Annex 1

SUMMARY OF MAIN LEGISLATIVE ACTS REGARDING TUBERCULOSSIOS IN ROMANIA

October 2016

No.	TOPIC	LEGISLATIVE ACTS	MAIN REGULATIONS APPLICABLE TO TB Comments (in italics)
1.	Right to protection of health	**Constitution of Romania**	- Citizens' rights ARTICLE 34 Right to protection of health "(2) The State shall be bound to take measures to ensure public hygiene and health."
2.	The right to medical care of the highest quality	**Patients' rights law no. 46/2003**	- Patients have the right to health care of the highest quality that the society has, according to human, financial and material resources - ***art.2***
3.	Equal access to the patients to medical care	**MoH order no 386/2004** regarding the aproval of the Norms for applying the patients' law no 46/2003	Medical units have to provide equal access of patients to medical care, without discrimination on race, sex, age, ethnic, nationality, religion, political views or personal antipaty – ***art 2- (1)*** Medical units shall use all means and resources available for providing high quality medical care - ***art. 3***
4.	Right to free of charge medical care for TB patients	**Law no. 95/2006 on health reform**	***Art.224 (1) letter e) -*** *The following categories of persons are covered by insurance without paying contributions:* e) patients with diseases included in national health programs established by the Ministry of Health, with no income from employment, pension or other resources;" *Conclusion: all the persons who are or not contributing to social health insurance system are entitled to TB treatment for free (This right is also mentioned in MoH Order 1171/2015 (issued on October, 7, 2015) re. approval of the "Methodological Guidelines for implementation of the national prevention, surveillance and control of tuberculosis programme")*
	Providing the treatment for free, based on medical prescription	**Government decission no 161/2016**	Drugs without personal contribution for outpatient treatment are given on prescription issued by physicians who are into contracts with health insurance funds. Starting with the entry into force of this decision, contracts for the supply of medical services, drugs, with or without personal contribution in outpatient care and medical devices will be signed by 31 December 2016. - ***art. 168***

	- Providing medical inpatient services only based on refferal ticket/ recognition of the ticket based on agreement signed - Medical services provided under (continuous) hospitalization	**Government Decision no. 161/2016** for the approval of service packages and the Framework Contract which regulates medical assistance care, medicines and medical devices in the health **insurance system for the years 2016 - 2017**	Hospital services under continuous hospitalization and day care are provided on the admission ticket issued by: a) family physician; b) doctor specialist from outpatient health care facilities, regardless of organizational form; c) physicians from medical and social assistance units; d) doctors from private dialysis centers under contract with the health insurance / National Health Insurance House, as appropriate; e) doctors who work in TB dispensaries, mental health laboratories or mental health centers, and outpatient psychiatric centres, dental units that are not in a contractual relationship with the insurance of health and how structure in hospitals as units without legal personality; f) occupational doctors - ***Annex. 1 Cap. II, item f pt. 11*** Houses health insurance sign agreements with medical and social institutions, with hospitals for TB dispensaries, mental health laboratories or mental health centers and outpatient psychiatric clinics for dentistry which are not in contractual relations with insurance funds health and hospital structure is as units without legal personality, as well as occupational medicine cabinets organized under the law in force for the recognition of admission tickets issued by doctors who work in these units. - ***Art. 89 - (1)*** **(-) Provisions regarding TB package of services that can be offered (*with reimbursed*) to family doctors were not included in the new Framework Agreement.** **(!) In order to create the premises for the ambulatory treatment of TB patient, it is recommended to include the TB services into the basic package under the frame contract with NHIH, taking into account a possible performance-based financial incentive. Also, the reintroduction of the fee for TB services under the point system used by NHIH, could be taken into accout as part of a mixed payment method (*including the curently*).**
		Ministry of Health Order no. 763/377/2016 regarding the approval of the Methodological Norms in 2016 of the Government Decision no. 161/2016 for the approval of service packages and the Framework Contract which regulates medical assistance care, medicines and medical devices in the health insurance system for the years 2016 – 2017 Copy-acte normative\OMS763_377_2016_Methodological Norms.pdf	**Reimbursement for hospitalization to medical units is based on the admission ticket.** **Health insurance funds conclude agreements with medical and social units, hospitals for doctors who work in TB dispensaries** [...] - for the recognition of admission tickets issued by doctors that work in these units (***Art. 16 of Annex 23*** – *The Conditions of providing medical services in hospitals with beds and payment thereof* - *the* ***Convention model is set out in Annex no. 42***) - for recognition of the medical prescriptions for drugs with or without personal contribution issued by them (***Annex 36, art. 1, (7)*** ; ***the model agreement is set out in Annex no. 41 notes***) The Health insurance house (CNAS) is required to monitor monthly hospital services provided on the basis of admission tickets issued by doctors who work in TB dispensaries with whom there were concluded conventions. The obligation is included in the *convention on*

			*issuing a admission ticket – **art.3** of the convention as for the model provided within Annex 42*
			Hospital services offered are: continuous hospitalization and day care. *Day care services type are completed in accordance with the accordance with those provided within **letter B of Annex 22*** Conditions of providing medical services in hospitals with beds and payment thereof - ***Annex. 23 of Order.*** Providing hospital services is granted based on hospital contracts with health insurance funds, given the specific indicators of hospitals, as well as appropriate a) quantitative and qualitative indicators ***Art. 4 - (1) of Annex. 23*** For 2016, the amount contracted by the hospitals can not be higher than the maximum 25% of the contracted amount in the previous year for continuous hospitalization for acute patients. - ***art. 5 of Annex 23*** The total value contracted by the hospitals with health insurance funds shall consist of the following amounts, as applicable: a) amount for the hospital services for acute conditions, payment of which is done on a fee per case solved (DRG) for the hospitals funded on DRG bases, or average tariff on resolved case for non DRG hospitals, shall be as follows: - Number of cases discharged contracted x Case Mix Index 2016 x price per weighted case for 2015, respectively - Number of cases discharged contracted x average price per case resolved per specialties a1) contracted amount (SC) by every hospital mentioned in ***Annex no. 23*** to the order with house health insurance for continuos hospitalization for acute conditions in DRG system is calculated as follows: **SC = P x (No_bed x IU_bed /DMS_ hospital) x ICM x TCP** In the previous formula No_bed represents the number of beds aproved and wchich can be contracted after aproval of the National Plan for Hospital Beds, which not include the beds for departments of intensive care. IU-bed, DMS-Hospital, TCP and ICM represents the index of using beds, the average using of hospitalization at the hospital level, price per weighted case and case mix index.

			Average duration of hospitalization atthe hospital level – DMS_hospital is mentioned ***in annex 23 A.*** The value of the precentage of reference is set based on the hospitals clasification depending on competences and it is as follows: a) for category I: P = 85%; b) for category IM: P = (P - 4)%; c) for category II: P = (P - 3)%; d) for category IIM: P = (P - 5)%; e) pentru categoria III: P = (P - 5)%; f) for category IV: P = (P - 15)%; g) for category V: P = (P - 23)%; h) for hospitalis which cannot be clasified: P = (P - 33)%. For 2016, the amount contracted by the hospitals can not be higher than the maximum 25% of the contracted amount in the previous year for continuous hospitalization for acute patients, excepting the hospitals provided at positions 29, 30, 31, 57 and 263 of ***Annex 23A***. List of hospitals for which payment is made by price per case resolved, ICM, TCP and DMS valid for 20156are listed in ***Annex no. 23***. b) the sum for hospitals for chronic diseases as well as chronic wards and departments (provided as separate structures in the hospital structure approved / endorsed by the Ministry of Health) from other hospitals, is determined as follows: number of cases discharged x length of hospitalization specified in ***Annex. 25*** or, where applicable, actually lenght of hospitalization x price per day of hospitalization 1. Number of cases discharged The number of cases discharged on hospitals / wards / departments is negotiated by: - The average cases discharged from hospital in the last 5 years (taking into account the structural changes approved / Ministry of Health, as applicable) and the county; - Cases expected to be discharged on hospital and on ward in 2016, depending on the number of beds which can be contracted, the average index use of beds for wards / departments for chronic patients nationwide and length of stay specified in Annex. 25 or, where appropriate, length of stay actually carried out, for wards / departments where it was lower than that prescribed in Annex. 25, but not more than 75% compared to this, in compliance with art. 4 para. (1), by case. The annual number of cases discharged negotiated broken down into quarters. In determining the number of cases discharged contracted by hospital / ward / department to take account of

			the manner the qualitative indicators were achieved in the previous year; For this purpose, hospitals will keep track of these indicators. The number of cases discharged, obtained under the conditions set out above, may diminish by negotiation between providers and health insurance funds, with the number of admissions in hospitals for the year 2015 for which the hospitalization is not justified. 2. Duration of hospitalization on wards applies to all categories of hospitals as stipulated in ***Annex. 25***. For wards / hospitals with compulsory admissions for patients under art. 109, art. 110, art. 124 and Art. 125 of Law no. 286/2009 on the Criminal Code, as amended and supplemented and arranged by the prosecutor during the trial or prosecution, for patients requiring long-term hospital care (years) and for sections / departments of neonatology - the premature from grade II and III maternity, psychiatric and chronic lung disease adults and children consider the length of stay actually achieved in 2015. 3. The price per day of hospitalization ward / department is negotiated based on daily hospitalization fee proposed by each hospital for its wards and departments, given the documents to substantiate the charge, depending on the particularities of each type of hospital, respecting the amounts approved at the level of health insurance intended for hospital services. Prices per day of hospitalization negotiated can not be higher than the maximum rates set out in ***Annex. 23 C***.
5.	Continuous hospitalization and day care	**MoH Order no. 1.782/2006** regarding the registration and statistical reporting of patients receiving continuous inpatient medical services and day care	Day care service represents the services as *medical-surgical emergency in emergency rooms and medical surgical emergency within hospitals structures for which funding is not from the Ministry of Health budget* as included within the List referred to in subparagraph B section. B.3 of point. 3.2 of Annex 22 to the MoH Order 763/377/2016 - positions 37 and position 38. - differentiate records of hospitalization is registered: by case solved or service, work done in emergency rooms and in reception emergencies of the hospitals for which funding is not from the Ministry of Health and ministries and institutions with own sanitary network not requiring hospital admission – *for wchich the sheet is compelted different taking into account the model set out in Annex. 3 to Health Minister Order no. 1.706 / 2007 regarding the management and organization of emergency units (UPU)* Obligation to include within the patient sheet a mandatory mention regarding the type of admission ticket as follows: 1 - without admission ticket; 2 – FD admission ticket (BI MF); 3 - Specialist admission ticket (BI MS); 5 - Admission by request; 9 - Other: {…}, **doctors who work in TB dispensaries,** For hospitalization, the services are provided based on a *General clinical observation sheet (*

			FOCG) for the departments Pneumology (1301); Paediatric Pneumology (1302)
		Government Decision no. 449 / 2014 regarding the approval of the National Plan of hospital beds for the period 2014-2016	***Art.1, letter c)*** **–** for 2016, the total number of beds approved at national level is 119.579, including also the beds from of continuous hospitalization departments for acute or chronic care.
		MoH order no. 412 / 2016 approving the rules of confirmation as for the clinical and medical data at patient level for continuous hospitalization cases and day care and the methodology of evaluation of unconfirmed cases in terms of clinical and medical for which the reconfirmation is requested.	Starting July 2016 includes the obligation for the hospitals to report , by electronical means: - the minimal set of data as for the continuous hospitalized patients - discharged ones –***art. 2*** - the minimal set of data as for the day case hospitalized patients - for the solved cases/services provieded within the month of reporting.
6.	Reimbursment of the medical services in ambulatory care specialised services	**The Government decision no 161/2016**	➢ is done by doctors who work in TB dispensaries [...] that have not contract with the health insurance fund, which is in hospital structure as units without legal personality – ***art.32, (1), letter h)*** ➢ As for ***art.32 para(2),*** the Health insurance houses reimburse specialized outpatient medical services for paraclinic specialities, based on refferal tickets issued under the conditions established by norms, by: a) family doctors under contract with a health insurance house; b) specialty physicians in outpatient units, are in contractual relationship with a home health insurance c) physicians in medical offices belonging to ministries and institutions with their own medical network from defense, public order, national security, which are in contractual relationship with a health insurance house. d) dental practitioners and dentists from school and university dental cabinets, only for pupils and for students, dentists and dentists from dental cabinets from prisons, only for inmates for retroalveolar and panoramic dental radiography. e) **doctors who work in TB dispensaries, in laboratories for mental health, or in mental health centers and outpatient psychiatry, family planning, dental offices that are not in a contractual relationship with health insurance house, which is in hospital structure as units without legal personality** – *for specialized outpatient medical services for laboratory specialties see art. 78 - (1)*
		Order of Ministry of Health no. 386 / 2015 on the approval of the norms for technical achievement of national public health programs for 2015 and 2016	Drugs that are granted for outpatient treatment of patients with HIV / AIDS and tuberculosis are issued by closed-circuit pharmacies belonging to medical units which run these programs on prescription / medical registry. In order to justify the consumption of specific drugs provided under programs such prescriptions / fillet registry shall be submitted to public health departments or, where appropriate, to units of technical assistance and management, together with the schedule summary and reports of closed-circuit pharmacy- ***Art. 13*** TB medical units or units which have in their organizational structure wards / clinics for lung

			diseases, provide treatment and monitoring therapeutic response for Tb patients. *** may prescribe recipes, including in outpatient care and can performe treatment under direct observation**
7.	Encoding algorithm of the organizational structures of the medical units	**MoH Order No. 457/2001** on the regulation of naming and codifying of the organizational structures (sections, departments, laboratories, offices) of the medical units in Romania.	There is a general classification on units / departments of Pneumology (code - 1291), respectively Pneumoftiziology (code-1 301) (-) There is a single code for Pneumoftiziology departments without differentiate TB and non-TB **Is recommended to introduse new codes in order to differentiate between susceptible and multidrug resistant (*eg adding subdivisions - X.01, TB wards, X.02 type -MDR condition, X.03, pediatrics, etc).* Thus, the legal framework should be amended accordingly!**
8.	Codification of primary and secondary diagnoses - *coded according to the disease List as for the RO DRG v.1 classification*	**MoH Order no. 1.199/2011 regarding the introduction and utilization of clasification of RO DRG v.1**	Established the medical codification of diseasses in the hospitals and codification of medical procedures in the hospitals and specialized outpatient units ***–art. 2 (1-2)***
9.	Family doctors & school doctors	**Law no. 95/2006** on health reform **MoH[1] Order no. 1171/2015** re. approval of "Methodological Guidelines for implementation of national prevention, supervision and control of tuberculosis programme"	- Family doctors & school doctors are ensuring identification of suspects and TB contacts and applying the treatment of patients under direct observation during ambulatory phase prescribed by pulmonologists from Health Ministry network and other ministries with their own network of health services.
10.	Doctors who work in TB dispensaries – prescription of anti-TB drugs	**Ministry of Health Order no. 763/377/2016** regarding the approval of the Methodological Norms in 2016 of the Government Decision no. 161/2016 for the approval of service packages and the Framework Contract which regulates medical assistance care, medicines and medical devices in the health insurance system for the years 2016 – 2017 Annex 36 – Method to prescribing, supplying and reimbursement for drugs with or without personal contribution in ambulatory treatment ***Art. 1 (7)***	- Doctors who work in TB dispensaries have the right to prescribe drugs for patients in ambulatory system.

[1] MoH – Ministry of Health

		Government decizion no. 161/2016	**Doctors who work in TB dispensaries,** mental health laboratories or mental health centers and outpatient psychiatry, family planning, dental office that are not in contract with health insurance house and are in the hospital structure as units without legal personality, can prescribe treatment whith or without personal contribution in outpatient treatment, adequately to DCI- provided in Government Decision no. 720/2008- ***Art. 146 -(2).*** Health insurance houses enter into agreements with physicians / dentists from school and university cabinets, doctors from homes for the elderly, doctors in institutions under the coordination of the National Authority for Persons with Disabilities, with sanitary units for doctors who work in TB dispensaries, mental health laboratories or mental health centers and outpatient psychiatry, family planning, dental offices that are not in contract with health insurance house, which are in hospital structure as units without legal personality and with doctors from units and emergency departments of the hospitals that are financed from the state budget for the recognition of prescriptions for drugs with or without personal contribution issued by them - ***Art. 146 - (2)***
11.	Doctors who work in TB dispensaries (pneumologists) – their obligations in relation with NHIH	**Ministry of Health Order no. 763/377/2016** - Annex 41 - *Convention on issuing referral documents for clinical health services, issuing referral documents for laboratory medical investigations and / or issuing electronic prescriptions for drugs* (compensated or not) - Art.4	- **Doctors who work in TB dispensaries,** [...] which are included in hospital structure as units without legal personality - can prescribe drugs with and without personal contribution in ambulatory treatment - ***Annex 36, art. 1, para. (6), last para*** - May issue refferal tickets for clinical health care - May issue prescriptions for drugs with or without personal contribution in ambulatory treatment - May issue refferal tickets for paraclinical medical tests *** Prescribing, release and reimbursment of drugs with or without personal contribution in ambulatory treatment is regulated within Annex 36** **Copy-acte normative\OMS763_377_2016_Methodological Norms.pdf** - NHIH has the following obligations in relation with TB dispensaries doctors: • to keep separate records of issued electronic prescriptions / special prescriptions; • to monitor daily consumption of 100% compensated drugs, based on the reports validated by informatics platform of health insurance; • to monthly monitor clinical medical services provided on the basis of referral documents issued by doctors; • to monthly monitor the laboratory referral documents.
		MoH no. 674/2012 approving the electronic form of prescription for drugs with and without	Establishes the obligation to mention within the prescription, at AOB section a numerical identification:

		personal contribution within outpatient care and the its Methodological Norms regarding the use and how to complete the those electronically forms.	- Number 1 for the conventions signed with the doctors who work in the TB dispensaries {…} - Number 2 for any other conventions signed with other doctors and stipulated with the Frame contract and its Methodological Norms
12.	Community medical care *Community medical care is designed to serve communities at local level and especially vulnerable persons who cannot access health services in the usual manner.* *NB* *The development of the community healthcare network and the measures taken to ensure medical and social services will be linked to the National Strategy with impact on poverty reduction and promoting social inclusion.*	**Government Emergency Ordinance 162/2008** on the transfer of Ministry of Health's functions and powers assembly to local government authorities – *Including the recent amendments of Law no. 198/2016 which states the possibility for the local authorities to insure, by their own local budgets, the medication and sanitary materials for a proper activity of community workers as well as the possibilities to grant incentives.* !! on **26 October 2016**, the Government adopted a new Law regarding **community healthcare** wich repeales the Chapter II (art.4-11) from GEO 162/2008 *The new project aims to provide a coherent framework for the development of medical and social services oriented to the needs of the community and its demographic profile thereof, for increasing access to health services, programs, services and activities of public health provided at the community level, to people belonging to vulnerable groups in order to improve access to health services especially those focused on prevention.*	- **Community Healthcare** = represents all activities and health services performed by integrated social services at the community level, in order to solve health and social problems of persons, in order to maintain the persons in their own environment. - *Art.4.1.)* **(+)- conditions for DOT in ambulatory care** - Community medical care involves an integrated health programs and services with social services, focused on the needs of the healthy and sick person and on the community needs, given the integrated social services. (Art.4.2.) - Budgeting community medical care: • from state budget to local budget, via MoH budget (Art.3.1) • annual budget approved as an Annex to MoH Budget, for each county, (Art.3.2) • at the county level, the budget is transferred by County Public Health Directorates ("Direcții de sănătate publică") (Art.3.2) *Even if the GEO 162/2008 stipulates that the annual budget for community medical care (for each county) is approved as an Annex to MoH annual Budget, there is no such public document regarding the counties budgets for 2015.* - Community medical care activities: community training for health, promoting healthy life style behaviours, social and medical counselling etc –***article 6*** Providers - services and community healthcare activities are provided by community nurses and health mediator - ***article 8, alin. 1)*** Their individual employment contract is signed with the local government authority in whose jurisdiction they operate - ***article 9, alin.2)*** The salaries are covered from the local budget through the Ministry of Health. Base salary: - To health mediator are set for the position of instructor education (minimum 510 Lei, maximum 863 lei - October 2008) - For the nurse, minimum 630 lei, maximum 1078 lei - October 2008 Currently, the Ministry of Health provides funding to over 1,350 community nurses and 450

			health mediators. For 2016 the Ministry of Health approved funding for the healthcare community are 62 million RON. Also for 2016 were approved 181 additional new posts for community nurses and 19 posts for health mediators. Beneficiaries: categories of vulnerable people, for example, people with low income, with no income, low education; elderly, people at risk of social exclusion, etc.**- *Article 7, paragraph 2)*** **(+) Including persons diagnosed with TB** **Resource allocation** - Financial resources for the healthcare community services are ensured through transfers from the state budget to local budgets, through the Ministry of Health **- *Article 3, paragraph 1)*** - Amounts are approved annually by the State Budget Law as an annex to the Ministry of Health, distributed by counties and Bucharest. - Breakdown by administrative units is made by the county public health departments and Bucharest or the authorities / national public health institutes **- *Article 3, paragraph 2)*** - The amounts are allocated under an agreement signed by local government authorities with public health departments.**- *Article 3, paragraph 3)*** Responsibilities of the local authorities: Public local authorities are responsible for guarantee community medical care in their area and especially for the disadvantaged communities. **- *Art.21.1)*** - Coverage of community healthcare, healthcare in schools and medical and social care to the local population and especially the disadvantaged communities - Expenditure for goods and services necessary for maintenance and function of medical offices in schools and pre-school as well as in the establishment of new medical offices in schools with legal personality; the amounts are allocated from the local budget for this purpose. **- *Art. 21, para. 1-2).*** - Development of a bi-annual report on healthcare services and activities performed and submit it to community council or, where applicable, the county council and units under the Ministry of Public Health – ***Art 11, paragraph 2)*** *Currently the community assistance network (including rroma mediators) is weak. Althoug the local authorities do not pay community workers from local budgets (but from MoH via local health directorates), they are in geenral reluctant to hire this category of staff.* *Since local authorities are responsible for AMC[2] network, they should seriously consider AMC services needs assessment so that resources be used to yield the best at upgrading and expanding health services and social investment focused on this area, to support the*

[2] AMC= Asistenți medicali comunitari/ ”Comunity Nurse”

			development staff working in the health system, cover with sufficient human resources to communities if they want to improve access to health services or the people they serve in general and vulnerable groups, in particular to increase the number and diversification of health services provided at Community and fulfillment of expectations community. **(!) In order to create the premises for the ambulatory treatment of TB patient, it is recommended to include the TB services also for community health providers, taking into account a possible incentive such as *fee for services.***
		Government Decision no.1028/2014 for approval of 2014-2020 National Health Strategy and of 2014-2020 Action Plan for implementing the National Strategy	According with 2014-2020 National Health Strategy: • One of strategically area for health services is "a system of basic community care services for vulnerable groups" (according with Law of social assistance, "vulnerable group" designates individuals or families who are at risk of losing their ability to meet the needs of daily living because of cases of disease, disability, poverty, drug or alcohol or other circumstances that lead to economic and social vulnerability.") • Regarding health services system, the Strategy aims to ensure gradually greater coverage to the health needs of the population through the basic system services (community care services, assistance services provided by the family doctor and by the ambulatory units) (Cap.3.2) • The Strategy highlights the greater role and responsibility for individual and community, of community medical care and of family doctors. These services have the role to support and empower individuals to take more responsibility for maintaining their own health. (Cap.4.1.) • Regarding Objective 2.3. of the Strategy – "Reduction of TB morbidity and mortality and maintaining adequate rates of screening and therapeutic success" – the Strategy mentions as one of the measures: "Ensuring an effective system of social, psychological and informational support for patients and community, with the support of the community medical care and NGOs for the purpose of early diagnosis, increasing the rate of successful treatment by preventing lack of adhesion and abandonment of treatment and preventing new cases in the community." • Regarding Objective 4.1. of the Strategy –"Development of Community integrated and comprehensive care services, mostly for rural population and vulnerable groups, including Roma" – the Strategy highlights: "The development of health services at community level is a cost-effective alternative for granting access to population, especially in rural areas and vulnerable populations, including the Roma population, to basic healthcare services (...)." The Strategy stipulates following measure for this Objective: "Ensuring a favorable legal and institutional framework to the optimal development and operation of community care services

			(...)", "standardization of evaluation methodology and periodically evaluation of the operation of integrated community care services", "training of central and local authorities for health and social assistance for the development of integrated community care services, according with community's needs".
13.	Community nurse/"Asistent medical comunitar" – for vulnerable populations & Health Mediator /"Mediator sanitar" –for rroma communities	**Government Emergency Ordinance 162/2008** on the transfer of Ministry of Health's functions and powers re. community medical assistance network to local government authorities - ***Art.6*** ***(Also art.6 from the new recently adopted Law)***	- Attributions of Community nurse = home care, psychiatric activities, social activities and other related activities provided to vulnerable members of communities.
		Government Decision no. 56/2009 approving the Methodological Norms for the application of GEO no. 162/2008 regarding the transfer of functions and powers exercised by the Ministry of Health to local government authorities *Methodological Norms for implementing Government Emergency Ordinance 162/2008 on the transfer of Ministry of Health's functions and powers assembly to local government authorities (approved by Government Decision no. 56/2009)*	- Main Attributions of **Community nurse** ***(Methodological Norms, Art.7):*** • team work related to the implementation of national programmes; • active monitoring and supervision of children with TB; • to inform family doctors about communicable disease discovered during field work • to identify medical and social risk families in the community; • to determine medical and social needs of at risk population; • to collect data about the health status of families in their work area; **(+) there is a legal framework for involving the community health care worers in TB-DOT** **(-) small number of community health care worers** **(-) lack of financial motivation** - Attributions **of Health Mediator*** ***(Methodological Norms, Art.6):*** ** the health mediators are designed to work in rroma communities* • to participate in active case detection of TB and other communicable diseases under the guidance of the family physician or health professionals; • on request of health professionals and under their strict guidance, explains the role of prescribed medication, their possible side effects and oversees the administration of drugs, e.g. DOT for patients with TB; • to accompany medical staff in activities related to the prevention and control of epidemic

			situations, facilitating the implementation of appropriate measures, explaining to the community members the role and purpose of the measures to be pursued; • to report in writing to county public health departments about access issues of Roma community members to health care services for active case detection of TB; • to facilitate communication between members of the Roma community and health professionals; • to explain the advantages of personal hygiene an housing hygiene in Roma community; • to mobilize community members to public health actions: vaccinations, information campaigns, education and awareness of health promotion, chronic disease screening actions etc.; - Community nurse & Health Mediator are employed (work contract/"contract individual de muncă") either by public social services organized by local government authorities or, where appropriate, by the mayor's specialized departments. ***(GEO 161/2008, Art.9)*** - Payment of salaries for community nurses and health mediators – from local budget (***GEO 161/2008, Art.10.3).*** Source of funding is the State Budget through the MoH's budget. - No. of community nurse & health mediator – determined by MoH. - Each public social service organized by local government authorities or, where appropriate, by the mayor's specialized departments report on a half-yearly basis to local/county council and MoH departments about the performed services and activities***. (GEO 161/2008, Art.11.2)*** - Ministry of Health, through the county public health departments and Bucharest, provide technical and methodological guidance at county level and in Bucharest. (***Article 4)*** The sanitary units with beds receive in addition amounts which shall be used only for destinations to which they were allocated as follows: a) from the state budget through the Ministry of Health, amounts for personnel expenses for medical residents, for doctors who perform practice supervised / assisted, for staff engaged in research activity, for employees of family planning cabinets in hospitals, in units and hospital wards for dystrophic and neuropshychomotric recovery profile, children with HIV / AIDS in TB dispensaries and clinics, mental ilness laboratories, infectious diseases, according to Law no. 95/2006, as amended and supplemented, and through the budget of the Ministry of Education, Research and Innovation, for clinical hospitals with univeristy departments; Art. 19 (letter a, b of the Norms) b) from the local budgets for hospitals from county or local level***. (art. 19 of the Norms)***

14.	Interdepartmental Commission for Community Nursing - Regulates the establishment of the Interdepartmental Commission for Community Healthcare and the coordination of the national programs of community healthcare.	**Government Decision no. 1499/2006** for the approval of powers, composition and rules of organization and operation of the Interdepartmental Commission for Community Nursing	- The Commission is organized and operates as a body without legal personality subordinated to the Prime Minister. - The Commission works with National School of Public Health and Health Management. - Main attributions: • to identify and propose (to the central and local government institutions) integrated programs and projects for the development of community medical care; • to establish and propose initial and on-going training programs for staff working in community health care network; • to assist the competent authorities in developing programs and projects;
	Medical leave for TB patients	**Government Emergency Ordinance no. 158/2005** on leave and health insurance allowances	- 1 month medical leave (as a rule) up to a maximum of 18 months only for surgical pulmonary tuberculosis and for osteoarticular tuberculosis; People with medical insurrance are entitled to leave and allowance for temporary work incapacity without the period contribution conditions, and for surgical emergencies, tuberculosis, infectious diseases Group A, malignancies and AIDS. - ***Art. 9***
		Order no. 60/32/2006 approving the Norms for the application of Government Emergency Ordinance no. 158/2005 on leave and health insurance allowances *- regulates the duration and lenght of sick leave or compensation for patients diagnosed with TB*	People with medical insurrance diagnosed with pulmonary or extrapulmonary tuberculosis are entitled to sick leave until the maximum duration prescribed by law ***(art. 28)*** without conditioning the contribution period ***(article 14)*** The duration of the leave and the allowance for temporary work incapacity is higher in case of special diseases and differs as follows: a) one year within the last 2 years for pulmonary tuberculosis [...] b) one year and renewable for up to one year and 6 months by your social insurance expert, within the last 2 years, for meningitis tuberculosis, peritoneal and urogenital, including the adrenal glands, AIDS and cancers, depending stage of the disease; c) a year and 6 months within the last 2 years, for operated pulmonary tuberculosis and osteoarticular TB d) 6 months with possibility of extension up to a maximum of one year within the last 2 years for other forms of extrapulmonary tuberculosis with the social insurance expert medical advice. ***Art. 24 (3)*** - The physician must prepare a medical report which will be sent to the cabinet for medical examination and recovery of working capacity in whose jurisdiction the

			insured's domicile. The gross monthly allowance for temporary work incapacity, caused by tuberculosis [...], and emergency and surgery is 100% of the base - is determined as the average of monthly income for the last 6 months 12 months that is a period of contribution, up to the limit of 12 minimum gross monthly wage, which is calculated based on contribution for holidays and allowances ***(art. 10)***
		Government decision no. 1186/2000 approving the list of medical and surgical emergencies and infectious diseases in Group A, for which the medical ssured people receive compensation for temporary work incapacity without conditions related to the contribution period.	Tuberculosis (all forms and locations) **- *paragraph 32*** of the list of infectious diseases Group A
15.	Epidemiological control	**MoH Order no. 1078/2010** approving the Regulation of organization and functioning and organizational structure of county and Bucharest public health departments	County public health departments and Bucharest are concentrated public services with legal personality, subordinated to the Ministry of Health, - Performs at local level, the national health policies and programs, develop local programs, organizes health structures, statistical evidence on health issues and planning and implementing investments financed from the state budget for the health sector. - assess, coordinate and monitor how the curative and profilactic health care is provided in medical units from local level, including medical units under the Ministry of Health, taking measures to ensure access to health care to anyone in the county. - through the services of medical supervision, coordinate, organize, evaluate and participate in implementing the national health programs that take place in the territory and exercise specific powers ascribed to control public health in the fields of competence by staff authorized by the Ministry of Health. - in collaboration with local authorities, education institutions and governmental and nongovernmental organizations, organizes activities in the medical field of public health. **The department of epidemiological surveillance and control of infectious diseases** from public health departments in the county and Bucharest, perform tasks such as: - Coordination and implementation at the county level, of the specific activities within the national and territorial public health programs for infectious diseases in order to achieve objectives and strategies assumed by national and local programs - Organizing, collecting, analyzing, verifying, managing, interpretation and dissemination of data on infectious diseases from all existing sources in the territory, lead and manage a

			register of the county for infectious diseases, vaccination and undesirable adverse reactions after vaccination - including TB, nosocomial infections and epidemiological risk situations; - Check how family physicians detect and report cases of infectious diseases for surveillance of the infectious disease according with the existing legal provisions ***(article 3, section VII of the Regulation)***
		Ministy of Health Order no.386 / 2015 on the approval of the technical achievement of national public health programs for 2015 and 2016 *- Activities implemented on the epidemiological departments of local health departments* *- epidemiological control*	Collaboration between epidemiologists of Public Health, Family Doctors and TB dispensary for investigation and implementation of the necessary control measures in epidemiological TB outbreaks of at least 3 cases. - The establishment and implementation of measures to prevent and control the nidus of disease, including nidus of tuberculosis with more than 3 cases: conducting epidemiological investigation, contact tracing / population at risk, collection of biological samples, conducting prophylaxis, except chemoprophylaxis for tuberculosis according to specific methodologies, notification and reporting, making disinfection in collaboration with primary-care network - ***Annex. 2, Chapter I, Title I.2*** "national program of surveillance and control of infectious diseases priority" letter C "Activities" Section 2 "Activities implemented on the services / offices Epidemiology DSP", paragraph 2.3 ** New provision introduced by Order of the Ministry of Health no. 219/2016*
16.	C2 list of NHIH re. anti-TB drugs (drugs with 100% compensated price) for the treatment of M/XDR TB	**Government Decision no. 720/2008** approving the list of international common names for medicinal products for insured persons, based on prescription, with or without personal contribution, in the health insurance system, as well as international common names for medicinal products granted under national health programs The drug list – with all amendements can be consulted here: http://www.cnas.ro/page/lista-medicamente-2016.html	*http://www.cnas.ro/casmb/media/pageFiles/Lista%20medicamente%20sublista%20C%20sectiunea%20C2%20anexa%202%20,%203%20valabila%20de%20la%2001%2001%202016.pdf* *Re M/XDR TB: The current C2 list includes: Amikacine, Ofloxacine, Protionamide, Cicloserine, Kanamicin (not on the market); Not included on C2 list: Bedaquilin, Levofloxacine, Capreomicine, Clofazimine, Linezolid, Amoxiciclin, Imipenem Cilastatine* *- through Government decision no 877/2015[3], Annex to decision nr. 720/208 modified and completed with Bedaquilinum (J04AK05[4]).* *- some of the missing drugs from the list are off label or not yet authorized in Ro, and present inclusion criteria are not applicable to those missing anti-TB drugs for M/XDR-TB; it is therefore mandatory that the regulations have to be changed in order to update the list.*

[3] Published in the Offical Journal no. 791 from 23 October 2015

[4] The substances witihn the List of prrescribed medicines in the ambulatory and hospital treatmeant (C2). The list can be accesed here http://www.casan.ro/casot/page/lista-medicamente.html

		Ministry of Health Order nr.1605 / 875/2014 on the approval of the calculation, the list of trade names and prices of medicines prescribed to patients through the national health programs and methodology of calculation.	- Approve the list of trade names and prices of medicines prescribed to patients enrolled in the national health programs according with the international proprietary names (INN) in Section C2 of the sub-list C of the Annex to the Government Decision no. 720/2008
17.	Procurement (anti-TB drugs and lab. consumables)	**Law no. 95/2006 on healthcare reform - *art. 58*** - *Sets the primary framework for the procurement of medicines*	Procurement of medicines, sanitary materials, medical devices and other products is done through open tender organized by the Ministry of Health or health facilities with beds implementing national health programs, as appropriate, according with the legal provisions on public procurement. - MoH powers in national health programs - MoH organize at the national level procurement procedures for the purchase of goods and services required for the implementation of national health programs, in compliance with legal provisions on public procurement ***-art. 55, letter e)***
		MoH Order no. 457/2001 regarding the purchase of medicines given in the hospital and outpatient, of some vaccines, medical supplies and other materials needed to conduct health programs	Establishes the modality to purchase such medicines under the NTP - by tender at the national level, according to the law – for the following medicines - Hidrazida - Rifampicina - Rifabutin - Pirazinamida - Streptomicina - Amicacina - Kanamicina - Etambutol - Cicloserina - Protionamida-Etionamida - Ciprofloxacina-Ofloxacina - Claritromicina - Combinatii: - Hidrazida-Rifampicina - Hidrazida-Rifampicina-Pirazinamida - Pas (Acid paraminosalicilic).
		MoH Order 658 /2013 aproving the List of drug, sanitary materials, medical equipement, protection equipement, services, car park fuels and lubricants, for which hospitalsnt procedures is organized**.**	- Establishes the list of products and services provided by MoH through centralized procurement since the fourth quarter of 2013 *–TB medical devices and medicine.*

		Ministry of Health Order no. 386/2015 on the approval of the technical norms for implementing the national public health programs for 2015 and 2016	Ministry of Health, as the central procurement unit, designated under the law, carried out at national level, centralized procurement of drugs, medical supplies and other products for implementing the national program for TB control - ***Art. 12 - (1)*** In accordance with O.U.G. no. 34/2006, the Ministry of Health can organize nationwide open tender for purchase of medicines, sanitary materials, medical devices and other products, as appropriate. Following completion of procurement procedures organized by the Ministry of Health, Supply contracts are signed by suppliers selected and the Ministry of Health or, where appropriate, public health departments. - ***Art. 14 - (1-2)*** Ministry of Health may enter into contracts with units under its authority, as provided by legislation on public procurement.- ***art. 16 - (1)***
		Law no. 98 /2016 on public procurement	- stipulates that centralized bids can be performed also by centralized public procurement units.
		- **Emergency Government Ordinance 71/2012** designating the Ministry of Health as a centralized procurement unit	- designates the Ministry of Health as a centralized procurement unit Until the completion of implementation at national level of the centralized procurement of drugs, medical supplies, medical equipment, protection equipment, services, fuels and lubricants for the car park, the Health Ministry can approve as an exception, conduct procurement by public health units - ***art. 4*** ❖ *The acquisition of laboratory supplies: National Tuberculosis Programme[5] sends to MoH the needs by type of consumables/reagents/tests for TB diagnosis (solid, phenotypic, genetic, liquid) required for next 2 years.* ❖ *The centralised procurement of anti-TB drugs was organized in 2013 and was completed by the signing of framework contracts with various drug suppliers.* *- The present centralized procurement method is actually a standardisation of costs for anti TB drugs.* *- This method leads to three consequences:* *1. Needed medication required by each health unit with beds for each month is based on a*

[5] National Tuberculosis Program (Government Decision No. 121/2015) = NTP

			Notice. All Notices are centralized by NTP and submitted for approval by Ministry of Health. Based on approvals, medicines included in notices are being bought. *All the orders are being limited by budget and do not respect the rule of drugs' management: "3 months + 1 buffer month ". (According with Art. 23(n) of HM Order 386/2015: stocks of medicines, sanitary materials and medical devices will be dimensioned at the average monthly consumption level of the previous year properly for a period of 3 months.)* *2. The procurement of drugs used for several other diseases (eg. Moxifloxacin) should be centralized purchased by Ministry of Health* *3. Issues regarding reporting: lack of correlation between quantities from Notices versus purchased quantities*
		MoH Order no. 1.292 / 2012 approving the Methodological Norms for centralized procurement at national level, of medicines, medical supplies, medical equipment, protection equipment, services, fuels and lubricants for car park	MoH, by the specialized unit, organizes and conducts public auctions at national level, for the purchase of medicines, medical supplies, medical equipment, protection equipments, services, fuels and lubricants for the car park. **– *Art. 1*** Based on auctions conducted, the specialised Unit sign framework agreements in the name and for public health units. Annually or whenever necessary, the Ministry of Health develops the list of medicines, medical equipment, protective equipment, services, fuels and lubricants for the car park, named hereinafter „list", for which it is organised centralized procurement, at national level. **- *Art. 2 - (1)***

18.	Social services	**Government Ordinance 68/2003** of social services ***(Art.12. (3))***	***Art.12.3*** - Social assitance public services from local and county level can make partnerships among them and with social services providers as well as contracts for social services delivery with social service providers mentioned at article 11." ***Art.11. (1)*** Social service providers can be individuals or legal entities, public or private. (2) Public social service providers can be as follows: a) public social services at county and local level; b) other public specialised services at county or local level; c) public institutions with social assistance compartments; (3) Private social service providers can be as follows: a) associations, foundations, religious cults and other organised forms of civil society; b) authorised persons according to the law; c) branches of international associations and foundations that are recognised according to the legislation in force; d) international organizations in the field; (4) Social service providers can organise and provide social services only on the basis of accreditation according to the legislation in force."
		Law 292/2011 of social assistance	Funding of social services, according to law - from the local budget, from the contribution of the beneficiary and / or, where applicable, his family, from the state budget and other sources. -**art. 39, letter c)** At local level, for the organization, management and provision of social services, public authorities may sign contracts for public-public and public-private for financial and technical support of local authorities in the county, to support the development of social services .-***art. 112, para. 3), letter f*** Community services are social services organized in a territorial-administrative unit (commune, town, municipality), concerning services provided at home and in day care canters as well as residential services addressed exclusively to citizens of the respective administrative-territorial unit; They are similar to social services provided in the community" - ***Art.6 ii)***
		Law 215/2001 local public administration	***Art.91 (6)*** - County Council meets the following main categories of tasks: a) ensure its competence and according to the law, the framework for providing public social services of county interest on:

			2. social services for child protection, the disabled, elderly, family, and other individuals or groups in social need. *Conclusion: support services (social, psychological) for persons affected by tuberculosis (patients and also their families) could be organised and financed at county level, based on an existent legal tool.* The responsibilities of the County Council include managing public services subordinated and thus provides the framework for providing public services of county interest such as social services for child protection, persons with disabilities, the elderly, families and other individuals or groups in ***-art.91 social need, par. (5), point 2.***
		Joint Order Ministry of Justice / MoH no. 429 / C / 125/2012 on healthcare insurance of detainees in the custody of National Administration of Penitentiaries	- the pulmonology exam it mandatory for patients with clinical signs of pulmonary tuberculosis (cough, weight loss, sweating, fever, fatigue, chest pain) or those with previous history of tuberculosis ***-art. 14 (5)*** Diagnosis, treatment and surveillance of patients with TB is done in accordance with National Tuberculosis Control Programme. - ***Art. 117*** Extrapulmonary tuberculosis cases are hospitalized in internal medicine wards of the prison hospital that have in their structure pulmonology departments. ***-art.118, para. (2)***
		MoH order no 653/2001 regarding medical care for children, pupils and students	Medical and dental care for children, pupils and students is ensured in medical and dental offices in kindergartens, schools and higher education institutions, established following the reorganization of the medical facilities in these units, integrated in local hospital structures and financed by the state budget - ***Article 1.***
19.	Medical and social assistance units	**Government Decission no.412/2003** approving the Norms regarding the organization, operation and financing of medical and social care units	The **units of medico-social assistence** are specialized public institutions with legal status, subordinated to the local authorities, providing care, medical services and social services to the persons with medical and social needs ***(art. 1, para. 1 form Norms)*** Beneficiaries: people with medical -social needs (*as established by the law*), which, where appropriate, **requires supervision**, assistance, care, **treatment and social reintegration services and employability.**
		Government Decission no. 459/2010 approving the standard cost / year for services rendered in medico-social and legal personnel of the medico-social assistance units and personnel engaged in community healthcare	The standard cost level / year / bed for services provided in medical and social institutions is 29 865 lei and includes the following categories of expenses: a) personnel expenses related to medical and healthcare professionals, as well as expenses with drugs and medical supplies - are covered from the state budget through the Ministry of Health from funding allocated by transfers to local budgets -in the limit amount of 8.804 lei / year / bed; b) personnel costs for non-medical personnel and the costs for food and goods and services necessary for maintenance and operation of medico-social, repairs, consolidations, equipment -

			are borne by the local budget in the amount of 21.061 Euro / year / bed Norming of medical staff and social units shall be as follows: a) health professionals - 1 doctor for 25 beds; -1 superviser with medium qualification for 15 beds / shift; b) auxiliary staff: - 1 nurse for 12 beds / shift; c) TESA personell (*including management):* - 10% of the total number of posts in the positions; d) workers and other service personnel: - 10% of the total number of posts in the positions. *(Article 3)* Norming of personnel engaged in the **community healthcare** is performed according to the following normative staff: **a) 1 community nurse to 500 people assisted;** **b) 1 Roma health mediator to 700 people counseled**. The local public authorities which manages medical and social units **are responsible with the distribution of funds transferred** from the Ministry of Health for funding - on time and in good condition – from their own budgets the necesarry amounts allocated and their organization according to legal provisions. ***(art.5*)**
20.	Public health units at county and local level	**Government Ordinance no. 70/2002** concerning the management of county and local public health units, approved with amendments by Law no. 99/2004 *- provides the legal framework for achieving the health and social care through medical and social assistance units*	Ministry of Health exercise the control over public health units also regrading the application of the healthcare legal provisions in force in ***(Article 1, paragraph 4)*** Ministry of Health, as the central health authority has the following atributions: a) develops the personnel norming, which are approved by the Minister of Health Order ; b) approves the organizational chart of public health units with legal status; c) receives the quarterly and annual public health units financila records, according to legal provisionsin force; d) ensures the distribution and balanced redistribution of doctors in the public health facilities, based on the local authorities' communication regrading the vacant posts and surplus of doctors, according to the Norms. With the Ministry of Health, Ministry of Interior and the Ministry of Labor, Social Solidarity and Family approval, county councils and local councils may establish medico-social assistance units by reorganizing the public health units; they are organized as a public institution with legal status financed from own revenues and subsidies from local budgets, according to subordination ***(art. 5 para. 1-2)*** Multifunctional health centers may be set up, under the law, based on the proposal of hospital management authorities as units without legal status, within the county, municipal or city

			hospitals in order to provide a package of health services adapted to the local communities needs. ***(art. 5[2] , para. 1)*** Multifunctional health centers with or without legal status may have as structure: a) specialized cabinets; b) between 5 and 20-day care beds; c) medical laboratories, radiology and medical imagistic; d) other medical structures without inpatient beds for continues hospitalization. The financing of the multifunctional health centers -as legal person- is subject to conditions laid down by the framework agreement on the conditions for granting medical assistance within the health insurance system and its implementing rules. ***(art. 5[2] , alin. 11)***
		Decentralization framework Law no. 195/2006	The local authorities from the villages and towns exercising sole power management on the local public health units **-** ***art. 21***
21.	Free practice cabinet for public services related to medical care	**Government Ordinance no. 124/1998, republished on the organization and operation of medical offices**	Nonprofit organizations, foundations and associations with medical activities, professional associations and religious groups legally constituted, based on the governing bodies' decision, can establish and organize within their structure, medical offices providing outpatient medical services. – ***art. 16***
		Emergency Ordinance no. 83/2000 regarding the organization and operation of the free practice cabinets for public services related to medical care.	- The Practice Cabinet represents the unit, without legal status, providing necessary public services related to medical care, in order to achieve ambulatory medical care: preventive, curative and rehabilitation services. ***(Art. 1, paragraph 1)*** The services related to medical care can be provided by MOH authorized persons, <u>other than physicians</u>, to exercise independently pne of the following professions stipulated in the Nomenclature of functions of the MOH: dental technician, biologist, biochemist, chemist, physicist, physio-therapist psychologist, speech therapist, **sociologist,** professor of medical physical culture, opticianoptometrist, prosthetics and orthotics technician, technician hearing aids, medical equipment technician.
22.	NTP for 2015-2016	**Government Decision no. 206/2015** approving national health programs for 2015 and 2016	- NTP is financed from MoH budget ** The financial resources to fund the National Public Health Programs comes from the state budget and from the MOH revenues and from other sources, including donations and sponsorships, in conformity with th elegal provissions (**Art. 4 - (1) –MoH Order 386 / 2015)***
		Law no. 95/2006 on health reform – *art. 55*	a) approves the Strategy of national health programs, as part of the National Health Strategy; b) propose for approval to the Government the National Health Programs;

		- *MOH atributions regarding the national health programs*	c) approves the Methodological Norms for the implementation of National Public Health Programs; d) approves the Methodological Norms for the implementation of the Curative National Programmes issued by NHIH e) organizes –at national level – the national procurement procedures for the purchase of goods and services required for the implementation of National Health Programs, in compliance with legal provisions on public procurement; f) achievs the organization, monitoring, evaluation and enforcement of the National Public Health Programs; g) provides funding for National Public Health Programs.
		Law no. 95/2006 on health reform	**Public hospitals within the local authoritie' network** conclude contracts with county Public Health Departments (PHD) and Bucharest in order to: - implement properly the National Public Health Programs; - insure the salaries benefits of the personell workingwithin the medical cabinets included in the organizational structure approved under the law: sports medicine units, family planning, HIV / AIDS, dystrophic, **TB**, LSM; - insure the expenses for the goods and services required for the medical practices sports medicine, **TB cabinets,** cabinets LSM contained in the organizational structure of the hospital approved under the law **- *art. 194*** **Public hospitals within the Ministry of Health** and the ministries and institutions with own health network (with *the exception of the hospitals from the local public administration autorithies*) **receives, in addition, money from the state budget or local budgets,** which will be used only for destinations which they were allocated as follows: a) State Budget, through MOH budget or of the ministries and institutions with own health network, as well as through Ministry of Education budget for the clinical hospital with universitary sections; b) the budget of the county, for county hospitals; c) the local budgets for the county or local interest hospitals - ***Art. 193 - (1)***
		MoH Order no 1043/2010 regarding the norms for elaborating the budget of the public hospitals* *The last budget template was modify by **MoH order no. 1.102 from 30 September 2016** regarding the modification of Annex 1 of the Methodological Norms*	- stipulates a budget template´ RAA-oct2016\Copy-acte normative\OMS 1043_2016.pdf According to the amended text, the amount of expenses related to personal rights is subject to approval by the principal loan manager with the opinion of the Administrative Board.

		Government Decision no. 121/2015 approving the National Strategy for Tuberculosis Control in the Romania 2015 - 2020 *- provides the legal framework for implementing the Strategy objectives: reducing the incidence and mortality of tuberculosis by providing prevention, screening, diagnosis, treatment and increase adherence to treatment, as recommended by the World Health Organization (WHO).*	TB 2015-2020 focuses on three lines of action as follows: - Integrated services for prevention and patient-centered care - Development and implementation of control TB policies in Romania - Innovative research and evidence-based strategies
23.	TB Dispensary funded budget	**Government Decision no. 161/2016 - *Art. 195 - (1)***	- TB dispensaries are funded from state budget/other sources, but not from National Fund for Health Insurance (FNUASS*). Services that **<u>are not reimbursed by the FNUASS</u>**, their value being borne by the insured, by the soliciting units, **from the state budget** or **from other sources**, as appropriate, are: ş) Activities of particular interest to achieve public health strategy: **<u>TB dispensaries</u>**, mental health laboratories or mental health centers and outpatient psychiatry **- *Art. 195 - (1)*** **(FNUASS = is composed by health insurance paid by insured persons, employees, subsidies from the state budget and other sources - donations, sponsorships, interest exploitation of heritage houses of NHIH. - Art. 220 Law 95/2006)*
24.	Reimbursement for hospitalization towards medical units (based on hospital inpatient admission document /bilet de internare)	**Ministry of Health Order no. 763/377/2016** regarding the approval of the Methodological Norms in 2016 of the Government Decision no. 161/2016 for the approval of service packages and the Framework Contract which regulates medical assistance care, medicines and medical devices in the health insurance system for the years 2016 – 2017	**Art. 16 of Annex 23** – The Conditions of providing medical services in hospitals with beds and payment thereof: *Health insurance houses conclude agreements with medical-social institutions, with hospitals for the doctors who work in TB dispensaries…." in order to recognise {for the purpose of reimbursement of costs} the inpatient admission documents issued by the doctors who work in these institutions. The* ***Convention model is set out in Annex no. 42.***
25.	Centers of permanence - *insuring continuity of primary health care*	**Law no. 263 / 2004** insuring continuity of primary health care through the Centers of permanence.	Continuity of primary health care is ensured through Centers of permanence by family doctors, general practitioners and nurses who practice their profession, under the in law.

26.	Family Doctors	**Government Decision no. 161/2016** for the approval of service packages and the Framework Contract which regulates medical assistance, medicines and medical devices in the health insurance system for the years 2016 - 2017	- Family doctors are paid: 50% for the service, 50% per capita. ❖ *Family physicians are not reimbursed for:* *-suspect and contacts identification and referral to medical services,* *-supervision of anti TB treatment in TB cases.*
		Ministry of Health Order no. 763/377/2016 regarding the approval of the Methodological Norms in 2016 of the Government Decision no. 161/2016 for the approval of service packages and the Framework Contract which regulates medical assistance care, medicines and medical devices in the health insurance system for the years 2016 – 2017	***Annex. 2 of the MOH Order*** - Methods of payment for primary medical care for providing medical services as establish in the medical services packages ***Art. 1 - (1)*** The payment arrangements in primary care are: payment "per capita" by price per person insured, according to its own insured people registered and, pay by price on the medical service expressed in points for certain medical services provided in Annex no. 1 to the MOH Order As for 30 september 2016, - the minimum guaranteed value of the point "*per capita*", unique in RO, is **4.3 lei,** valid for the year 2016. Starting the fourth quarter of 2016, the minimum guaranteed value for point "*per capita*", unique in RO, is **4, 6 lei.** - the minimum guaranteed value of the point "*pay per service",* unique in RO, is **2 lei,** valid for the year 2016. Starting the fourth quarter of 2016, minimum guaranteed value for point "*per service*", also unique in RO, is **2, 1 lei.** *The optimal number of people to be listed to a FD - in terms of ensuring quality services at primary health care level to be taken into account to determine the need for family physicians on administrative unit / urban area - is 1.800.* In case of extension of the work program for a list of between 2,200 and 3,000 people enrolled - the daily program increases by 1 hour; for a list of more than 3,000 enrolled -the daily schedule increases by by 2 hours. **In case where the number of insured persons listed to a FD exceeds 2,200 and the number of points "per capita" / year exceeds 18.700 points, the number of points that exceed this level will be reduced as follows:** - by 25%, when the number of points "per capita" / year is between 18.701 - 22.000; - by 50%, when the number of points "per capita" / year is between 22.001 - 26.000;

			- by 75%, when the number of points "per capita" / year is over 26.000 For family doctors who have enrolled on their lists over 2,200 insured and a number of points / year exceeding 18,700, but not more than 22.000 points including, the payment "per capita" is 100%; - for FD who have enrolled on their lists over 2,200 insured and a number of points / year exceeding 22,000 but not more than 26,000 points including, the number of points exceeding this level is reduced by 25%; - for FD who have enrolled on their lists over 2.200 insured and a number of points / year exceeding 26.000 but not more than 30.000 points including, the number of points exceeding this level is reduced by 50%; - for FD who have enrolled on their lists over 2.200 insured and a number of points / year exceeding 30.000 points, the number of points exceeding this level is reduced by 75%.
27.	NTP Budget	**MoH Order no. 386/2015** on the approval of the technical norms for achievement of national public health programs for 2015 and 2016 ** Amounts are updated by the MOH Order no.931/05 August 2016*	**NTP FINANCING for 2016** Total amount = 17.564.000 lei (*aprox.3.946.966 euro),* from which - 4.032.000 lei - State budget - 13.532.000 lei - MOH **NTP FINANCING for 2015** Total amount = 20.258.000 lei (aprox.4.552. 359 euro) from which: - 5.741.000 lei - State budget - 14.517.000 lei - MOH
28.	NTP financing method	**Law no. 95/2006 on health reform - *art. 251***	In order to achieve the objectives of the National Strategy for Health, Ministry of Health develops health programs in collaboration with NHIH
		Law no. 95/2006 on health reform - *art. 58 para. (1)*	- is done: a) from MOH budget, through state budget and own revenues, for the National Programs for Public Health b) from FNUASS budget, for curative Health National Programs; c) from other sources, including donations and sponsorships, under the law. For the National Public Health Programs, the categories of eligible expenditures and their funding is approved by the Technical Norms for carrying out the National Public Health Programs ***(MOH Order no. 1171/2015)***
		Government Decision no. 206/2015 regrading	The National public health programs are implemented by the Ministry of Health.

		the approval of National health programs for 2015 and 2016	* The financial resources for funding the National public health programs derived from the state budget and the own revenues of the MOH and from other sources, including donations and sponsorships, under the law ***(Art. 4 - (1)–OMS 386 / 2015)*** The National program for prevention, surveillance and control of TB - NTP aims: a) reducing TB prevalence and mortality; b) the maintenance of the detection rate of new cases of pulmonary TB smear positive; c) the treatment of TB patients; d) the maintenance of therapeutic success rate of new cases of pulmonary TB positive. NTP grants free treatment of all TB diagnosed patients, on prescription / medical registry, through pharmacies with closed circuit within the medical units where health programs are being implemented. NTP sends to the Ministry of Health requirements, depending on the type- supplies / reagents / tests for TB diagnosis (*solid, phenotypic, genetic, and liquid).*
		MoH Order no. 386/2015 on the approval of the technical norms for achievement of national public health programs for 2015 and 2016	- ***Art. 7*** - National public health programs are financed from the state budget and the revenues of the Ministry of Health budget titles from 20 "goods and services" and 51 "Transfers between government units" referred to in classification indicators on public finances. - ***Art. 8 - (1)*** The financing of programs / national public health sub-programs is made from the Ministry of Health budget on a monthly basis, for total title, based on specialized units' applications that implement them, together with their supporting documents in relation to: a) the use of funds previously made available; b) unused account balance; c) the budget approved for this purpose; d) achievement of physical indicators in the previous period;
29.	Categories of expenses funded by MoH	**MoH Order no. 386/2015** on the approval of the technical norms for achievement of national public health programs for 2015 and 2016	- *MOH* may finance[6] a number of charges*:* - Medicines, medical supplies, reagents, disinfectants, materials laboratory, office supplies, goods inventory objects with lifespan of more than 1 year and unit value below 2,500 lei, fuels for vehicles of equipment, spare parts, mail, communications, internet, materials and functional services, goods and services for maintenance and operation, food for people, uniforms and protective equipment, internal displacement of its own personnel, according to legal provisions, books and publications, training, safety, vouchers for blood donors, medical services, other categories of goods and services, expenditures for the functions and activities of

[6] Form the funds allocated under Title 20 "Goods and Services" and Title 51 "Transfers between public government units"

			the national public health programs. - ***Art. 9. - (1)*** From the funds allocated to the specialized units that implement National public health programs <u>cannot be funded</u> utilities expenses and capital nature - ***Art. 9, par. (3)*** The eligible expenses are: 1. drugs used prophylactically: Isoniazid, Rifampin, Pyrazinamide, Ethambutol, Fluoroquinolone - individualisation of any prophylactic treatment will be carried out only with the county medical staff approval and with drugs used in curative treatment, in accordance with **GD no. 720/2008** *approving the list of international common names for medicinal products for insured persons, based on prescription, with or without personal contribution, in the health insurance system, as well as international common names for medicinal products granted under national health programs*; 2. sanitary materials: PPD, disposable needle syringes, needles, cotton wool, rubbing alcohol, gloves, masks, containers for collecting used syringes, vacutainere, syringes 2, 5 and 10 ml disposable cups 3. ELISA type IGRA - QuantiferonTB Gold, reagents and solutions for bacteriology laboratory to carry out microscopic examination and culture: solid and liquid environments and environments for early diagnosis and susceptibility to first and second line drugs, phenotypic methods solid and liquid, genetic methods to detect cases of chemoresistance and strains identification AgMPT64); 4. lab materials**;** 5. radiographic films for both traditional and digital equipment, developing solution (developer and fixer set); 6. disinfectants; 7. services for: 7.1. organization of staff training activities, human resource development: organization and conduct of training courses, symposia, roundtables; 7.2. editing and printing of reports, templates and registers, methodological guides and educational materials, copying and bindery documents and their dissemination; 7.3. maintenance, licensing, maintenance, metrologizare, equipment calibration and ensuring bacteriology laboratory and radiology; 7.4. maintenance, operation and providing computer equipment, copy machines, faxes, photocopies and MFPs equipement; 7.5. maintenance, operation and transport - activities needed for a proper function of NTP: contacts/suspects transportation, TB pacients, biological materials, medicine transportation to the FD cabinest or patients' homes, doctors in the program activities, car insurance, vignette, technical inspections, repairs; 8. office supplies: *pencils, pens, markers, paper, folders, dividers files, binder covers, sheet protectors, binder sheets, binders, envelopes, labels, post-it notes, photocopy and printer paper, paper clips, staples, punch, stapler, staple remover, cutters, string, Scotch tape, correction fluid, computers, office scissors), toners / cartridges for printer, fax, copier,*

			multifunction, CDs and DVDs; 9. spare parts and accessories for equipment bacteriology laboratory / radiology, computers, faxes, printers, copiers, multifunctional equipement; 10. inventory items of little value: radiographic boxes of different sizes, different laboratory containers, racks laboratory, UV lamps, computers, copiers, fax, copier and multifunctional equipement 11. protective equipment needed to prevent transmission of TB infection**;** 12. internal displacement: transport costs, accommodation and subsistence for their staff, road taxes; 12.1. reimbursement of costs made with transportation of biological samples collected from the territory delivered to the regional and national TB bacteriology laboratories; 13. fuel for its vehicles for performing the activities under the NTP; 14. personal expenses and / or service contracts.
30.	Implementation of NTP	**Law no. 95/2006 on health reform**	***Art. 53. - (1)*** Implementation of national public health programs is done from the Ministry of Health budget, state budget and own revenues, as follows: a) through public and healthcare providers from the Ministry of Health; b) by medical providers of local authorities and ministries and institutions with own health network, public and private providers of health care.
		MoH Order no. 1171/2015 (in force as of October, 7, 2015) re. approval of the "Methodological Guidelines for implementation of the national prevention, surveillance and control of tuberculosis programme"	National Programme for Prevention, Surveillance and Control of Tuberculosis (PNPSCT) establishes a series of goals to be achieved at national level until 2020. The Guider provides a standard aproach for the Pneumoftiziology network of prevention and control of TB with the scope of providing guidance to the professionals in the health services on TB case management. (*Is detailed also the detailed job descriptions of all personnel involved, the standard reporting documentation, etc.)* Reiterates the gratuity of all activities for the diagnosed tuberculosis patients regardless of their social status (*insured or uninsured*). These activities are, for example, diagnosis and treatment of TB patients, control of their contacts, preventive treatment, outreach, education, communication, etc. The Methodological Guide for implementing the National Programme for prevention, surveillance and control of tuberculosis can be accessed here: *http://www.ms.ro/documente/GHID%20Metodologic%20de%20implementare%20a%20Programului%20national%20de%20prevenire,%20supraveghere%20si%20control%20al%20tuberc*

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		MOH Order no.386 / 2015 on the approval of the technical achievement of national public health programs for 2015 and 2016- ***Art. 21, letter i*** *- obligation of the specialized units under contract with the PHD (Public Health Directorates) to insure adeqvate stocks*	**The specialized units under contract with the PHD** for implementing **the** national health programs have the following obligations: i) to ensure adequate quantitative stock value of drugs, medical devices and medical supplies and medical devices required in programs,dimensioned on the monthly average consumption level of the previous year, corresponding to a 2-month period; for the national program of prevention, surveillance and control of HIV and that the national program of prevention, surveillance and control of **tuberculosis -TB** stocks of medicines, medical supplies and medical devices **is dimensioned on the monthly average consumption level of the previous year, corresponding to a 3-month period** ***** *New provision introduced by MOH Order no. 219/2016*
		MOH Order no.386 / 2015 on the approval of the technical achievement of national public health programs for 2015 and 2016- ***Art. 21, letter n*** *- Authorising Officers obligation to purchase adequate stocks of medicines -* ***Art. 23, lit. n***	The Authorizing Officers of the specialized units implementing the national health programs have the following obligations: n) are responsible for ensuring adequate quantitative stock value of drugs, medical devices and medical supplies and medical devices required in programs,dimensioned on the monthly average consumption level of the previous year, corresponding to a 2-month period; for the national program of prevention, surveillance and control of HIV and that the national program of prevention, surveillance and control of **tuberculosis -TB** stocks of medicines, medical supplies and medical devices **is dimensioned on the monthly average consumption level of the previous year, corresponding to a 3-month period**
31.	NHIH attributions regarding NTP	**Law no. 95/2006 on health reform**	***Art. 56 - a)*** Participates in preparing the draft of Government decision approving national health programs b) Develops and approves technical standards to achieve curative national health programs, with the assent of the MOH c) achievs the organization, monitoring, evaluation and control of the implementation of curative national health programs; d) provides funding for the curative national health programs; e) communicate to the structure with responsibilities in the development and coordination of the national health programs - quarterly, annually and whenever needed - the indicators of the curative national programs, as well as the analysis of how they are carried out -*art. 56*
32.	Salary / medical staff bonuses	**The Framework Law no. 284/2010** regarding the unitary remuneration of personnel paid from public funds	The staff within the sanitary- veterinary and food safety public institutions who is engaged and active in the specialty - *as for the specific functions in the Annexes* - benefits of the following categories of bonuses and rights: *a) Bonuses:* - Bonus for harmful conditions / hazardous involving risk of disease and / or direct or indirect

			contagion, respectively associated risks due to specific conditions of work - **from 25% to 35%;** - Bonus for **particularly dangerous conditions such as TB**, brucellosis, avian influenza, transmissible spongiform encephalopathies, salmonellosis and other zoonotic diseases, plague, FMD, enzootic and other diseases, pathological anatomy, necropsy and forensic medicine – corresponding to the actual work carried out in these conditions and corresponding to the specific activity of sanitary and food safety laboratories - **from 25% to 75%;** In relation to the conditions in which the activity is carried out, for the staff in health facilities and medical and social institutions paid according to the provision of the Annex, under the law, the following categories of incentives may be granted: - *Art. 7 *) - (1)* a) for the activities carried out in the stroke units, units and departments of neurology, neurosurgery and which involves a very high psychic tension, as well as staff of units, sections and departments **of infectious diseases**, neonatology, birth rooms and of medical analysis laboratories operating in hazardous conditions, **an increase (bonus) of up to 25% of basic salary;** b) for the particularly dangerous conditions: leprosariums, pathological anatomy, **TB**, AIDS, dialysis, neurological recovery, neuropshychomotric, neuromuscular and neurological, psychiatric, forensic medicine, emergency medical nursing and transport provided through ambulance services and establishments of emergencies UPU - SMURD, UPU and CPU units and departments ICU and intensive care units and departments palliative care, staff employed in the operating unit for the transfusions points from hospital, cardiology interventional laboratories, endoscopy interventional laboratories,as well as the surgeouns - *particularly serious epidemics and others*, as established by the MOH, **the bonus amount is 45-85% of basic salary** The bonus level is determined by the management of each health units with legal status in agreement with the representing unions signatories of the collective work agreement - at branch sanitary level and within the approved personnel expenses in the income and expenditure.
		GEO no. 70/2014 concerning remuneration of staff in the public health system and the public system of social assistance in 2015. - *regulates the activity in hospitals and social care*	The **public health system** - means public health units <u>with and without beds</u>, diagnostic centers and treatment, medical centers, health centers, multifunctional health centers, units specialized in emergency and medical transport service, including health units subordinated to ministries and institutions with their own health network, staff within the medical practices organized in penitentiaries, school medical staff and community nurses network as well as other public healthcare and medico-social establishments. **As of December 1, 2015, the gross basic salaries / function incentive / function salaries / allowances of employment of the staff from the public health system, <u>was increased by 25%</u> compared to the benefits for September 2015*

			The public social assistance system means - in accordance with Law no. 292/2011 on social assistance - public institutions and social assistance establishments providing social services, public social services from county councils, sectors of Bucharest, Bucharest General Council, municipalities and communes, as well as persons providing home care, as well the personell providing educational, social and psychological counseling to detainees within the custody of the prison system. **As of December 1, 2015, the gross basic salaries / function incentive / function salaries / allowances of employment of the staff from the public social assistance system, was increased by 25% compared to the benefits for September 2015*
		Law no 330/2009 updated, regarding the unitary remuneration of personnel paid from public funds.	Incentives for hard working conditions - for particularly dangerous conditions, including TB - the incentive is **50-100% of the basic salary** The incentive level is established by the manager of each health unit by consensus with the unions representatives (*signatories of the collective agreement)* and within the approved personnel expenses in the income and expenditure –***art.10 od Annex III*** - *Specific regulations for civil servants.*
		MoH Order no. 547/2010 for the approval of the Regulation on granting the increases of base salaries, in accordance with the provisions of note from Annex II / 2 to the Framework Law no. 330/2009 regarding the unitary remuneration of personnel paid from public funds.	In the units who have in their structure sections or departments of different profiles, **a salary increase is given only to staff working permanently** in those units or compartments –as set out in the Annexes to this Regulation (**TB, infectious diseases**, psychiatry, child neuropsychiatry, sanatoriums, sanatorium, social assistance units and medico-social, etc. (***art. 9 Regulation***) Takes advantage of salary increase under this regulation, all the staff working in the units and external departments which are established separate from the unit with legal status profile of TB, AIDS, infectious diseases, psychiatry, neuropsychiatry infant, nursing homes, etc. preventoria (***Art. 10 Regulations)*** *Increases granted under the provisions of paragraph "Bonuses and other specific rights" pt. 1 lit. b) of Annex. II / 2 of this regulation* **Salary increase of 50-100%** from the basic salary is granted to: - staff working in Pneumophysiology units (hospitals and nursing homes) - Institute of Pneumology "Prof. dr. Marius Nasta" Bucharest - specialized healthcare personnel, specialized within the paraclinic departments and auxiliary sanitary units and departments with beds for TB, osteoarticular TB, genital TB,

			lymph TB; nodes, - Laboratories or departments serving these beds, within TB medical practices and **Pneumophysiology health clinics (TB) - *Annex. 2 of the Regulation***
33.	Criminal penalties for offenses against public health; thwarting disease control	**Law no. 286/2009 - Criminal Code**	Failure to comply with measures for the prevention or combating infectious diseases whether it has resulted in the spread of such a disease, shall be punished with imprisonment from 6 months to 2 years or a fine. If the offense in para. (1) is committed by negligence, the penalty is imprisonment from one month to six months or fine **- *art. 352***