo with limited interaction with the NHM counterparts.

12. *Sub-district level:* At the sub-district level, the TB Unit manages day-to-day program activities. Regarding fiduciary responsibilities, the alignment of TB Units with the block-level administrative structures of the NHM has been sporadic, with the district being the last accounting centre in majority of the states.

Figure 1: Institutional Arrangements



2.2 Program Scope

13. The proposed Program Towards Elimination of TB (PTETB) will support the Government of India's RNTCP as defined in the National Strategic Plan (2017-25). The NSP 2017-25, costed at US$8.3 billion, envisages an aggressive scale-up of high impact interventions towards TB elimination building on key achievements of the GOI's previous TB control strategy (2012-17).

14. The Program for Results (PforR) Program boundary of US$1.33 billion has been carved out of the NSP 2017-25, which included identified results areas, geographical area limitations and time frame, described in Table 2 below.

Table 2: Program Scope

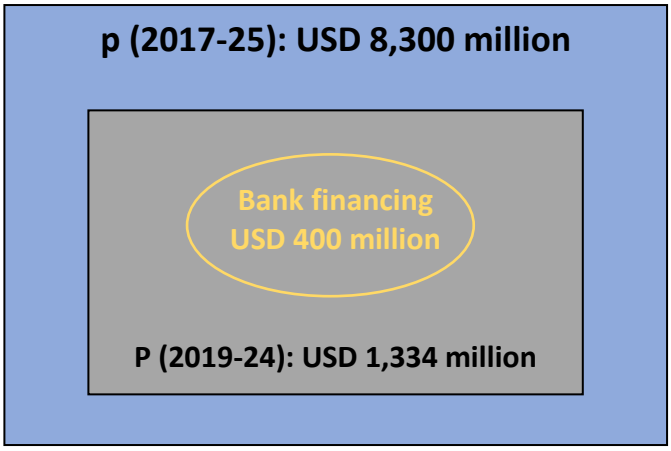
S.No.	Particulars	Details
(a)	Results area	Of several NSP result areas, the Program focuses on four: (i) scaling up private sector engagement; (ii) rolling out TB patient management and support interventions; (iii) strengthening diagnostics and management of DR-TB; and (iv) strengthening program management capacity and information systems.

S.No.	Particulars	Details
(b)	Geographical area	Nine priority states[2] have been selected from the pan-India RNTCP, considering both the estimated TB burden and the gap between private notification and the estimated TB burden.
(c)	Time slice	The Program will cover five years (2019-24) of the RNTCP's eight-year lifespan (2017-25).

2.3 Scope of IFSA

15. The US$1.33 billion Program (Bank program "P") is estimated to contribute 25 percent of the funding required by the NSP during the Program period (2019-24). During this time, the Program expenditure will account for approximately 74 percent of total government expenditures on TB in the nine priorities states. The Program expenditure includes select central and state-level expenditures, contributing towards the identified results area which include: salaries, private sector support, honorarium, training, supervision and monitoring, patient support and transportation, and procurement of equipment, laboratory materials and anti-TB drugs (procured centrally).

Figure 2: Comparison of Government program "p" and Bank Program "P"



16. The total IBRD loan for the PforR program is US$400 million, which is 30 percent of the total estimated Program cost of US$1.334 billion. The Government budget will contribute 70 percent of the Program cost. Please refer to table 3.

[2] The nine priority states are: Assam, Bihar, Karnataka, Maharashtra, Madhya Pradesh, Rajasthan, Tamil Nadu, West Bengal, and Uttar Pradesh.

Table 3: Financing details for the operation

Description	Amounts in USD million	percent
Government program (2017-25) - 'p'	8,300	
Bank Program PforR (2019-24) – 'P'	1,334	25% of 'p' for the relevant time slice
Counterpart Financing	934	70%
IBRD financing	400	30%

17. Scope of the IFSA: The Integrated Fiduciary System Assessment (IFSA) was conducted at the national level for the Central TB Division (CTD) and Central Medical Services Society (CMSS). In seven out of the nine selected states (Assam, Bihar, Maharashtra, Madhya Pradesh, Karnataka, Rajasthan and UP) the IFSA focused on the financial systems of the TB cells, housed within the respective Health Societies at the state and district levels. Based on the Bank's experience and understanding of the financial systems in the other states, these states may be considered as a representative sample. However, the systems vary from state to state.

Section 3: Review of Public Financial Management Cycle

3.1 Planning and Budgeting

18. Planning: The planning process for NHM, at an overall level, is initiated in November for the next government financial year (April to March). The Central level NHM at MoHFW shares guidelines with the states for preparation of the Program Implementation Plan (PIP). The respective counterparts within the SHS and TB Cell work together and identify the resource envelope for the next year and communicate the GoI guidelines and state calculations to the DHS for consolidated inputs of all schemes under the NHM aegis. The consultations at the districts are held between the District TB Cell, sub-district level officials and the DHS to compile the District Health Action Plans, which are then submitted to the SHS for consolidation, generally during December or January. The consolidated estimates are reviewed at the SHS and approved by the appropriate authority, defined by each state (for instance, Executive Director and CEO (Principal Secretary, Health) of the SHS in Bihar; Executive Committee and Governing Body of the SHS in Rajasthan). The approved estimates are submitted to GoI in February in the form of a PIP proposal.

19. At the Centre, state-wise National Planning Coordination Committee (NPCC) meetings are held to deliberate the above-mentioned proposal, generally starting in April. These meetings are attended by the SHS representatives and led by the Principal Secretary, Health and Mission Director of the NHM. The outcome of this meeting is the approval of the NHM annual plan in the form of Record of Proceedings (RoP) for the state. States have reported receiving the RoP at varying times – for instance Rajasthan received the RoP for 2018-19 in June 2018, whereas UP received it in August 2018. The RoPs and PIPs are publicly disclosed on the NHM website.

20. Medium-term strategic plans have been defined in the NSP. The states' overall program objectives are consistent with the NSP, however, the NSP does not show linkages with the RoP (i.e. annual implementation plans).

21. Upon receipt of the NHM RoP, the SHS notifies the budget to each of the schemes, based on a desk exercise of culling out the scheme wise data from the RoP. The guideline is to complete this process in 15 days, however, it takes approximately one to two months after receipt of the RoP. The planning process is completed by September or October of the current financial year, thus, leaving only six months of the financial year.

22. Budgeting: As evidenced above, the planning processes run into the first six months of the financial year, which does not link with the timeline for providing original budget estimates for the states and GoI. The budgets in India are approved by the legislature before the start of the financial year, in February or March. The budget estimates are calculated by MoHFW and the states based on the previous year's allocation, utilization reported, and the resource envelope calculated at the start of the PIP process. Any excess requirement identified in the RoP is requisitioned as a Supplementary Budget, at the time of submission of Revised Estimates at the GoI and State level for legislative approvals (November/ December of current year). There appears to be sufficient predictability in the availability of resources for the implementation of the Program.

23. The provisions for preparation of budget and its approval in the Parliament (and Legislative Assembly for the states), are enshrined in the Constitution of India. The process involves legislative scrutiny and the Parliament (and Legislative Assembly for the states) exercises full control over the annual budgetary system, an effective instrument of financial control of government activities.

24. The need for creation of a separate budget line is not envisaged, as the Bank is financing ongoing RNTCP. The GoI and the state's budget for the RNTCP is included under the Demand for Grant of MoHFW/ DoHFW respectively. There is no separate line item for RNTCP in the budget, rather it is part of the flexi pool of funding arrangement of the NHM budget (which covers four Centrally Sponsored Schemes of the GoI, including RNTCP) under two separate budget lines for Externally Aided Component (EAC) and General Component (GC).

25. CMSS: The centralized procurement is done by CMSS, which was established as a Society, with a one-time grant of INR50 crores (approximately US$9 million at the then prevailing exchange rate) from MoHFW in 2012-13. There have been no additional grants in the subsequent years. The CMSS levies a 3 percent administrative charge and 1 percent testing charge on every procurement; such fees cover the operational expenses of the Society. The budget is prepared only to the extent of the operational expenditures of CMSS for which the annual estimates are INR 18 crores (US$2.7 million) (FY 2018-19). CMSS is treated as a part of MOHFW for the purpose of Program implementation and this assessment.

3.1.1 Adequacy of budgets

Expenditure on RNTCP in the last three years

26. Overall the level of the GoI's expenditure on RNTCP has increased over the last three years. There are three broad categories under which the RNTCP budgets are reported:

Table 4: RNTCP expenditure in the last three FY (Centre)

	Total expenditure in USD millions		
Description	**FY 2016**	**FY 2017**	**FY 2018**
Externally Aided Component	33.73	47.76	156.19
Domestic Funding	53.92	45.14	50.48
Supplies & Materials - Release for Procurement of Anti TB Drugs/ Equipment	95.89 (52.24%)	103.54 (52.71%)	171.34 (45.33%)
Total	**183.54**	**196.44**	**378.01**

27. It is important to note that the state contribution is in addition to the above reported expenditures. The GoI state sharing pattern is at the aggregate NHM level – i.e. 90:10 sharing pattern for North Eastern and Hill states, 60:40 for other states and 100:0 for the UTs presently. The state shares are not explicitly provided in the budget documents of the states, and the practices and timelines for providing this contribution vary across states, thereby making it difficult to ascertain the exact share for RNTCP. Assuming that the maximum possible percentages (40 percent and 10 percent) would have been contributed by the states, the total expenditure (in Table 4 above) has been adjusted to reflect the GoI and state share.

Table 5: RNTCP expenditure in the last three FY (Centre and State)

	Total expenditure in USD millions		
Particulars	**FY 2016**	**FY 2017**	**FY 2018**
Add: Provision of state contribution (to the maximum possible)	11.54	17.00	16.20
Adjusted expenditure to reflect the GoI and maximum state contribution	195.09	213.45	394.22

28. The NSP 2017-25 is costed at US$8.3 billion, which is a substantial increase from the current expenditure levels of RNTCP, as evidenced in Table 5 above. At the current levels, the estimated expenditure for the eight-year RNTCP timeframe may be US$3.2 billion; however, the NSP has an ambitious expenditure target of US$8.3 billion. This is due to the significant increase in activities, including patient support and nutritional support, resulting in multifold increase in TB case notification (from 1.61 million cases in FY16 to 3.35 million cases in FY20).

3.1.2 Budget out-turns at Central and State level

29. The budget out-turns for RNTCP at the GoI level for the last three years have varying results.

Table 6: RNTCP expenditure in the last three FYs (Centre)

	Amounts in INR crores		
Particulars	**FY 2016**	**FY 2017**	**FY 2018**
Budget Estimates (original)	1,340.00	1,640.00	1,840.00
Expenditure reported	1,339.85	1,434.04	2,759.50
Budget out-turns	100%	87%	150%

30. For FY18, as a result of increased donor commitment, the utilization is 150 percent of the original budget, leading to a substantial increase in the Externally Aided Component. The increase was factored in to the Revised Estimate submitted to the Legislature, as the outturn of the expenditure to the Revised Estimate is 99 percent, validating the linkages of the RoP to the Revised Estimates passed in the Supplementary budget.

31. At the state level, as the RoP provides approvals for the annual activities, the out-turn with the RoP approved estimates provides an insight into the planning process (realistic estimates), as well as implementation. The out-turns with the RoP approved amounts for each of the nine priority states are indicated in the table below:

Table 7: RNTCP expenditure in the last two FYs (States)

S.No.	State	FY 2017	FY 2018
1	Assam	38%	45%
2	Bihar	49%	48%
3	Karnataka	65%	77%
4	Maharashtra	80%	78%
5	MP	69%	85%
6	Rajasthan	55%	69%
7	Tamil Nadu	87%	62%
8	West Bengal	69%	79%
9	UP	78%	69%

3.1.3 Program expenditure link to Budget documents/ financial reporting

32. As stated earlier, the Program boundary for this operation includes the state and central level expenditures (including centralized procurement of anti TB drugs). These expenditures are part (sub-set) of the following identified line items in the GoI budget, under Flexi Pool for Communicable Diseases (General Component):

Table 8: Budget head for RNTCP (Central level)

Budget Head	Particulars	Details
State Level transfers *(please note these are not expenditures – expenditures will be tracked at the states level)*		
3601.06.101.13.03.31	Grants in aid to States	With respect to the state level expenditures, MoHFW transfers the funds as grants to the states for RNTCP implementation. The state wise allocation is provided in the RoP. The budget lines provide a consolidated entry for all state releases, segregated into Union Territories, North East states, and other remaining states (each of these have a sub categorization of TSP (Tribal area sub plan), SCP (Scheduled Caste Plan) and others.
3601.06.789.04.03.31	Grants in aid to States – SCP	
3601.06.796.04.03.31	Grants in aid to States – TSP	
2552.00.288.10.00.31	Grants in aid to NE States	
2552.00.789.65.00.31	Grants in aid to NE States - SCP	
2552.00.796.68.00.31	Grants in aid to NE States - TSP	
Central level expenditures		
2210.06.001.09.10.21	Supplies & Materials - Released for Procurement of Anti TB Drugs/Equipment	Procurement done through CMSS, funded by donors and domestic funding appear under this budget line
2210.06.001.09.08.20	Other Administrative expenses	Expenditure pertaining to cloud server, call centre, Nikshay portal, funded by donors only, appears under this budget line
2210.06.001.09.08.26	Advertising and Publicity	Expenditure towards advocacy campaign for DR-TB, funded by donors only, appears under this budget line
2210.06.001.09.08.28	Professional Services	Expenditure towards contractual staff for CTD, funded by donors only, appears under this budget line
2210.06.001.09.08.31	Cash grant to NGOs and NRLs	Direct contracting done by CTD for Private Sector Support, funded by donors only, appears under this budget line

33. The details of GoI releases to the individual states are captured through the sanction orders prepared at central NHM, which are also available on the NHM website. The states provide for the RNTCP budget under the NHM's flexi pool Grant in Aid – few states provide the details of state and central share. The detailed allocation, as per the economic classification, is available in the state RoP, and the states submit expenditures against these standardized reporting heads (referred to as 'FMR codes') on a quarterly basis to CTD. The following state level expenditures (Table 9) and the relevant FMR codes have been considered within the Program boundary across the nine priority states:

Table 9: Budget head for RNTCP (States)

FMR Code	Particulars	Details
H.2	Laboratory materials	Supplies & Materials - Procurement of Anti TB Drugs/Equipment
H.15	Procurement of drugs	
H.17	Procurement of equipment	
H.12	Contractual services	Salaries and Benefits
H.20	Annual increment (program management staff)	
H.21	EPF (Employer's contribution)	
H.3	Honorarium	Honorarium to non-salaried, field health workers
H.6	Training	Training for field and project staff
H.9	PPM FOCUSED PERSONNEL/NGO/PP support	Private Sector Support
H.18	Patient support & transportation charges	Travel & other support to patient for diagnostics and treatment
H.19	Supervision & monitoring	Supervision and monitoring of the operation

The above-mentioned FMR codes are proposed to be revised at the NHM level and are expected to be rolled out in 2019-20. A one-to-one mapping table of current and new FMR codes has been done for RNTCP and is provided in the table below to avoid ambiguity in reporting of relevant Program expenditures:

FMR Codes currently applicable	Particulars	Proposed FMR code (expected to be rolled out in 2019-20)
H.2	Laboratory materials	6.2.14.1
H.15	Procurement of drugs	6.2.14.2
H.17	Procurement of equipment	6.1.1.18. a
H.12	Contractual services	16.8.1.4.1; 16.8.1.4.4; 16.8.1.4.5; 16.8.1.4.6; 16.8.1.4.7; 16.8.1.4.8; 16.8.1.4.9; 16.8.1.4.10; 16.8.1.5.11; 16.8.2.2.1; 16.8.2.2.4; 16.8.2.2.5; 16.8.2.2.6; 16.8.2.2.7; 16.8.2.2.9; 16.8.2.2.10; 16.8.2.2.11; 8.1.1.5; 8.1.5; 8.1.13.1; 8.1.3.8; 8.1.13.10; 8.1.13.11; 14.1.1.2
H.20	Annual increment (program management staff)	
H.21	EPF (Employer's contribution)	
H.3	Honorarium	3.2.3
H.6	Training	9.5.14.1; 9.5.14.3
H.9	PPM FOCUSED PERSONNEL/NGO/PP support	15.5.1; 15.5.2
H.18	Patient support & transportation charges	7.5; 3.2.3
H.19	Supervision & monitoring	16.5

3.1.4 Procurement planning

34. The expenditure on supplies and materials under CTD are estimated to account for 62.8% of total expenditure in the PforR Program. CMSS has received indents for the requirement of 2017-18 for 35 anti-TB drugs and cartridges. A contract for Current Cartridges has already been awarded. The estimated cost for 35 drugs is INR 652 crore (equivalent to US$93.14 million assuming an exchange rate of US$ 1 = INR 70) and the contract cost of Current Cartridges is INR 285 crore (equivalent to US$40.7 million assuming an exchange rate of US$ 1 = INR

70). The total estimated cost of indents received by CMSS from CTD is INR 952 crore (equivalent to US$136 million assuming an exchange rate of US$ 1 = INR 70). As per the current position, the expenditure on procurement by CMSS will be 34 percent of the PforR program, which may increase if some future demands are generated and CMSS receives more indents from CTD.

35. The Central TB Division (CTD) of the Ministry of Health & Family Welfare Government of India, is the lead implementing agency at the central level which is responsible for procurement planning. They are presently implementing the Government of India's (GoI) RNTCP. The procurement of TB control drugs and diagnostics equipment areas are financed from GoI funds. These procurements are done by the Central Medical Services Society (CMSS) in accordance with General Financial Rules (GFR 2017) of GOI. The requirements of each drug and diagnostic equipment will be assessed and consolidated by CTD in the form of an Annual Procurement Plan, based on which the annual indents along with the relevant technical specifications and consignee list (with consignee wise quantity requirement), will be sent to CMSS to arrange procurement. The annual indents from CTD are supposed to be received in CMSS by April every year but are often delayed. For example, the indents for 35 types of first line anti-TB drugs for the requirement of 2018-19 was received only on August 14, 2018. Delays in the receipt of indents result in the delayed start of procurement process.

36. A few consultancy assignments under the Program will be procured by the Central TB Division itself in accordance with GOI procedure, for example, selection of media services and selection of laboratories for CTD's requirement of lab-testing of drugs, as per GFR of Government of India following QCBS/ LCS method of selection. The RFP for these selections will be prepared by CTD in due course as per GOI's RFP for Consultancy (based on GFR 2017 of Government of India).

3.1.5 Procurement profile of the Program

37. The key procurable activities under the Program will be procurement of first line of anti-TB drugs and medical equipment by CMSS, and a few consultancies at CTD level, plus procurement of consumables and emerging requirement of drugs by the states. As such, the procurement under the Program will consist of the following:

- First line of TB control drugs, to be procured by CMSS
- Medical equipment to be procured by CMSS
- Laboratory medical equipment to be procured by CMSS
- A few consultancy assignments, e. g. media agency, laboratory services, independent verification agency for verifying the achievement of DLIs and any other small consultancy assignments to be procured by CTD
- A few consumables and emergent requirement of drugs will be procured by the states in accordance with the guidelines provided by CTD

38. The maximum size of the long-term agreements finalized in 2016-17 and 2017-18 were equivalent to US$ 13.11 million and US$28.18 million respectively, as shown in the following Table. It is expected that the size of any contract for drugs or medical equipment will not exceed US$50 million (the OPRC threshold for goods for the projects with substantial risk rating).

Table 10: Long term contracts for RNTCP drugs (Centre)

Description	2016-2017	2017-18
The total value of long term agreements for RNTCP drugs finalized	INR 918 million (equivalent to US$ 13.11 million approx.)	INR 5104 million (equivalent to US$ 72.91 million approx.)
Largest value of the long-term agreements processed	INR 918 million (equivalent to US$ 13.11 million approx.)	INR 1973 million (equivalent to US$ 28.18 million approx.)

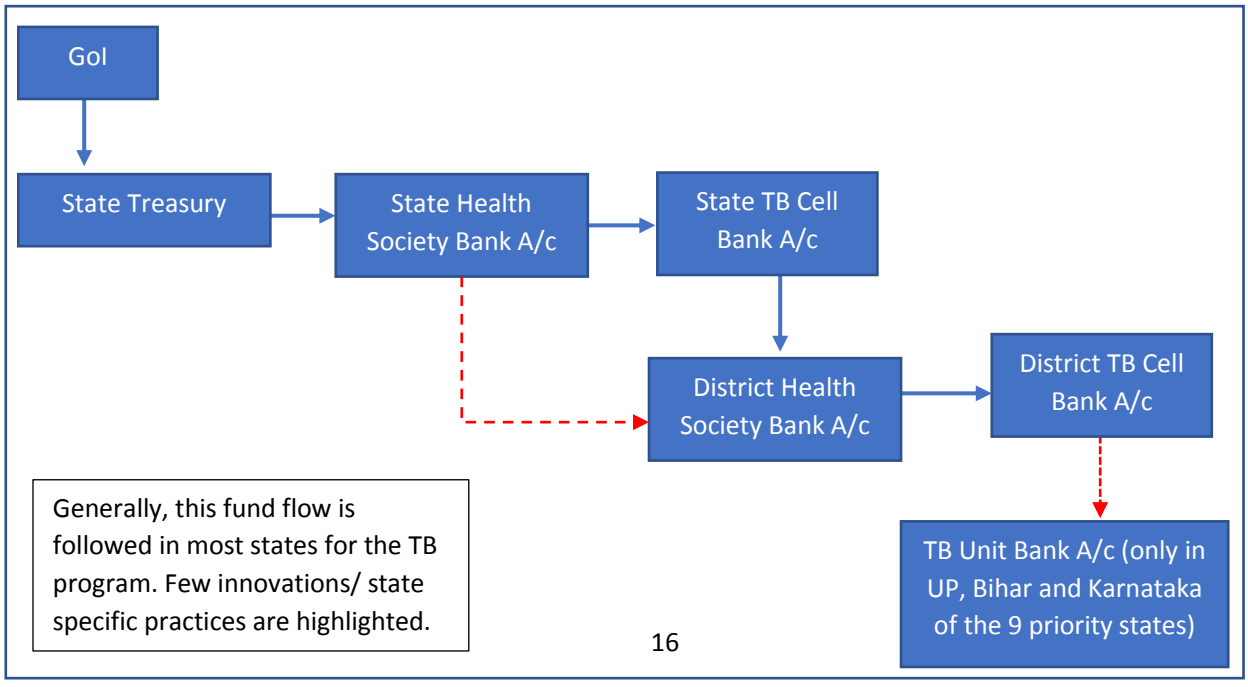
3.2 Budget Execution

3.2.1 Funds flow

39. At the central level, the fund flow will remain within the existing financial management systems of MoHFW, which operates through the centralized Pay and Accounts Office.

40. At the states level, the funds are routed through the State Treasury and transferred through multiple layers from the state level, to the district, block, and TU (in a few states only). Separate bank accounts are maintained at the state for the SHS and State TB Cell; and district for DHS and District TB Cell. State Treasuries transfer the entire funds (including the state share, in some cases) to the bank accounts of the SHS; to State TB cell; then to DHS (based on the requirement of the district), to District TB Cell and eventually to the TU (as per the requirement, namely in Karnataka, UP and Bihar). A few states are exploring variations in modalities for onward fund flow from the SHS – for instance, the Maharashtra SHS transfers the districts' share directly (without routing it through the State TB Cell); MP follows a parent-child bank account modality to ensure aggregation of funds in a common account and funds are not physically transferred across the different levels of implementation – the funds are maintained at the SHS parent account and the child accounts can draw on the latter to the extent of authorization received for each transaction.

Figure 3: Fund Flow Arrangements at States



41. The first installment of the central share is transferred to the States after approval of the GoI budget, generally in April. The amount of the first installment is calculated based on the previous year utilization and unspent balance available with the state. No new activities are considered at this stage, as the PIP process is still ongoing – only the regular activities and establishment costs are considered for this 'provisional' installment calculation. The second installment is processed in December or January generally, aligned to the RoP for the year; followed by a third installment (depending on requirement) in March.

42. As mentioned earlier, the state shares are calculated at the overall NHM level. It is difficult to attribute and identify any shortfalls by the state in providing the matching share for RNTCP. The states have reported varying experiences in this respect. For instance, Karnataka and Rajasthan reported receipt of the state share at the time of release of Central share; UP reported release of state share separate from the central share after considerable delays. NHM is cognizant of these delays and the former tracks the release of state share at an overall basis. As a conditionality for release of the first installment in a given financial year, the state share for the previous year is verified, and the states are given one month to transfer the shortfall, if any. This reconciliation is taken up by NHM from time to time.

43. Delays have been reported in transfer of funds at all levels, primarily at the level of the State Treasury (ranging from one to two months) and in receipt of the state share. These concerns are not limited to the RNTCP and pertain to the efficiency of the state's treasury and financial management systems, which may not be adequately addressed through this intervention. NHM has created a provision to allow the levying of penal interest on retention of such transfers by the Treasury beyond 15 days – however, the provision is not adequately exercised. Further, the agencies that operate outside the Treasury (in this case all implementation agencies within the state), do not face the issue of lapsing annual budgets, and the unspent balances in bank accounts roll over into the next financial year. To mitigate the risk of hampering RNTCP progress due to delays in fund flow, NHM has allowed the various schemes to access temporary loans from available balances at SHS – and this modality is often used at the states level to continue smooth implementation.

44. A multi-year perspective in expenditure planning and budgeting has been lacking in India. While the States have enacted the FRBM Act, which stipulates the requirement of Medium Term Fiscal Policy (MTFP), the detailed medium-term expenditure framework for various sectors are not worked out. Thus, the budgeting remains strictly annual without a multi-year perspective relating to expenditure commitments of various sectors.

45. CMSS: The procurements are done at CMSS as and when the Indent (requisition for procurement of drugs/medical equipment) is received from CTD or any other program. Once the supplier is identified after finalization of the procurement process (as per the prescribed procurement procedures), and the Letter of Acceptance (LoA) from the former is available at CMSS, a demand is raised to CTD for release of funds (to the extent of the LoA amount, plus 3 percent administrative charges and 1 percent testing charges). Subsequently, CTD releases the funds as advances, in a timely manner into a bank account maintained at CMSS, of which payments are made to the vendors as per the terms and conditions of the contract. Any excess funds with respect to the LoA are retained in individual flexi bank accounts to ensure a better rate of interest on the unutilized balances.

3.2.2 Accounting and financial reporting

46. There are currently no provisions for presenting a mid-year budget execution report to the Parliament. The aggregated monthly accounts prepared by the Controller General of Accounts (CGA) for GoI and Comptroller & Auditor General Office [C&AG] for States, compiled from the departmental accounts, provide monthly accounts of budget implementation. The monthly accounts of the central government are important in yearly budget reports that are accessible to the general public through the website of the CGA/State Finance departments. However, the actual expenditure reported at national level are based on fund releases and therefore, do not facilitate meaningful assessment of financial performance.

47. The budget classification system in India follows the COFOG functional classification system and is consistent with the GFS manual of 1986 based on the cash accounting system. The budget classification system as determined by the C&AG office is uniformly applied across all Indian states. The budget classification system in India has improved over the years. A uniform classification was established for the budget accounts, which clearly presents the objectives and purposes of government expenditure. The budget and accounts present department wise programs and activities which bring together all expenditures under appropriate functions (major), program (minor), and activities (subhead) irrespective of the organization administering it. There is also now timely generation of accounts for monitoring expenditure on programs and activities.

48. The accounting standards prescribed by the Government (President of India) on the advice of the CAG, IGAS, are not fully aligned with the Cash IPSAS prescribed by the IFAC. There are differences between the Government Accounting system in India and cash basis IPSAS relating to the structure, disclosures and basis of accounting.

49. Of the nine states, six have the district TB Cell as the last accounting center for RNTCP. Incidentally, these six states were part of the earlier Bank financed IPF projects. Only three states, namely Bihar, UP and Karnataka have accounting centers at the block level. As the SHS and DHS route the funds to the TB Cells, the accounting is not done at their level. The accounting at the state TB Cell is computerized (off-the-shelf accounting software) along with maintenance of manual records. At the districts and below (in case of the three states) the accounting is manual. There is no unified accounting system, and reporting is done manually in excel by the states.

50. In line with the Government Financial Rules (States and Centre), monitoring of financial progress, including processing of fund releases, is typically centered around the submission of Utilization Certificates on an annual basis. Utilization certificates are submitted by the blocks to districts (if applicable), collated or prepared at the district and sent to the State TB Cell and onward to the Finance cell at CTD for reviewing the financial progress of the Program.

51. Annual financial statements are prepared at the level of the DHS and consolidated at the SHS. The states are required to prepare and submit annual program audited financial statements, incorporating receipts and expenditures of the districts and the underlying implementing agencies.

52. Public Financial Management System (PFMS): The PFMS developed by the CGA, GoI is a fund tracking and expenditure filing system that is a viable alternate for unified expenditure reporting. Until now, the

implementation of PFMS has been sporadic, limited to the particular nature of expenditures in the Program. The CTD, SHS and DHS all use the portal for transfer of funds. The TB Cells use PFMS to file expenditure and make payments for particular nature of activities. It is important to note that PFMS does not have a full-fledged accounting functionality yet. Differences have been noted in the expenditure filed in PFMS and those reported in the quarterly Statement of Expenditures prepared by each of the states on the basis of their accounting records. Capacity building support has been provided by the CTD to the states to triangulate the financial progress entered in PFMS and reported through the quarterly SoEs. The roll out and usage of PFMS will be mainstreamed during the Program and all Program expenditure will be reported through this system by the states.

53. Nikshay (MIS): The CTD has developed an online monitoring system 'Nikshay 2.0' to monitor physical progress of the RNTCP. The MIS does not capture any financial data, except for the DBT transactions that are initiated through the portal and pushed to the PFMS portal for payment purposes.

54. CMSS: Accounting is centralized at the CMSS Headquarters in New Delhi. The books of accounts are maintained in Tally with adequate mapping of transactions to the respective government program; thus, making it possible to track client wise transactions and ascertain the unspent balances received from the latter. Annual financial statements are prepared at CMSS in a timely manner.

55. Financial reporting is done by CMSS presently, for each LoA separately, within nine months from the close of the LoA, in accordance with the guidelines issued by MoHFW. A detailed listing of the invoices against which payments are made to the vendor under the respective LoA, is submitted as part of this report to CTD. This report is used for documenting advance adjustment in the books of CTD. Given the one-time financial reporting after the close of the LoA, the advances are adjusted at such time only, instead of regular adjustments. It is recommended that CMSS provide periodic reports on LoA status and available balances to maintain updated records at CTD and improve transparency.

3.2.3 Procurement procedures and processes

56. There is no public procurement legislation at the Central level. However, Public procurement by the Government of India (GoI) and its entities, are governed by General Financial Rules, 2017 ((GFR 2017), particularly in chapters five to eight, which deal with procurement and contract management. Accordingly, the key procuring agencies under the Program, viz. CTD and CMSS will follow the basic principles of GFR 2017 in their procurement procedures.

57. CMSS has developed a SBD for procurement of drugs and medical equipment which is based on the GFR 2017 of GOI and is of acceptable quality for this Program. The other statutes applicable to Government procurement are as follows: (i) Indian Contract Act (1872), (ii) Sale of Goods Act (1930), (iii) Arbitration and Conciliation Act, 1996, (iv) Right to Information Act (2005), and (v) the Competition Act (2002). Additionally, the Delegation of Financial Powers and Rules, Government Orders (GO) and the guidelines issued by the CVC and Manual on Policies and Procedures for Goods, Works and Consultancy contains broad and generic guidelines applicable to all procurements of the government. The bidding document of CMSS stipulates that SME firms (Small and Micro Enterprises) are exempted from payment of earnest money but have to give a notarized undertaking

mentioning the following: in the event of non-fulfillment or non-observance of any of the conditions stipulated in the contract, the SME Unit shall pay a penalty, equivalent to the Earnest Money Deposit to offset the loss incurred by the Tender Inviting Authority consequent on such breach of any bid condition. Twenty percent of the annual requirement of procurement of goods and services will be from the SME. The Government has also earmarked a sub target of 4 percent of procurement of goods and services out of 20 percent from SMEs owned by SC/ST entrepreneurs, as per the Government's notification, effective since 1st April 2012. However, this policy of purchase preference to SMEs for 20 percent quantity does not have any impact on prices as the participating SMEs in a tender, quoting price within the band of L1 + 15 percent would be allowed to supply a portion of the requirement by bringing down their price to the L1 price, in a situation where the L1 price is from someone other than an SME. The bidding document also mentions that it should be ensured that there is no compromise on quality due to these purchase preferences.

58. The procurement of TB control drugs is financed from Government of India (GOI) funds. The procurement of the first line of drugs from GOI funds will be done by the Central Medical Services Society (CMSS) in accordance with General Financial Rules (GFR 2017) of GOI. CMSS is also mandated to procure diagnostic and other equipment as per need of the Program. The requirements of each drug and diagnostic equipment will be assessed (based on last year's consumption, stock available, expected deliveries against ongoing contracts and other relevant factors) and consolidated appropriately for economy of scale by CTD. The indents along with the relevant technical specifications and consignee list with consignee wise quantity requirement, will be sent by CTD to CMSS to arrange procurement.

3.2.4 Procurement by CMSS:

59. CMSS will be the main procurement agency under the Program and as such, this IFSA has reviewed their procurement processes and procedures in detail. The procurement procedures of CMSS are based on the GFR 2017 of the Government of India circulars of CVC and any further instructions of Government of India, which are clear mandatory and enforceable rules, and are freely accessible by the public.

60. Although CMSS was established in August 2011, the procurement function for three programs of the MOH&FW started in 2015-16 and for RNTCP, it was started in 2016-17. At present, CMSS is providing procurement services to four programs of the MOH&FW, i.e. RNTCP, National Vector Borne Disease Control Program (NVBDCP), Family Welfare Program (FWP), and National Aids Control Organization (NACO). The scope of services of CMSS include tendering, bid evaluation, procurement decision, concluding rate agreement, placing purchase order, receiving stores, sampling, and testing, releasing payment to suppliers, and keeping stocks of drugs available in their warehouses for distribution to state TB Cells.

61. All procurement in CMSS is done with two envelope systems through e-procurement on the NIC platform. Most of their tenders are open to national competitive bidding with an exception of one International LIB in 2016-17. For specific requirements they prepare their bidding document based on their SBD. The bidding document contains the technical specification and adequate requirement for quality assurance.

62. The bidding document of CMSS also requires that:

- The Tenderer shall be a manufacturer of Anti TB Drugs (DSTB-IP) with a valid manufacturing license and Certificate of Pharmaceutical Product (COPP), as recommended by WHO for the product offered as per specification given in the tender. The manufacturing license and COPP should be valid on the date of tender opening.
- For all regulated products, the bidder should have at least two years of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender.
- The Tenderer should have supplied 50 percent of quoted or similar Anti TB Drugs quantity during the last three financial years (copies of to be submitted).
- The Tenderer should furnish the Manufacturing License valid on tender opening for each and every product quoted in tender. The license must have been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded.
- The Tenderer shall submit a valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO and a valid WHO/GMP as applicable in current tender for the product offered.

63. Clause 16 of the bidding document further stipulates the following required Quality Control measures:

- Compliance with the technical specification contained in the bidding document
- Ensure quality parameters of supplied goods during complete specified shelf life as indicated in technical specification/bid document/ official compendium
- CMSS will ensure that tendered goods meet the required standards throughout the specified shelf life. For this purpose, CMSS reserves the right to carry necessary inspections and/or tests at any of, or any combination of the following stages:
  i. Pre-Dispatch stage
  ii. Delivery Stage: inspection done once the goods reach consignee location and before taking over supplied goods in inventory
  iii. Post Delivery Surveillance: The drugs and goods shall have the active ingredients and all other parameters at the prescribed level as indicated in official compendiums or technical specifications throughout the shelf life period of the drugs and goods. Quality Monitoring,
- Activities may also be organized by CMSS post-delivery. The supplies will be deemed complete only upon receipt of the quality certificates from the laboratories.

64. CMSS starts the procurement process for RNTCP after receipt of the indent from CTD. After scrutiny of the indent, the bidding document is prepared, and the tender is issued. The bidding document is available on the CPPP portal as well as on the CMSS website. An abridged advertisement is published in the newspapers for information for the bidding community. The time allowed for preparation of bids is three weeks. The submission of bids is online, and the technical bids are opened online on the next day of submission. A spot statement is prepared and uploaded on the portal.

65. The evaluation of technical bids is done by the Technical Evaluation Committee (TEC) consisting of CMSS officers, Program Officer (TB), and one external expert usually from a hospital. The committee examines the

availability of bid security and other documents, conducts a technical evaluation, and verifies the qualification criteria. The report of the TEC is to be approved by the sub-committee of CMSS consisting of DG&CEO (Chairman), OSD, Internal Finance Department (IFD) of Ministry, Director (EPW) of Ministry and Director of Program division (RNTCP). After approval of the sub-committee, financial bids are opened only for technically responsive bidders. A spot statement is prepared and uploaded on the portal. The commercial evaluation is done by a committee called Price Bid Evaluation Committee (PBEC). The committee determines the reasonableness of prices obtained against the tender and prepares a Bid Evaluation Report (Commercial), which is put up to the sub-committee of CMSS (same as for technical BER). This committee recommends approval to the Governing Body of CMSS. The Governing Body of CMSS consists of 16 members with AS&DG as the Chairman. The quorum is comprised of any five members.

66. It was observed that the total time taken in the procurement process, from receipt of indent from CTD, to the issue of LOA, to the successful bidders, ranges from 90 to 240 days. However, there were some improvements in the lead time during the last 10 months. After that, the time taken in receipt of performance security, signing of the long-term agreement, and issue of purchase order for the first tranche requirement, takes another 30 days. The receipt of drugs in CMSS warehouses takes another 60 to 90 days and the drugs on receipt are kept in quarantine status. Sending the samples to the nominated labs for testing and receipt and scrutiny of test reports at CMSS takes another 50 to 60 days. In case of an acceptable test report, the status of the drug is changed to “Active” from “Quarantine”. The dispatch to the GMSD and the transportation takes about 30 days. The drugs received in the GMSD are again subjected to testing by the labs nominated by the states which may also take up to 30 days. After a satisfactory test report, the drugs are sent to the districts and then to the TU and PHI, which may take another 30 days. As such, the minimum time taken for the drugs being available to the consumption unit, takes about 360 days in normal cases after the date of receipt of indent at CMSS.

67. To maintain uninterrupted supplies, the CMSS finalizes Long-Term Agreements (which is similar to a Framework Agreement) with a minimum of two suppliers, for the tendered product with 70 percent of the orders given to L1 and the balance 30 percent to the next Matched Lowest Tenderer. After that the L1/Matched tenderer shall pay a Security Deposit at the rate of five percent of the total value of goods to be awarded. Subsequently, the CMSS issues Purchase Orders against the Long-Term Agreement, as per the demands and requirements, advised by CTD. CMSS then sends the demand for funds to CTD immediately after finalizing the Long-Term Agreement, including their service charges at 3 percent of the value of purchase. As per their revised system, the testing charges as per actuals are claimed later.

68. CMSS had issued five tenders in 2016-17 for RNTCP, out of which two tenders were cancelled (no bid was received in one case and a single bid was received in the other case). A Long-Term Agreement was finalized against one tender in 2016-17, against which one purchase order was issued. The decision on the remaining two tenders of 2016-17 was taken in 2017-18 and two Long-Term Agreements were finalized against which seven purchase orders were issued. Similarly, nine tenders were issued during 2017-18 out of which five tenders were cancelled and four Long-Term Agreements were finalized. Five tenders from 2017-18 were canceled due to technical reasons and low demand.

69. Any procurement related complaint and its contents are examined and analyzed by the concerned officer on the case file and put forward to the competent authority. The format of Bid Evaluation Report of CMSS contains a paragraph named "Complaints and Representations". Any procurement related complaint and its contents are examined and analyzed by the "Technical Evaluation Committee" and/or the "Price Bid Evaluation Committee" as appropriate and discussed in the Evaluation Report(s). The discussion on complaint(s) contained in the evaluation report(s) is uploaded on the website. There is no system to acknowledge the complaint or to send a reply to the complainant.

70. Complaints are addressed by the same staff who handle the procurement, which would not qualify for an impartial and independent system since some of these complaints may be about these staff. In order to address this, an electronic complaint handling mechanism will be developed to deal with grievances including procurement related complaints, which would be handled by an independent team separate from the procurement team. This portal will be used for handling complaints by CMSS for all purchases. The portal should mention the method of filing an e-complaint and the protocol to address the complaints on staff by an independent authority not involved in the procurement process or its approval. This would include monitoring and publishing information on complaints received, the percent of complaints addressed, and the time taken to resolve complaints to build their awareness of the system, and confidence that their complaints will be addressed so that they can utilize it. This would be suitably reflected in the PAP.

71. CMSS has a system of debarment of firms. The debarment of a firm is initiated in case of submission of forged documents, default, or serious quality failure. In such cases, a show-cause notice is issued to the firm and their reply is examined by the concerned GM and then put up to the DG&CEO for approval, followed by an issuance of the 'Order for Debarment'.

72. A few consultancy assignments under the Program will be procured by the Central TB Division itself in accordance with GOI procedure; for example, selection of media services and selection of laboratories for CTD's requirement of lab-testing of drugs, as per GFR of Government of India following QCBS/ LCS method of selection. The RFP for these selections are as per the standard RFP for consultancies of Government of India.

73. Contract administration : The contract administration and logistic functions will be done by CMSS for the contracts awarded by them, which includes but is not limited to, obtaining and maintenance of performance security, keeping a watch on delivery periods, receipt of goods at the consignee warehouses (out of the 20), inspection and testing of the received goods, verification and review of test reports, acceptance of goods, payment to suppliers, and dispatch of goods to the respective state drug stores.

74. Distribution of medicines and medical supplies, storage, and Quality Control: The distribution of medicines and medical supplies, storage and inventory management are done by CMSS through 'e-Aushadhi' software. Procurement of TB medicines is done by the CMSS head office and the consignee list along with the quantities for each consignee is mentioned in the Purchase Order. The distribution of the supplies to the consignees shall be through 20 warehouses of CMSS. Upon receipt of the material from the supplier at the concerned warehouses of CMSS, the inspection and quality testing of medicines starts. Quality testing is being done through empaneled laboratories, and the empanelment has been undertaken through an advertised

tendering process. Laboratories that have qualified the acceptance criteria viz: valid license issued by the State/Central Licensing Authority; valid NABL certificate; experience and analyzing Drugs/ Medicines; qualified staff in the quality control department; available instruments equipment, total capacity of testing; and no involvement in manufacturing activity. During the current year, this system has not been followed and the Government laboratories have been empaneled. The drugs are tested on a sampling basis upon receipt at any of the 20 warehouses under CMSS as per contractual requirement. The arrangements for testing the procured drugs are in place to ensure that the standard of quality is met in every batch that will be distributed to the State and Union Territory authorities. However, delays by the Government labs in submitting test reports have come to light, which needs to be addressed and monitored during implementation of RNTCP.

75. The medicines are quarantined until the clearance of the quality control department based on the laboratory reports has been issued. Only those medicines which are cleared by the quality control department are distributed to the respective units. The 20 warehouses of CMSS have the responsibility of delivering medicines and medical supplies to the respective state warehouses and Government Medical Stores Depots (GMSD). The state warehouses and GMSD further distributes the medicines to the respective health centers, TUs, PHI and end users. Inventory control system needs to be strengthened. The supply chain management of drugs from the CMSS warehouse to the states warehouses, GMSDS, TUs and PHI is monitored by CTD through "Nikshay Aushadi" software management tool. CTD also carries out random testing of the drugs across the country through third party agency and through accredited testing laboratories.

76. To address these risks of quality and stock out of drugs, regular monitoring of quality assurance activities and stock position will be done. The software is to be further improved to ensure accuracy of data up to TU and PHI level.

77. The following key features of the procurement process have been noted:

- Technically responsive tenders are evaluated based only on the "landed price" (all-inclusive price), i.e. Rate per Unit inclusive of all taxes, duties, transportation and other charges as given by the tenderer.
- Bidders are required to quote for at least 50 percent quantity. Bid security is proportional to the quantity quoted between 50 percent and 100 percent.
- CMSS or its authorized representative(s) has the right to inspect the factories of Tenderers before accepting the rate quoted by them, before releasing any purchase order(s), or at any point of time during the continuance of tender. The authorized representative also has the right to reject the tender or cancel the purchase orders issued and/or terminate future orders, based on adverse reports brought out during such inspections. In such a situation, CMSS reserves the right to take other actions against the tenderer including forfeit of security deposit or debarring/blacklisting for the appropriate period.
- In exceptional situations where the requirement is of an emergent nature and it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat orders up to 50 percent of the quantity of the goods and/or services contained in the running tender/contract up to a period of twelve months from the earliest date of receipt of letter of acceptance (LOA). This should be at the same rate or a rate negotiated (downwardly) with the existing vendors, considering

the reasonability of rates based on prevailing market conditions and the impact of reduction in duties and taxes, etc.

- To maintain uninterrupted supplies, the CMSS will place orders with a minimum of two suppliers for tendered products, with 70 percent of the orders given to L1 and the balance of 30 percent to the next Matched Lowest Tenderer.
- In case of requirement of large quantities, CMSS may place orders with three suppliers in the ratio of 50:30:20.
- Partial payments for supply will be considered only after a supply of 50 percent of drugs ordered in the individual purchase order provided reports of Standard Quality on samples testing are received from approved laboratories of CMSS.

3.3 Internal Controls

3.3.1 Internal Controls

78. The internal control framework at national and state levels are embodied in the Budget Manual, Financial Rules and Treasury Code. This is complemented by the the Store purchase manual and Works Manual, and other related employee rules. The RNTCP Manual 2006, Costing norms for NSP 2012-17 and the NHM guidelines govern the internal control framework once the funds are transferred outside of the State systems to the SHS. The latest Finance and Costing norms, as part of the NSP for 2017-25 and aligned to the NHM guidelines, have been developed and are expected to be approved and implemented by next financial year 2019-20.

79. These documents contain principles covering budgeting, revenue and expenditure, delegation of authority, accounting, procurement, pay, allowances and pensions, stores, works etc. While the control systems are applied consistently for expenditure processed through the Treasury systems, there is variation in practices and control environment once the funds are transferred outside of the State systems. The expenditures are not subject to Treasury controls nor are these audited by C&AG at the state level.

80. Payroll controls are robust for payments through Treasury systems; these controls however, do not extend to RNTCP staff engaged on a contractual basis. The payroll of the contractual staff is processed at the individual agency level, with controls such as biometric attendance and transfer of salary to employees' bank accounts through PFMS. The PFMS portal has the functionality of processing a one-time beneficiary validation at the time of registration of the beneficiary (in this case, employee) on the portal - the banking details provided by the employee are uploaded in PFMS, which interacts with the Core Banking System of approximately 100 banks and validates the information provided. At this point, the PFMS allows payments to be made to the beneficiary, minimizing the risk of payment to ghost employees and double payments. There are however, occasional delays reported in the processing of salaries.

81. The Program expenditure includes minimal levels of capital assets, limited to office furniture, computers etc. at TB Cells, which are typically subject to asset management systems at the level of the individual agencies.

There is no evidence of planning for cash flows. Regular Internal Evaluations are initiated from the Central and State levels to review the progress of implementation and compliance to norms and guidelines.

82. CMSS: CMSS is under the administrative control of MoHFW, led by an official of the rank of Joint Secretary to the GoI. The internal control framework of CMSS is governed by GFR 2017. As stated earlier, CMSS is a lean organization with centralized accounting at the Head Office. Regular reviews are held by the management to review the progress of the contracts.

83. Regular meetings are organized to review Program progress at the various levels of implementation and are chaired by NHM representatives. However, there is no periodic review meeting of the TB finance officials at the state, district, or central level. To improve monitoring and oversight over the financial management arrangements of the Program, periodic review meetings of the financial management officials from the state and district TB Cells with the CTD financial management cell are recommended. Such meetings will be organized every six months, with the agenda to review financial progress reporting, PFMS roll out, audit findings and compliance, and other financial management issues.

3.3.2 Internal audit

84. A concurrent audit is conducted on a quarterly basis by private Chartered Accountants appointed by the SHS and DHS. For the DHS, the concurrent audit is required to cover 60 percent of the facilities every year at the district level (including operations below the district). The consolidated report for the district is prepared by the concurrent auditor and submitted to the DHS which is then submitted to the SHS. Similarly, a consolidated report for the state is prepared by the concurrent auditor at the state level, covering all cells every quarter, and submitted to the SHS. The reports are then forwarded to the Central NHM for review. As noted during the discussions at the states, there is a one quarter lag in the state concurrent audits; and the coverage at the district level appeared inconsistent with the requirement of two visits every year. In case of any findings pertaining to RNTCP, the Central NHM shares the Executive Summary of the same with CTD for information and action.

3.4 Program governance and anticorruption arrangements

3.4.1 Governance and anti-corruption

85. Although implementation of the governance and accountability arrangements on the ground varies from state to state, overall these systems provide a good foundation for improving transparency and accountability of RNTCP. In general, the line department oversight is fulfilled by a chief vigilance officer, and Vigilance Committees are also established at district levels with varying degrees of effectiveness. CTD and CMSS operations fall under the purview of Central Vigilance Commission (CVC), Comptroller and Auditor General (CAG) as well as the Right to Information Act of Government of India.

86. Under the RNTCP multiple innovative ICT enabled surveillance and treatment adherence systems have been developed and piloted. One such initiative is the NIKSHAY platform, an integrated ICT system for TB patient

management and care. The operation intends to further strengthen NIKSHAY (referred as NIKSHAY 2.0) platform by way of integration with the Public Finance Management System (PFMS) to: i) enable DBT and ii) streamline financial operations with the National Health Mission (NHM) and Aadhaar (Unique ID) platform which will enable authentication of beneficiaries, thus preventing any duplication or false entries in the system.

87. As part of the PAP, it is recommended that CTD includes a "Beneficiary Satisfaction Survey", which will not only evaluate on DBT aspects but also other aspects of the TB program.

88. Regular meetings are organized to review the RNTCP progress at the various levels of implementation, chaired by the NHM functionaries. However, there are no periodic review meeting of the TB finance officials at the state and district levels at the central level. To improve the monitoring and oversight over the FM arrangements of the Program, periodic review meetings of the FM officials from the state and district TB Cells with the CTD FM cell are recommended. Such meetings will be organized every six months, with the agenda to review the financial progress, reporting, PFMS roll out, audit findings and compliance, among other FM issues. Every state has an Audit Committee at the NHM level, that meets two to three times a year to discuss the audit plan, findings, and compliance.

89. All Government officers, as well as the officers of CMSS, are governed by stringent anti-corruption laws applicable in India. The Prevention of Corruption Act 1988, which is the primary anti-corruption statute in India, criminalizes the receipt of illegal gratification by public servants and payment of such gratification by other persons. In addition, the Central Government has constituted the Central Vigilance Commission (CVC) pursuant to the Central Vigilance Commission act 2003. CVC is the Government watchdog that is tasked with inquiring into (or commissioning enquiry into) offenses alleged to have been committed under the PCA. It is also responsible for advising planning, executing, reviewing, and reforming vigilance operations in Central Government organizations. One CMSS officer has been nominated as Vigilance Officer and looks after vigilance functions in CMSS. The Lokpal and Lokayukt Act 2013 is a recent Act which provides for the establishment of a corruption ombudsman, called Lokpal at the central level and Lokayukt at the state level, which act independently from the executive branch of the Government. These bodies have been empowered to investigate allegations of corruption against public functionaries, including offences under PCA. In addition, there are several other safeguards and statutes to deal with corruption among public officials. Despite these rules and regulations, the risk of corruption cannot be completely ruled out. However, the existence of such stringent laws in India provide a reasonable assurance against the Fraud & Corruption (F&C) risk.

90. The Program will be subject to the Bank's Governance and Anti -Corruption Guidelines, namely the Guidelines on Preventing and Combating Fraud and Corruption in Program-for-Results Financing.

3.4.2 Sharing of Debarment list of firms and individuals:

91. The Government of India commits to using the Bank's debarment list to ensure that persons or entities debarred or suspended by the Bank are not awarded a contract under the Program during the period of such debarment or suspension. The current list of debarred firms is available on the Bank's website

"www.worldbank.org/debarr and will be updated regularly on the Bank's website. List of suspended firms could be accessed through e-Biz website of the Bank.

92. In addition, the GoI also agreed to include some disclosure measures in bidding documents for works, goods, and services to be financed under the Program, including ensuring that firms and/or individuals declare that they have not been debarred or suspended and/or have any links with a debarred entity or individual.

3.4.3 Sharing information on fraud and corruption allegations

93. In line with the ACGs, the government (through MoH&FW) will share with the Bank all information on fraud and corruption allegations, investigations and actions taken on the Program, including on procurement as needed. The details of this reporting would include the types of allegations and the status of actions taken.

3.4.4 Investigations of fraud and corruption allegations

94. After informing the Bank, the MoH&FW shall start its own independent investigation of F&C allegations and take suitable action as per laws of India. The Bank INT may undertake its own F&C investigations. To this extent, the Program Participation Agreements to be entered into between MoH&FW and the procuring agency, will ensure that MoH&FW and INT are able to acquire all records and documentation that they may reasonably request from the Program Implementation Units regarding the use of Program funding. The Government of India has committed to implementing the Program within the Bank's Anti-Corruption Guidelines.

3.5 Program Audit

95. Audit of the Program is conducted by private Chartered Accountants (empaneled by C&AG) at each state. The auditors issue a consolidated audit report for the SHS as well as an individual report for the RNTCP. This practice has been standardized to a certain extent across the states. The same audit arrangements were followed during the previous Bank funded IPF projects, and the audit reports well received with delays of two to three months from the agreed timeframe. No major observations were reported in these RNTCP audit reports. The consolidated SHS audit reports are disclosed on the NHM website.

96. CMSS: An audit is conducted by a Chartered Accountant (empaneled by the CAG), which is submitted to the CAG for endorsement and issuance of an entity audit report for CAG. This report is issued during September/October each year – the report for the year 2017-18 was submitted to CMSS on October 29, 2018. No major observations haven been highlighted by the CAG as part of the statutory audit report. Additionally, a transaction/ procurement audit is conducted by the CAG – this audit has been due for the last two years and is expected to be undertaken in late November 2018. The audit reports are submitted to the Governing Body for review and discussion. The audit reports are available to the public as part of the Annual Report published by CMSS.

97. For the Program, the World Bank will rely on the existing audit mechanisms of the state and will monitor the following audit reports over the Program implementation period. The audit reports will be shared by CTD with the World Bank.

- State TB Cell audit reports (providing adequately detailed expenditure identified under the Program boundary), audited by private Chartered Accountants. The report should be submitted to the Bank within six months from the close of the financial year, i.e. September 30, 2018.
- Entity audit report of CMSS that includes expenses incurred under the Program - the report should be submitted to the Bank within six months from the close of the financial year, i.e. September 30, 2018.
- Audit report for central level expenditure incurred at CTD under the Program, audited by CAG - the report should be submitted to the Bank within six months from the close of the financial year, i.e. September 30, 2018.

98. The external audit scope would include these specific points: (i) review of contracts to ensure that contracts are not awarded to sanctioned firms; (ii) focus on internal control systems for assessing their effectiveness; (iii) verification on a sample basis of all contracts to ensure no High Value Contracts over the OPRC limits are funded under the Program without approval; and (iv) complaints received were satisfactorily addressed. The Terms of Reference would be finalized before negotiations.

99. Program Audit Arrangements: The audit arrangements applicable for the Program are shown in the Table 11 below:

Table 11: Audit report submission timetable

Scope of Audit	Responsibility	Due Date for submission to the Bank
All nine State TB Cells	Private CA firms	Within six months of close of each financial year
CMSS	CAG	
Central level expenditure incurred at CTD	CAG	

3.6 Procurement and Financial Management Staffing Capacity

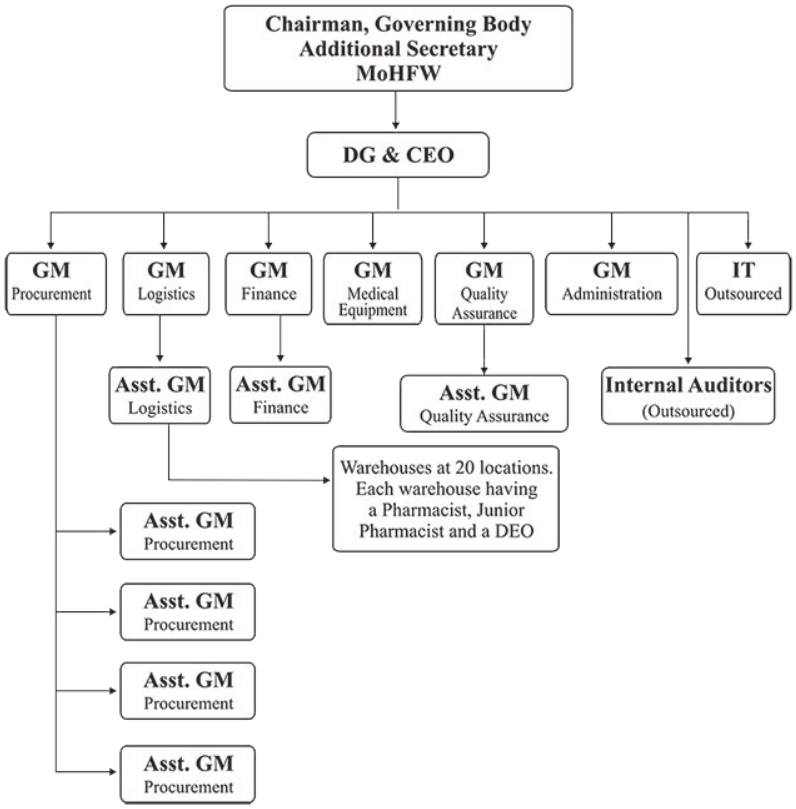
3.6.1 Staffing

100. At CTD, the finance function is headed by Additional DDG, supported by a fully staffed FM Cell with seven consultants appointed from the open market. At the state and district levels, there are vacancies in the Finance function, leading to work overload on the existing staff. Certain states – Karnataka and Bihar - have highlighted that Accountant posts are not present uniformly across all districts in the state. Adequate staffing is required to be maintained throughout the Program life.

101. CMSS is a very lean organization consisting of a total of about 30 employees at their Head Office in New Delhi. The DG&CEO of CMSS is a full-time employee of CMSS in the rank equivalent of Joint Secretary to Government of India. The DG&CEO is responsible for overall management of CMSS. All General Managers report to the DG&CEO through OSD. The General managers are responsible for the following functions; (a) procurement, (b) logistics, (c) quality control, (d) bio-medicals, (e) finance, and (f) administration. The total manpower in the

head office is comprised of 13 Managers and 17 Support Staff. All staff and officers are on contract appointment except the DG&CEO and the OS. The organizational structure of CMSS is provided below:

Figure 4: Institutional structure of CMSS



102. The posts of General Manager- GM (Medical Eqpt) and one post of Asst. General Manager-AGM (Proc) have not been appointed so far. Further, the post of one AGM (Proc) has been vacant for quite some time and selection process for filling the post is in progress. Each warehouse has only three employees, two Pharmacists and one IT person - packers and loaders are outsourced.

The staffing in the procurement unit of CMSS (the main procuring agency) is inadequate to support the magnitude of work load. As a result, some key issues are not given the necessary attention. For example, the retrieval of data and records takes more time than necessary, due to an inadequate record keeping system. There is only one GM assisted by three AGMs and three support staff for all four programs under which procurement is done by CMSS. For RNTCP, only one AGM is available 50 percent of the time, as one AGM post has been vacant for some time. The magnitude of procurement is expected to increase manifold due to the implementation of this project and will put additional pressure on existing staff weakness. This may result in delayed disposals and delays in finalizing the procurement related matters and inefficiencies in managing procurement processes, and inadequate contract management. These risks will need to be addressed, monitored, and evaluated throughout the Program. It is noted that, CMSS has initiated the process of filling the vacant positions.

3.6.2 Capacity Building:

103. The Program has been in the process of rolling out PFMS for expenditure filing. It has been agreed that only expenditures recorded in PFMS will be used as a basis for expenditure reporting by the states. This will need capacity building support and hands on training of staff across the different levels of implementation.

Section 4: Program Systems and Capacity Improvements

104. Based on the assessment, the following key risks and proposed mitigation actions have been proposed as PAP:

Table 12: Fiduciary Risks and Proposed Mitigation Measures

Risk	Mitigation Action	Timeline	Type of action (PAP, DLI etc.)	Responsibility
Strengthen the capacity of CMSS to manage the procurement and supply chain management for drugs and equipment in line with increased workload emanating from the Program	a) Filling the five vacant staff positions (b) Expanding number of laboratories to conduct post destination quality assurance (presently five labs), and (c) enhancing CMSS/Supplier interface and overall procurement efficiency	Sept 30, 2019	PAP	CMSS/CTD
Decentralize data entry on TB drug stock in the Nikshay Aushadhi software at TU level.	Nikshay Aushadhi software data reliability and accuracy at TU level verified.	Sept 30, 2019	PAP	CTD
Fraudulent documents submission by the bidders	The authenticity of experience certificates and other documents (submitted with the bid) will be checked and verified on a random basis or when in doubt.	Throughout the currency of the Program	Regular monitoring	CMSS/CMSS
Non- availability of good quality drugs at all stocking/ service delivery points	Regular monitoring of stock position at all GSMDs and ensure that the stock levels including reserve stock are always available.	Throughout the duration of the Program	Regular monitoring	CTD/CMSS

Procurement related complaints are not properly attended	An electronic complaint handling mechanism to be developed to deal with procurement related complaints. The portal should mention the method of filing an e-complaint and the protocol	Within six months of implementation of the Program	Clubbed with PAP action on Grievance redressal	CMSS and CTD
Ensuring quality of drugs on receipt at the CMSS warehouse as well as at the state GMSD	Ensure proper testing by empaneled independent Quality Assurance Lab	Throughout the duration of the Program	Regular monitoring	CMSS & CTD
Absence of unified accounting system and manual reporting across different implementing agencies	Implementation of PFMS to monitor and track real time fund utilization, including preparation of expenditure reports from PFMS	From start of the Program and throughout the Program life	PAP	CTD and States
Lack of support in PFMS roll out, leading to incomplete expenditure data	Establishment of a technical support unit at the central and state level to facilitate roll out of PFMS and adequate staffing		DLI	CTD and States
Scope to improve the monitoring and oversight over the FM arrangements of the Program	Regular FM review by CTD of the state and district TB cells (once every six months)	Within six months of Program implementation and throughout the Program life	PAP	CTD and States
CMSS sends utilization reports nine months after contract closure	Six monthly reporting of physical and financial progress by CMSS to the CTD	Within six months of Program implementation and throughout the Program life	PAP	CMSS

Monitoring Fiduciary Performance over Program Period

105. While key fiduciary areas requiring specific actions for strengthening government systems have been listed in the Program Action Plan, it will be important to also monitor the overall fiduciary performance during the duration of the Program. Table 13 below identifies the specific indicators which will be monitored (together with the relevant baseline position) to provide the framework to measure improvements in the performance of financial management and procurement processes.

Table 13: Key Performance Indicators

Indicator	**Measure**	**Baseline**
Funds transferred in a timely manner (measured in Days)	This will be measured at three levels:	Generally, 30-60 days

Indicator	Measure	Baseline
	• Funds transferred from Centre to state • Funds transferred from state to implementing agencies • State funds provided by state	
Effectiveness of internal audit function	Review at State TB Cell and CTD of concurrent audit findings of the District TB Cell on half yearly basis	No structured process for such review at CTD currently
Timely preparation of annual financial statements within three months from end of FY	Completeness and timeliness of annual reports prepared by states and submitted to CTD	Incomplete and untimely annual financial statements from few states
Periodic Financial Reporting submitted by CMSS	Regular periodic reports to be submitted by CMSS to CTD on LoA progress (submissions every quarter)	Currently at end of delivery of every procurement contract
Effectiveness of internal controls	Existence and effective use of financial management and cost norms. Timely and accurate information system for decision making	Notification of updated Finance and Costing Norms for NSP 2017-25 underway
Timely submission of audit reports within six months from end of FY	Submission of audit reports within the agreed timeframe of six months from the closure of the financial year by states and CTD to the Bank	Submission delayed by 2-3 months from the agreed timeframe in the previous IPF project (similar audit arrangements in this operation)
PFMS rolled out across states	PFMS rolled out for the Program and all transactions and reports are generated from the software	PFMS partially implemented
Average length of procurement processes from receipt of indent to award of contract	Number of days between date of award and date of receipt of Indent from CTD to CMSS and contracts are issued within original bid validity	Generally, 90 to 240 days
Time taken for supply of drugs after receipt of award by the supplier and receipt of drugs at CMSS warehouse	Number of days between the date of award and date of supply by the supplier and receipt of drugs at CMSS warehouse	60-90 days
Time taken for testing of drugs	Number of days between Quarantine to Active (receipt of drugs at GMSD warehouse to the clearance to further distribute the drugs to the state warehouse after testing)	Generally, 50 to 60 days
Percentage of procurement complaints addressed	Number of complaints received and addressed by the CMSS	No record of complaints are maintained in CMSS currently

Implementation Support

106. Based on the Program risk profile, the Bank team will undertake at least bi-annual implementation support and need-based short technical missions with the objective of reviewing the progress of the fiduciary related activities in the Program Action Plan.