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A judicialização do acesso à Oxigenoterapia Domiciliar Prolongada no Sistema Único de Saúde.

Judicialization of access to long-term home oxygen therapy in the Brazilian Publich Health System.

El acceso a la terapia de oxígeno judicialización Cuidado de la operación prolongada en el Sistema de Salud Púbica Brasileña.

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RESUMO: O objetivo deste trabalho foi analisar as ações judiciais de oxigenoterapia domiciliar prolongada (ODP) recebidas pela Coordenação Geral de Atenção Domiciliar do Ministério da Saúde em 2015. Foi realizada pesquisa em revistas científicas brasileiras de Saúde Coletiva indexadas internacionalmente sobre os perfis clínico e epidemiológico dos indivíduos que mais necessitam da ODP e por políticas públicas e/ou dispositivos vigentes que a regulamentam em âmbito federal, associando o escopo desses documentos com o perfil da população que a utiliza. Foi analisado os municípios que possuem Serviço de Atenção Domiciliar (SAD) implantados e que possuem organização para o fornecimento da ODP. Quanto aos perfis clínico e epidemiológico foi verificado que a maioria dos demandantes eram homens, idosos e com Doença Pulmonar Obstrutiva Crônica. Foram encontradas portarias que instituíram o Programa de Assistência Ventilatória Não Invasiva aos Portadores de Doenças Neuromusculares. Dos municípios com SAD, 69% possuem fluxo para fornecimento da ODP. As portarias existentes não são específicas para ODP e são restritivas aos indivíduos com doenças neuromusculares, fator que justifica as demandas judiciais recebidas, mostrando que, são necessários dispositivos específicos no SUS para esta terapia e que seja mais abrangente que as existentes.

Palavras-Chave: Oxigenoterapia, Judicialização da Saúde, Assistência Domiciliar, Direito à saúde, SUS.

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Abstract: This study aimed to analyze lawsuits filed against the General Office of Home Care of the Ministry of Health in 2015 to obtain home long-term oxygen therapy (LTOT). Internationally indexed Brazilian journals on collective health were examined to determine the clinical and epidemiological profiles of individuals who need LTOT the most, as were current public policies and provisions regulating this therapy at a federal level. The scope of these policies was compared to the profile of the population using LTOT. Municipalities that had implemented Home Care Service (SAD) and the organized provision of LTOT were also studied. In terms of the clinical and epidemiological profiles, it was determined that most plaintiffs were elderly men with Chronic Obstructive Pulmonary Disease. Regulations establishing the Non-invasive Assistance Program for Persons with Neuromuscular Diseases were also found. Out of the municipalities with SAD, 69% of them have flowcharts for the provision of LTOT. Existing regulations are not specific to LTOT and are limited to individuals with neuromuscular diseases, which justifies the lawsuits filed, and shows that the Brazilian Healthcare System (SUS) requires specific provisions on this therapy that are more comprehensive than current ones.
Keywords: Oxygen therapy, The judicialization of health, Home Care, Right to health, SUS.

RESUMEN: el objetivo de este estudio fue analizar las demandas que solicitan Oxigenoterapia Domiciliaria Prolongada (ODP) remitidas a la Coordinación General de Atención Domiciliaria del Ministerio de Salud, en el año 2015. Se realizó una investigación con base en revistas científicas brasileñas de salud colectiva, indexadas a nivel internacional, sobre el perfil clínico y epidemiológico de las personas que más necesitan la ODP, y se llevó a cabo una búsqueda de las políticas públicas y disposiciones actuales que regulan la ODP a nivel federal. Se comparó el alcance de estas con el perfil de la población que utilizaba la terapia. Por otra parte, se investigaron los municipios que cuentan con Servicio de Atención Domiciliar (SAD) y la provisión organizada de la ODP. En cuanto a los perfiles clínicos y epidemiológicos, se constató que la mayoría de los demandantes eran hombres de tercera edad con enfermedad pulmonar crónica obstructiva. Se encontraron dos normas para establecer el Programa de Asistencia Ventilatoria No Invasiva para los Portadores de Enfermedades Neuromusculares. De los municipios con SAD, el 69% disponen de un diagrama de flujo para la provisión de la ODP. Las normas existentes no son específicas a la ODP y se limitan a personas con enfermedades neuromusculares, factor que justifica las demandas recibidas, y pone de manifiesto que se requieren disposiciones en el SUS (Sistema Único de Salud brasileño) para esta terapia y que sean más integrales que las existentes.
Palabras clave: terapia de oxígeno, judicialización de la salud, cuidado del hogar, derecho a la salud, sistema único de salud.

INTRODUCTION

Therapeutic use of oxygen started around 1922 and since the fifties oxygen cylinder has already been prescribed in the treatment of individuals with Chronic Obstructive Pulmonary Disease (COPD) [1].

Oxygen therapy is giving oxygen in concentration and pressure that are greater than those found in the environment to ensure the proper transport of oxygen in the blood, reducing the respiratory work [2]. It aims to reverse the clinical changes occurring with insufficient oxygen in the blood, the maintenance of protein that carries oxygen (hemoglobin), the volume of blood pumped by the heart per minute and adequate blood supply for tissue nutrition [3].

The first studies that subsidized the current researches, as well as the consolidation at home, were from the beginning of eighties and demonstrated that the long-term oxygen therapy (LTOT) not just improves the quality of life, but also increases life expectancy for the individuals with lung diseases with insufficient oxygen in the blood, especially Chronic Obstructive Pulmonary Disease (COPD) [4,5].

For indicating LTOT the oxygen concentrator unit is needed, for at least, 15 hours a day and monitoring by health professionals [6, 7], making it to be considered as a costly therapy. Even so, the authors point out that it is more advantageous when compared to the hospital stay [8], because it allows the individual to remain at home and close to their family.

A study on LTOT cost in adults showed that the average amount for renting the concentrator was R$160,00 per month. And for the cylinders, the calculation depended on the quantity used by the individual, being R$ 110,00 per cylinder [9]. In children, using the concentrator to replace the cylinder allowed a 54% reduction in costs for this therapy [8].

However, these studies did not include expenses for electric power, which are funded by the individual and/or family. It turns out that there are State initiatives that minimize the treatment amount, such as the Ordinance MS/GM No. 630, 2011, that instituted the Social Tariff on Electric Power benefiting individuals with monthly income that is below three minimum wages. To be benefited, they must have some disease or disability (physical, motor, auditory, visual, intellectual and multiple) and whose treatment, medical or therapeutic procedure requiring the continuous use of apparatus, equipment or instruments, which for its operation, demands electric power consumption [10]. This Ordinance enables the reduction in therapy cost for people depending on LTOT.

The General Coordination of Home Care of the Health Department of the Ministry of Health (CGAD/SAS/MS) fosters and coordinates the actions of Home Care (HC) under the Brazilian Public Health System (SUS) through the Better at Home Program.

The Ordinance GM No. 825, April 25, 2016 [11], defines HC as:

> Modality of health care integrated to the Health Care Network (HCN), characterized by a set of actions for preventing, and treating diseases, rehabilitation, palliation, and health promotion, provided at home, ensuring continuity of cares [11].

This is a modality that provides a more humanized care, being powerful to produce new care practices, because the individual will be at their home or at a family home, within a known routine and with more privacy [12,13]. In the context of using the LTOT it is not different, and HC has an important role by enabling people to remain in their homes with more quality of life that as it is in a hospital.

Although the handbooks of the Ministry of Health, such as the Home Care Notebooks [10], address the clinical criteria for indicating and admission to Home Oxygen Therapy Program, it is known that there are no rules for supplying this input. Such fact contributes for the Judicialization of the LTOT and for the domiciliary care at SUS.

Judicialization of health is characterized by claims and modes of action of the Judiciary Power to guarantee the rights of citizenship widely affirmed in international and national laws. This phenomenon involves political, social, ethical, and sanitary aspects that go far beyond their legal component and public services management of lawsuits where there is request for inputs, and procedures and medications [14].

It is a recent phenomenon, and with great relevance, that has taken place in Brazil and in other countries, involving many stakeholders, such as the citizen, the technological health market, the associations, and the pharmaceutical industry [15]. In Brazil, it arose in the nineties from the requests for antiretroviral drugs for the Acquired Immunodeficiency Syndrome (AIDS) and represented an important role as the citizen's alternative to access to get aces to drugs in SUS, i.e. the right to integral health [16].

Many are the reasons that explain judicialization, but for Barroso [17] there are three principles. The first refers to the State's democratization, which allowed the individuals to exercise their citizenship and seek the Judiciary Power to protect their interests, in addition to expanding the Public Defenders for several parts of the country; the second highlights health as a right in the Federal Constitution, which turns it potentially into a legal claim [17] and; the third is the Brazilian constitutionality system that allows for questioning any law before the judge or court [17]

This phenomenon has not been spontaneous, not isolated, but stimulated initially by health social movements organized and empowered councils by the health councils [17] In the councils, entities for protecting people's rights with some injury or disease, such as diabetes, hemophilia, etc., were participating, having historically important role on health judicialization in Brazil [18].

It is known on the relevance that the issue has acquired in recent years, especially the impact on the public budget, and the judicialization being a challenge for health management and justice system. It is considered a multifaceted event, broad and diverse question of claiming assets and rights as inputs, facilities, medicines, health care, food, among other demands to be protected by the principle of the right to health [19]. In addition to exposing the institutional limits and possibilities, it instigates the production of effective responses by the health system public agents and justice system [20].

The 1988 Constitution also introduced the so-called solidarity federalism that imposed common competence to the Union, States, Federal District, and Municipalities for taking care on health, although one has opted for decentralization in implementing health services [21,18,9].

The fact that judicialization has been used as a tool for affirming the health as a right, some authors evidenced it as the recognition of individual pretensions to positive State provisions and that the gaps of the public policies and the gaps in their execution [22, 23] caused an important impact on the health system, both for the management as well as for SUS' funding system.

However, there are studies showing adverse effects, which can be divided into two main aspects. The first points out that the deferral of court orders may deepen inequities in access to health, breaking one of SUS' principles. This is because the individual actions are not extended to other carriers of the same pathological condition that could benefit with the object of the judicial action, as well as the favoring of those who have more access to the Judiciary Power to propagate their demand, to the detriment those that do not have it [24]. The second aspect refers to the security of the individual because of possible inappropriate prescriptions, in particular, in prescribing new drugs and/or new therapeutic indications for which scientific evidences have not yet been well-established [25].

Despite all the problems that judicialization carries for SUS' management, several authors consider it as a legitimate form for ensuring the exercise of the right to health, with the argument that this right is inviolable, regardless of political and budget-related issues [16,1]. In addition to the possibility of being seen as a diagnostic for the inputs or treatments that the population cannot access according to SUS' principles and, from that, studies may be produced that support actions aimed at reducing processes and assurance of health as a social right. Amongst these actions, the creation of public policies that guide the implantation and supply of health services is highlighted.

Given this scenario and the little existing scientific production on the LTOT's judicialization, this study sought to understand the legal demands concerning the long-term oxygen therapy at home received by the Ministry of Health and directed to CGAD/SAS/MS for technical advice in the 2012 to 2015 period.

METHODOLOGY

It is an exploratory and descriptive study that sought to learn on the judicialization of oxygen therapy at home and its connection with the lack of norms that regulate it, being this theme yet little studied.

The research went on from April to October, 2015. Data relating to court cases received in the Coordination in the years going from 2012 to April 2015 were analyzed during this period.

The first step was to perform a search in the databases being relevance to knowledge production health in health on the profile of people who use LTOT: PubMed, Bireme, and SciELO. For this, the descriptor home oxygen therapy was used.

The second step was the search of public policies and/or current provisions, in federal scope, governing the LTOT, in Health Legis electronic site of the Ministry of Health, associating the scope of these policies and/or provisions to the profile of the population that uses the LTOT.

However, the third step was analyzing CGAD/SAS/MS database related to LTOT provision, where one sought the municipalities with care organization, flowchart, protocols, or care lines, for the individuals using LTOT. These data were obtained from a questionnaire sent by e-mail by CGAD/SAS/MS to all HC managers of the Brazilian municipalities, with a view to ascertaining the working form of Home Care Services (HCS), containing the following questions: the municipality has organization for providing LTOT? If so, regulation is made by the HCS?

As for ethics in research, this article was based on an end-of-graduation-course paper and has been subsidized by the National Health Council resolution No. 466,December 12, 2012, fulfilling the requirements of respect for the human condition, autonomy, non-maleficence, justice and equity, amongst the other requirements that are explicit in the resolution. This did not require submission to the Research Ethics Committee, because secondary public data were used [26], subsidized by the Act of Access to Information, No. 12.527, November 18, 2011 [27].

RESULTS

LTOT requests accounted for 30.4% of court cases, that is, 24 among the 79 court cases during the period, 2012 to 2015.

Clinical and epidemiological profiles

As for the clinical and epidemiological profiles, the individuals who rely on this technology are, as per publication of Floriano et. al. (2012) [32], adults, and on age, Lacerda (2013) [6] pointed out that most of them were elderly and studies of Watanabe et. al. (2015) [9] found that the majority were male, smokers, and former-smokers [32, 6, 9].

According to studies from the American Thoracic Society (1995)[2] and the Brazilian Society of Pneumology and Phithisiology (2000 and 2004)[3], in adults, the primary lung disease that is accompanied with chronic oxygen insufficiency in the blood and needs LTOT, it is the Chronic Obstructive Pulmonary Disease (COPD)[2,3,33], corroborating with the fact of COPD being the most cited diagnosis in the court cases received by CGAD/SAS/MS.

However, in children, Lynn (2011) pointed out other diseases that are more prevalent in using LTOT, like cystic fibrosis[34].

Therefore, today LTOT is considered the main non-pharmacological treatment for individuals with LTOT, and it is indicated for patients with end-stage advanced disease[3].

Rules

Two rules from the Ministry of Health were found in force and effect: The Ordinance MS/GM No. 1370, July 3 2008[28], which instituted the Program of Non-Invasive Ventilatory Assistance to Patients with Neuromuscular Diseases, and Ordinance MS/SAS No. 370, July 4, 2008[29], that guides the organization and implementation of the Program, sets the list of diseases to be contemplated and establishes technical criteria for implementing the Program and the Ventilatory Assistance to patients with neuromuscular diseases needing it.

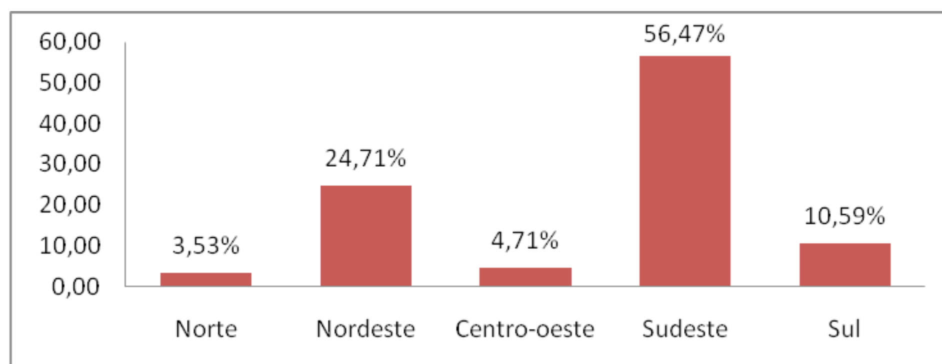
It was found that after the public consultation, on July 4, 2012, the procedure was incorporated to SUS (national health system) for treating the LTOT, by means of the First Extraordinary Meeting of the Plenary of the National Commission for Incorporating Technologies in SUS (CONITEC)[30].

In the year 2013, the Ministry of Health approved the Ordinance No. 609, which standardizes the Protocol and Clinical Therapeutic Guidelines (PCTG) for LTOT, which deals with the general disease concept, criteria for diagnostic, inclusion and exclusion, the guidelines for the treatment and the of regulation, control and assessment mechanisms[31]. PCTG has a national nature and must be used by the health departments of the States, Federal District, and Municipalities in the regulation of healthcare access, authorization, registration, and reimbursement of corresponding procedures. Among the procedures proposed for treating the LTOT, there is Long-Term Oxygen Therapy at Home, with the criteria for its prescription or not.

Providing LTOT by the Municipalities, States and Federal District

With regard to the organization of health care for the individuals needing the LTOT under municipal or state scope, from the 318 deployed HCS, i.e. in operation, about 38.7% (N=123) provided data for the Coordination. Of these, 69.10% (N=85) informed they have an organization for providing LTOT. It turns out that in most municipalities (66%) the regulation is not carried out by the HCS.

CHART 1 Percentage of Municipalities that have an organized service to provide LTOT in 2015, by region.



It turns out that five States have a state-managed program for providing LTOT, whereas one stands out for having focused only individuals coming from State-managed hospitals (CHART 2).

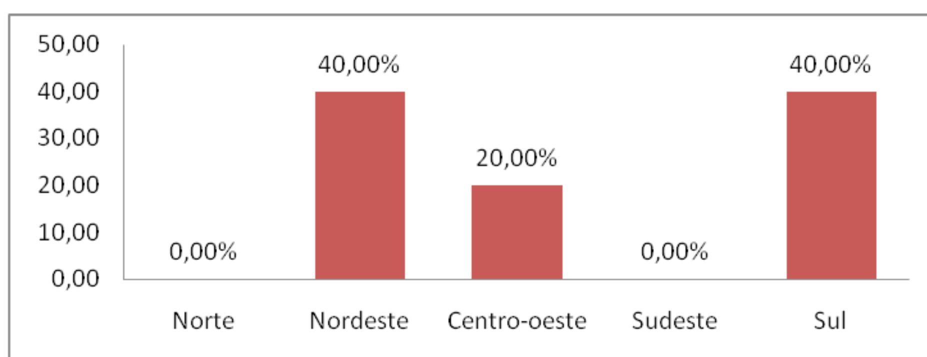


CHART 2 Percentage of States that have state-managed programs to provide LTOT in 2015, by region.

DISCUSSION

The results show that there are no ordinances of the Ministry of Health to regulate LTOT for individuals in general.

The existence of several documents, such as CONITEC report that incorporated LTOT to SUS (national health system), as well as PCTG and the Home Care Notebook, volume II, that bring out an indication for their use, indicate that the Ministry of Health has sought to meet the population's demands, recognizing the effectiveness of this therapy [30,31,10].

It is important to note that the Home Care Notebook, volume II, is comprehensive as for the indication of the therapy, not tied to a specific group of pathologies. However, PCTG of COPD includes the clinical profile concerning people who most need the LTOT, unlike Ordinances No. 1370 and No. 370, both from 2008 [10,31,28,29].

The existence of these documents shows that this therapy should be available in SUS and according to the precept of municipalization, the municipalities should offer it, showing a vulnerability of the

health system.

This weakness in the organization in the municipalities regarding the offer of LTOT by SUS, along with the lack of Union's guidelines regarding the provision of therapy are concerning, because, there is an increase in the number of individuals who need LTOT in various places. A multicentric study conducted in five major cities in Latin America found the prevalence of 15.8% of COPD in individuals being 40-year old or more [35]. However, the global prevalence of COPD pointed by the *Global Initiative for Chronic Obstructive Lung Disease* (GOLD), for all age groups, was 11.6/1000, for men and 8.8/1000 for women [36].

The demand for LTOT also has an important prevalence, particularly among individuals with home follow-up. In the Federal District, for example, a study conducted between the years 2012 and 2013, which examined the medical record of 857 individuals, found prevalence of 31.5% for LTOT utilization [37].

It is observed that using LTOT was more common in the elderly, according to Moraes et. al. (2010) [38]. It is important to note that with the progression of age, physiological changes do not culminate in illness; however, they make the individuals more susceptible to processes of loss of functional capacity, which requires cares that are more attentive to the aging process and the most prevalent pathologies [38].

Considering that LTOT is a scientifically consolidated therapy, with good cost-benefit relation both from a financial point of view as well as social, because it allows the individuals to live in their homes and close to their families, there could be greater effort from the public sphere to provide access to all needing it.

According to the results in this study, the ordinances about providing in force and effect, won't reach the clinical profile of the individuals who need it most, which indicates that there is a need for the services to be restructured in order to provide or expand the range of therapy offering. An example is Joinville municipality that during the 218[en] Annual General Meeting of the Municipal Council of Health in 2012, approved the accreditation of Long-Term Oxygen Therapy at Home, specifically for people with neuromuscular disease [39]. What exemplifies the induction power of federal ordinances and policies for organizing and providing services by the municipalities, which, in such a case, are restrictive given the clinical and epidemiological profiles found in this study.

Even if there are documents that, in theory, ensure the population's access, the lawsuits received in CGAD/SAS/MS highlight the weaknesses and failures related to the health system, in the case of this study, specifically in providing LTOT, showing that such documents may be insufficient to induce the organization of municipalities and states in implementing structured service in order to ensure access to therapy by the citizens.

With that, part of the population gets no access to the treatment, even with health being assured

as a social right in the Federal Constitution. In addition, SUS' legislation has principles that also ensure the right to full, universal and fair health [40], which imposes that such a service shall meet the user's needs.

Some authors have shown that the majority of the municipalities do not possess technical and financial capacity to fulfill alone the universalizing precept and integral health care, making them hostages of technical and financial cooperation of the States and the Union [18].

When this financial and technical cooperation does not happen properly amongst the federated entities, some municipalities fail to ensure access to inputs and treatments, that associated with the fact that the citizens have more knowledge about their rights, more access to the Judiciary Power and little knowledge on the public health policies and SUS' functioning, contribute for the increase in litigations.

It turns out that most of the states and municipalities have an organized health service in order to provide LTOT, both with the existence of flow, protocol, or even ordinances. However, in more than half of the municipalities (66.0%), regulating the supply is not made by HCS.

A possible justification for such a result is that there are some prerequisites for a municipality to claim the deployment of a HCS, as, for example, agreement in the Bipartite Inter-Managers Commission (Comissão Intergestores Bipartite - CIB), hospital back-up, Emergency Mobile Care Service (Serviço de Atendimento Móvel de Urgência - SAMU) coverage or similar service and population criteria[11], which may indicate which are the municipalities with more-structured health services.

In addition, despite the ordinance regulating HC that allow for smaller municipalities to group in order to deploy HCS, in the preparation period of this study there were only two groups, that is, most municipalities with HCS has over 20,000 inhabitants, which can also justify the data of municipalities who have HCS and provide LTOT.

AD notebook, volume II [10] may have influenced some HC services to organize the provision of LTOT with the financial resources intended for these teams or even assume the regulation of programs, protocols, and already existing flows.

A limitation of the study was that the data relating to supplying LTOT by the States, Federal District, and Municipalities are restricted to those who have deployed HCS and who provided data for CGAD/SAS/MS. In addition, the data are not clear to distinguish if the delivery happens to individuals in general or is subsidized by the Ordinances No. 1370 and No. 370, 2012, which limits the provision to people with neuromuscular diseases.

It can be assumed that municipalities with the Better at Home Program have more structured health services, since that joining the program depends on a health structure, however, more

studies are needed on the epidemiology of using LTOT, and analyzing the legal proceedings under a stratified way, in order to know whether the places with the highest number of demands have an organization or not for providing therapy, as well as studies that analyze all municipalities with and without HCS, in order to conclude if the solution would be the development of a specific policy or if it would be the creation of a provision in an already existing policy. It is noteworthy to better understand the existing organizations at the federal and state spheres so that they can be used to subsidize the development of this new policy or provision.

Knowing the high spending with the litigations by the three federated entities and the problems caused in managing the health services, the topic has been much debated and gained prominence. However, this attention is still discreet and with greater emphasis on the spending than on the phenomenon itself and what it can indicate. There is, then, the need for rapprochement between the health system and the judiciary in order to keep the permanent integration of these entities in order to discuss, reflect and think on joint solutions for this problem.

It is necessary to improve the dialogue amongst health managers, the three government spheres, and the Judiciary Power, in order to think on joint solutions.

In order to follow the solidarity federalism precepts, it makes sense that the discussion be shared between the Union, States, Federal District, and Municipalities. It is therefore necessary to discuss the theme in shared spaces of the three government spheres, for example, the Tripartite Inter-managers Commission (Comissão Intergestores Tripartite - CIT), aiming to find ways for organizing the federated entities for supplying LTOT, including, by ensuring tripartite funding and avoiding, so, that the municipalities assume alone therapy delivery.

FINAL CONSIDERATIONS

The results of this study show that the ordinances in force and effect do not contemplate the profile of individuals that are most needing LTOT, such a fact can justify the high number of litigations received by the Ministry of health requesting this therapy.

Knowing the problems that the judicialization can bring out on the management and operation of health services, but also considering that it is a form of citizens seeking to constitutionally ensure granted rights, the phenomenon should be better understood and ways to contain its growth should be found. It is necessary to jointly invest in ensuring access to health services and in improving and expanding public health policies, as well as in raining the managers, in order to ensure their implementation.

There is therefore the need to discuss under tripartite form LTOT judicialization in order to define actions that subsidize the municipalities for providing a therapy that, theoretically, should have been already be offered to the users. It is necessary to set the responsible actors and the flows to the LTOT, since that the public policies are dispersed in various normative acts, without a clear

systemization and, often, with procedural steps that contrast with the requirements made in the processes.

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