BRATISLAVA INTERNATIONAL SCHOOL OF LIBERAL ARTS

GKV-IPReG:

A LAW IN THE INTEREST OF PATIENTS?

Bachelor Thesis

Ruben Wöllert **Leipzig, 2022**

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Declaration of Originality

I hereby declare that this bachelor thesis is the work of my own and has not been published in part or in whole elsewhere. All used literature is attributed and cited in references.

Bratislava, July 04, 2022

Ruben Wöllert

Signed: Wöllert

Acknowledgments

I dedicate this work to all people who are affected by the GKV-IPReG due to their need for intensive care, their families and friends, their caregivers, and all other everyday heroes who every day anew try to make the lives of each other a little bit more worth living.

I dedicate this work to my family. Who knows what I would be without you?

I dedicate this work to my professors and classmates in BISLA. I am grateful for the time we spent together, the learning environment you created, and the education you provided.

Abstract

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The entry into force of the Intensive Care and Rehabilitation Strengthening Act (GKV-IPReG) changes the legal basis for out-of-hospital intensive care in Germany. This also means that people who are dependent on intensive care can no longer assert their claims regarding the location of care in the same way. They see this as an encroachment on their freedoms and rights. If this were to be the case, the legislature would have created a legal situation that is contrary to the interests of the patients concerned, contrary to its alleged intentions. This paper is an attempt to determine whether this is indeed the case. For this purpose, the comments on the GKV-IPReG submitted by patient associations, which are available to the Federal Ministry of Health, were examined and several main points of criticism were identified. These mainly concern the possible restriction of the freedom of choice over the place of care of the affected persons, and the guidelines which make this possible. Due to the decisive role that the Federal Joint Committee plays in the creation of these guidelines, it was examined critically and with regard to the distribution of power within it. It was found that the interest group of patients was not significantly involved in the decision-making process, and due to the structure of the Joint Federal Committee could not have been. Finally, based on the preceding investigation, it was determined that the GKV-IPReG is not a just law for those affected. The theoretical basis for the answer to this question, was provided through the theory of the justice, which A. Sen presents in his work *The Idea of Justice*. The summarized result of this work is that the GKV-IPReG is not a law in the interest of the patients affected by it, and in the future, it cannot be part of a health care system oriented towards these needs.

Abstrakt

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Vstup do GKV-IPReG mení legálne pozadie mimo nemocničnej intenzívnej starostlivosti. To taktiež znamená, že ľudia už závislí od intenzívnej starostlivosti, viac nemôžu rovnakým spôsobom nárokovať svoje práva týkajúce sa miesta starostlivosti. Toto pacienti vidia ako narušenie ich slobody a práv. Ak by sa takto stalo, nová legislatíva by vytvorila legálnu situáciu, ktorá je v zápore so záujmami pacientov, čo je takisto v zápore s cieľom tejto legislatívy. Táto práca sa pokúša identifikovať či dochádza k tomuto rozporu. Za týmto cieľom sme skúmali komentáre asociácií pacientov adresované na GKV-IPReG, ktoré sú dostupné na ministerstve zdravotníctva, a identifikovali sme v nich kritické aspekty. Tieto komentáre sa vzťahujú najmä na možnú reštrikciu slobodnej voľby miesta starostlivosti a usmernení, ktoré to umožňujú. Kvôli role ktorú v tomto usmernení hrá, sme kriticky skúmali Federálnu Združenú Komisiu a distribúciu moci v jej jadre. Videli sme, že skupiny pacientov neboli reprezentované pri rozhodnutí o tomto usmernení, kvôli štruktúre spomenutej komisie ani reprezentované byť nemohli. Nakoniec sme na základe predošlej diskusie rozhodli, či môžeme pokladať GKV-IPReG za spravodlivý zákon. Teoretickú bázu na základe, ktorej vieme odpovedať na túto otázku, a to odpoveďou „nie“, prináša teória spravodlivosti, ktorú prezentuje A. Sen vo svojom diele The Idea of Justice. Zhrnutý záver tejto práce je, že GKV-IPReG nereprezentuje záujmy pacientov na ktorých sa tento zákon vzťahuje a v budúcnosti nemôže byť súčasťou zdravotného systému, ktorý sa zameriava na tieto potreby.

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Introduction

On August 14, 2019, the German Federal Ministry of Health (BMG), under the leadership of Health Minister Jens Spahn of the Christian Democratic Union of Germany, presented the draft bill for a law to strengthen rehabilitation and intensive care services in the statutory health insurance system. In the "Rehab and Intensive Care Strengthening Act - RISG" (Reha- und Intensivpflege-Stärkungsgesetz - RISG), the legislator identifies several problems and formulates objectives of the new regulation. A bundle of measures, consisting of changes to the "Fifth Book of the Social Code" (SGB V), "Eleventh Book of the Social Code" (SGB XI), and the Hospital Remuneration Act, should serve to eliminate the problems and realize the goals. The draft bill also includes a justification for the RISG. Protests and critical statements on the RISG quickly followed.

ALS-mobil e.V., a self-help association for people affected by the disease amyotrophic lateral sclerosis (ALS), i.e., one of those groups of people often in need of intensive care and thus directly affected by the RISG, launched a petition calling the draft law a scandal and demanding that it be stopped because it interferes with their right to self-determination (Lasst Pflegebedürftigen Ihr Zuhause! Stoppt Das Intensivpflegestärkungsgesetz, 2019). To date (as of 04/19/2022), 262,936 people have signed this petition. At 300,000 signatures or more, it will become one of the most signed petitions on the site, according to Change.org (Lasst Pflegebedürftigen Ihr Zuhause! Stoppt Das Intensivpflegestärkungsgesetz, 2019). On Sept. 10, 2019, 120 demonstrators, including 35 intensive care patients in wheelchairs, gathered for the "1st

Demo for the Preservation of Self-Determination" in Berlin to protest the bill. Further protests followed, the last one for the time being two years later, on 09.09.2021.

As of 16/09/2019, the archive of the Federal Ministry of Health contains 88 comments (Stellungnahmen zum Referentenentwurf zum Reha- und Intensivpflege-Stärkungsgesetz - Bundesgesundheitsministerium, 2019) on the RISG. The authors include stakeholders from patients, physicians, caregivers, health insurers, municipalities, as well as civil society institutions. The range of opinions thus includes most stakeholders directly affected by the law. Many of the statements explicitly welcome the legislator's objectives (AbilityWatch, 2019, p. 2; Deutsche Interdisziplinäre Gesellschaft für Außerklinische Beatmung, 2019, p. 1; Deutsches Institut für Menschenrechte, 2019, p. 1; GKV-Spitzenverband, 2019, p. 5; Stellungnahme Des Bundesverbandes Der Pneumologen, Schlaf- Und Beatmungsmediziner (BdP) Zum Entwurf Eines Gesetzes Zur Stärkung von Rehabilitation Und Intensiv-Pflegerischer Versorgung in Der Gesetzlichen Krankenversicherung (Reha- Und Intensivpflege-Stärkungsgesetz - RISG), 2019, p. 2). However, with a few exceptions, every opinion criticizes that, through the reversal of the paradigm "outpatient before inpatient" constituted by § 3 SGB XI (*Vorrang der häuslichen Pflege*) seemingly provided for in the bill, there is a massive encroachment on the self-determination and freedom of choice of those affected (AbilityWatch, 2019, p. 2; AOK-Bundesverband, 2019, p. 6; Bundesverband der Pneumologen, Schlaf- und Beatmungsmediziner, 2019, p. 6; Bundesverband privater Anbieter sozialer Dienste e.V. (bpa), 2019, p. 5; Deutsche Interdisziplinäre Gesellschaft für Außerklinische Beatmung, 2019, p. 2; Deutscher Gewerkschaftsbund, 2019, p. 2; Deutsches Institut für

Menschenrechte, 2019, p. 2,3; Die Fachverbände für Menschen mit Behinderung, 2019, p. 2; GKV-Spitzenverband, 2019, p. 4; INTENSIVkinder zuhause e.V, 2019, p. 2,3; Vereinte Dienstleistungsgesellschaft, 2019, p. 3).

In addition, further points of criticism can be found in the statements. For example, the "INTENSIVkinder zuhause" association and the Bundesverband privater Anbieter sozialer Dienste (bpa) criticise the new regulation because the newly created service complex "out-of-hospital intensive care" can in future only be prescribed by "qualified contract physicians" (Bundesverband privater Anbieter sozialer Dienste e.V. (bpa), 2019, p. 4; INTENSIVkinder zuhause e.V, 2019, p. 3), and point out that there is a lack of qualified physicians. At the same time, they accuse the legislator of failing to make up for shortcomings, for example in the creation of sufficient specialist staff and facilities (for example, weaning centers), or the pressure on hospitals to discharge patients under the DRG system, at the expense of those in need of intensive care and their providers (Bundesverband privater Anbieter sozialer Dienste e.V. (bpa), 2019, p. 4; INTENSIVkinder zuhause e.V, 2019, p. 4). The German Federation of Trade Unions criticizes that "numerous already codified principles that make successful rehabilitation according to generally accepted standards possible in the first place" are not included in the objectives of the draft bill (Deutscher Gewerkschaftsbund, 2019, p. 2). In addition, there are repeated complaints about the generalization, discrimination and de-individualization of patients and others concerned. AbilityWatch, for example, doubts the need to take patients, for whom ventilator weaning cannot take place even in the long term, from their normalized households with the aim of ventilator weaning (AbilityWatch, 2019, p. 2). The German Institute for Human Rights opposes the denial of assistance based on the severity of an illness (German Institute for Human Rights, 2019, p. 3). The list is not yet exhausted but should suffice at this point to draw attention to the severity of the criticism.

The protest and criticism finally led the legislator to revise the RISG and submit a revised draft bill under the new name Intensive Care and Rehabilitation Strengthening Act (GKV-IPReG) on 06.12.2019. The GKV-IPReG was adopted as a cabinet draft on 12.02.2020, subsequently discussed in the Bundesrat and Bundestag and finally came into force on 29.10.2020. However, the problems remain, albeit in a partially weakened or amended form. As before, the petition of ALS-mobil e.V. against the GKV-IPReG is gaining popularity. As already mentioned, demonstrators went last 09.09.2021 against the law on the road. In conferences such as the Munich extra-clinical intensive care congress (MAIK), the law is discussed and debated. Trade journals take up the topic (IPReG Richtlinie - Eine Erste Einschätzung," 2022, pp. 10–13). And finally, the opinions of invited experts submitted to the Bundestag expressly oppose parts of the GKV-IPReG. It can be clearly observed that especially associations of affected persons consider the law "unsustainable" (Bundesvereinigung Lebenshilfe e.V., 2020, p. 2), as the preservation of the right of self-determination and the autonomy of the insured is still endangered (Bundesverband privater Anbieter sozialer Dienste e.V. (bpa), 2020, p. 5; Bundesvereinigung Lebenshilfe e.V., 2020, p. 2; Horst Frehe, 2020, p. 4; Verbraucherzentrale Bundesverband, 2020, p. 3). There are also other concerns, for example the "inclusion of a legislative initiative without first subjecting the underlying facts to a scientific empire" (Sebastian Lemme, 2020, p. 6), or the inadequate definition of "out-of-hospital intensive care" (Dr. Wilhelm Rehorn, 2020, p. 1).

A discussion of the GKV-IPReG not only reveals a multitude of profound problems in the German health care system which affect different actors in different ways and severity, but also raises fundamental doubts about its legitimacy. In this context, the legislative process in the health care system also plays a decisive role. The present work is an attempt to deal critically with the GKV-IPReG, by reading it through the perspective of the patients. Ultimately, it should be answered whether the GKV-IPReG is a law in the interest of patients or not.

Chapter 1 - Research design

The aim of this thesis was to examine whether the *Intensive Care and Rehabilitation Strengthening Act* (GKV-IPReG) is a law that is in the interest of patients or not. The examination was limited to articles 1 and 2 GKV-IPReG. In the first part, the relevant aspects of the GKV-IPReG were explained. In the second part, problems with the law were identified. In the third part, the role of the Federal Joint Committee in creating the guidelines necessary for the GKV-IPReG. Then results were evaluated, and a conclusion drawn.

The research of the problem was mainly based on three different data sets. First, legal texts of the Federal Republic of Germany. Second, the statements of selected stakeholders on the GKV-IPReG. And, thirdly, representative studies and data sets on various relevant topics.

The selection of the data sets was based on various criteria. The inclusion of legal texts was unavoidable, since this work deals with a law, and this can only be understood, interpreted, classified, and implemented through its connection to already existing laws. The GKV-IPReG contains changes from the Social Code (SGB) Fifth Book (V) - Statutory Health Insurance, as well as from the Social Code (SGB) Eleventh Book (XI) - Social Care Insurance. Accordingly, these legal texts, as well as the Basic Law of the Federal Republic of Germany, with which any jurisdiction of the German Federal Republic should be in accordance, became the subject of this work. In addition, it was important to understand how the GKV-IPReG could possibly make paradigms, which were created by previous supreme court rulings, null and void, or reverse them. For this purpose, those decisions had to be included in this work as a data set.

The opinions of patient stakeholders became a fundamental dataset of this work due to several factors. On the one hand, they represent the opinions of patients. Second, the opinions are part of the legislative process and thus particularly relevant. Furthermore, they are publicly accessible and thus facilitate the data collection for this thesis, which alternatively would have had to be carried out with the help of interviews with patients.

Representative studies and data sets, as well as journalistic publications, were particularly useful to get an overview of various relevant issues and to verify the truth of different positions based on them. They were researched in internet platforms and professional journals, and books. In the selection process, attention was paid to relevance and credibility, as well as transferability to the topic at hand.

In the first part of this thesis, the objective, and the content of the GKV-IPReG were examined. Due to the limitation of this thesis to articles 1 and 2 of the GKV-IPReG, the focus was only on these. In addition, relevant paradigms and regulations of the German health care system were presented. From the new regulation it resulted who is affected by the law as a patient. By the thus underlying definition, the stakeholders were finally selected. The reader who is unfamiliar with the topic should thus be provided with an overview of the essential aspects.

In the second part, problems with the law were identified. This was done based on the opinions of the previously identified stakeholders. Careful reading made it possible to identify several problems. The respective problems were then highlighted. Part 2 thus forms the basis for the following evaluation.

In the third part, we looked at how the legal framework provided by the GKV-IPReG is shaped by guidelines issued by the Federal Joint Committee. This serves on the one hand to clarify one of the problems identified in the second part, and on the other hand as an attempt to explain it.

The fourth part determined whether the GKV-IPReG is a fair law for those affected. The theoretical basis for this was Sen's theory of justice, from the work The Idea of Justice. The problems identified in the course of the work were examined with regard to the aspects of freedom and ability. The result allowed a clear conclusion regarding the question of justice, and thus contributes to answering the research question.

Subsequently, all results were briefly summarized once again and a look into the future of the GKV-IPReG and the German social system was dared.

The method described was chosen because it offers several advantages. Firstly, it is only through a review of the law in question that its problematic nature can be evaluated. The study of the text of the law was therefore inevitable. At the same time could be ensured by the elaboration of the most serious problems that the examination of the GKV IPReG, and the question whether it is in the sense of the patients, also on the basis the evaluation of concrete reference points could take place. It was limited due to the question consciously to the statements of the interest federations of the patients. While interest representatives of other concerned or involved actors, as for example care or health insurances, often speak in their statements in the name of the patients, the patients themselves have the last word in this question. At the same time, this restriction is a limitation, because other actors cannot be denied their expertise on good patient care.

Chapter 2: What Is The GKV-IPReG

The Act to Strengthen Intensive Care and Medical Rehabilitation in Statutory Health Insurance (Intensivpflege- und Rehabilitationsstärkungsgesetz - GKV-IPReG) is a law that was launched in 2019 by the Federal Ministry of Health of the Federal Republic of Germany. It consists of amendments to the Fifth Book of the Social Code (Article 1-2 GKV-IPReG), the Eleventh Book of the Social Code (Article 3 GKV-IPReG), and the Hospital Remuneration Act (Article 4 GKV-IPReG). According to Article 5(1) GKV-IPReG, it entered into force one day after publication in the Federal Law Gazette, on

29 October 2020. For the time being, the amendments to the Fifth Book of the Social Code listed in Article 2 are excluded from this (Article 5(2) GKV-IPReG).

Intensive care is generally understood to mean the monitoring and care of patients with life-threatening illnesses or disabilities. Often, care must constantly be given to ensure the survival of the patient. It is therefore also considered as special observation of the sick, or hospital avoidance care. The cases of illness or disability that led to this emergency are varied and include, for example, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), paraplegia, and craniocerebral injuries. People in a persistent Wake coma, who live a life that is restricted in terms of their mobility, are just as much a part of the patients in need of intensive care as people with a tracheostomy, who in many cases can live a comparatively unrestricted life. There is no such thing as a "typical" intensive care patient.

In Germany, intensive care can be provided on an inpatient or outpatient basis. In the sense of social law, inpatient care means care in "care facilities in which persons in need of care are cared for under the constant responsibility of a trained care specialist and can be accommodated and catered all day (full inpatient care) or during the day or night (partial inpatient care)" (§ 71 (2) SGB XI). Outpatient care takes place in "independently operating facilities which, under the constant responsibility of a trained nursing specialist, provide those in need of care with services of home care assistance within the meaning of § 36 in their homes" (§ 71 (1) SGB XI).

According to the legislator, the GKV-IPReG pursues several goals. "Those in need of intensive care are to be better cared for, disincentives in intensive care are to be eliminated and the self-determination of those affected is to be strengthened. In addition, access to medical rehabilitation is to be improved" (Bundesministerium für Gesundheit, 2020). For the then Federal Minister of Health Jens Spahn (CDU), the GKV-IPReG means that those in need of intensive care can be cared for in the place that is best for them, regardless of their financial situation (Bundesministerium für Gesundheit, 2020). Therefore, binding quality specifications for outpatient intensive care should be created, and inpatient intensive care should be made affordable (Bundesministerium für Gesundheit, 2020). Furthermore, hospitals and homes should be obliged to wean their patients off artificial respiration, if possible.

The main regulation dealt with in this paper is the expansion of the Fifth Book of the German Social Code to include § 37c Out-of-Hospital Intensive Care, Paragraph 1 and Paragraph 2. Through § 37c (1) SGB V, insureds with "a particularly high need for medical treatment care" are guaranteed for the first time a concrete entitlement to out-of-hospital intensive care anchored in the law. "A particularly high need for medical treatment care exists if the constant presence of a suitable nursing specialist (defined in § 71 (3) SGB XI) is required for individual control and readiness for action or a comparably intensive deployment of a nursing specialist" (§ 37c (1) SGB V). The requirement "covers the medical treatment care, which is necessary for the safety device of the goal of the medical treatment, as well as an consultation by the health insurance company, in particular for the selection of the suitable achievement place in accordance with paragraph 2 (§ 37c (1) SGB V)". From now on, this service may only be prescribed by a specially qualified panel doctor (§ 37c (1) SGB V). Together with the insured person, he or she should also discuss and determine a therapy goal (§ 37c (1) SGB V). Insured persons who are ventilated or tracheotomized are particularly singled out. The exact content and scope of the services is delegated by the legislature to the Federal Joint Committee with reference to § 92 (1) Sentence 2.

§ 37c (2) SGB V specifies the places in which insured persons can receive out-of-hospital intensive care. These include full inpatient care facilities, outpatient care facilities, residential units, the insured person's own household or any other suitable location. When choosing care, the "legitimate wishes of the insured" must be met. However, the Medical Service of the Health Insurance Funds (MDK), an advisory and assessment service, must check whether this wish can be met in accordance with § 37c (1) of theSGB V. The determination is to be reviewed annually. To implement the target agreement made with the patient, the health insurance fund only owes benefits in accordance with SGB V. If it is not possible for the MDK to carry out an assessment because it has been refused access to the patient's living quarters, patients who are treated in places in accordance with § 37c (1) Number 3 or Number 4 (this concerns, among other things, living units and the patient's own household) may be refused benefits at this place, or the insured person may be referred to benefits at a place in accordance with Sentence 1 Number or Number 2 (concerns, among other things, full inpatient care facilities).

The stakeholders affected by the GKV-IPReG are derived from Section 37c (1) and (2) of the German Social Code, Book V (SGB V). These are insured persons with a "particularly high need for medical treatment care", which exists if "the constant presence of a suitable nursing specialist is required for individual control and readiness for action or a comparably intensive deployment of a nursing specialist". The following were chosen as representative representatives of these stakeholders from whom a statement is available:

- Bundesarbeitsgemeinschaft Selbsthilfe von Menschen mit Behinderung und chronischer Erkrankung und ihren Angehörigen e.V.
- Bundesverband Schädel-Hirnpatienten in Not e. V.
- Bundesvereinigung Lebenshilfe e. V.
- Deutsche Stiftung Patientenschutz
- Deutscher Kinderhospizverein e. V. (DKHV)
- Interessenvertretung Selbstbestimmt Leben in Deutschland e. V. (ISL)
- Sozialverband Deutschland e. V. (SoVD)
- Sozialverband VdK Deutschland e. V.

Chapter 3 – Problems of the GKV-IPReG

The spectrum of opinions of the selected stakeholders ranges from full support (Bundesverband Schädel-Hirnpatienten in Not e.V., 2020, p. 1,3) to complete rejection (Bundesarbeitsgemeinschaft SELBSTHILFE von Menschen mit Behinderung, chronischer Erkrankung und ihren Angehörigen e.V. (BAG SELBSTHILFE), 2020, p. 2; Bundesvereinigung Lebenshilfe e. V., 2020, p. 2). Between these outer ends is the fundamental approval of the stated goals of the GKV-IPReG, but with the reservation that the law is not suitable for their achievement or its glaring errors (Deutsche Stiftung Patientenschutz, 2020, p. 2; Sozialverband Deutschland (SoVD), 2020, p. 3;

Sozialverband VdK Deutschland e. V., 2020, p. 2,4; Verbraucherzentrale Bundesverband, 2020, p. 3,5). While the complete approval of the GKV-IPReG on the part of the Bundesverband Schädel-Hirnpatienten in Not e.V. (Federal Association of Craniocerebral Patients in Need) is an isolated case, the right of self-determination of patients regarding their form of housing, which is endangered by § 37c (2) GKV-IPReG, was the main point of criticism in all other statements. Why this is the case will be examined in the following.

The most serious criticism of the GKV-IPReG, on the part of patients' stakeholders, is the possible restriction of patients' right to self-determination regarding their form of accommodation. This criticism arises from § 37c (2) GKV-IPReG, which regulates where insured persons receive out-of-hospital intensive care. Although the places listed in § 37c (2) are equally listed next to each other, and it is expressly mentioned that "justified wishes of the insured are to be met", requirements follow which must be fulfilled in order to meet these wishes. Thus, so the fear, it can be that, that last word in questions residence not in the hand of the insured ones (speak patients), but in that of the insuring ones (speak health insurance companies) lies. This would be a violation of Article 19 of the UN Convention on the Rights of Persons with Disabilities, which the Federal Republic of Germany ratified in 2009.(GG § 3(3) und GG § 13 siehe Zeitung)

According to § 37c (2) SGB V, insured persons can receive out-of-hospital intensive care at various locations. These include fully inpatient care facilities, facilities within the meaning of § 43a Sentence 1 in conjunction with § 71 (4) Number 1 of the SGB XI or premises within the meaning of Section 43a Sentence 3 in conjunction with § 71 (4)

Number 3 of the SGB XI (this includes, for example, the so-called "Pflege WGs"), the insured person's own household or any other suitable location. The places just mentioned, listed in § 37c (2) SGB V, are initially listed in the GKV-IPReG on an equal footing. Apparently, no place is explicitly preferred by the legislator, especially since the "legitimate wishes of the insured" are to be met (§ 37c (2) GKV-IPReG). ISL e.V. and SoVD positively acknowledge this equal enumeration (Interessenvertretung Selbstbestimmt Leben in Deutschland e.V. - ISL, 2020, p. 3; Sozialverband Deutschland (SoVD), 2020, p. 6). Nevertheless, like most patient representatives, they suspect that § 37c (2) of the GKV-IPReG implicitly deprives patients of the right to choose their place of care.

This presumption is based on the new requirement introduced by the GKV-IPReG for an annual examination by the Medical Service (MD) of whether and how medical care is ensured at the place of performance. The MD is the socio-medical advisory and assessment service of the statutory health and long-term care insurance system. Its tasks are the assessment to determine the need for care, as well as quality assurance. Formerly known as the Medical Service of the Health Insurance Funds (MDK), the MD can be understood as the right hand of the health insurance funds. The health insurance companies pay the insured benefits, which are assessed by the MD as necessary.

The review of the place of service provision by the MD, or the health insurance fund, is problematic from three points of view. Firstly, it does not emerge from the GKV-IPReG what happens if the judgement of the MD about the nursing care at the place of performance turns out to be negative. In the bill it was still intended that the desires of the insured ones are to be corresponded only if "the medical and nursing care at this place can actually and durably be ensured" (GKV-IPReG draft). It was criticized by a large number of stakeholders of the patients the consequence of a negative verdict, the transfer to an inpatient facility, against the wishes of the patient (Bundesarbeitsgemeinschaft SELBSTHILFE von Menschen mit Behinderung, chronischer Erkrankung und ihren Angehörigen e.V. (BAG SELBSTHILFE), 2020, p. 5; Bundesvereinigung Lebenshilfe e. V., 2020, p. 3; Deutsche Stiftung Patientenschutz, 2020, p. 5,6; Interessenvertretung Selbstbestimmt Leben in Deutschland e.V. - ISL, 2020, p. 3,4; Sozialverband Deutschland (SoVD), 2020, p. 6; Sozialverband VdK Deutschland e. V., 2020, p. 6; Verbraucherzentrale Bundesverband, 2020, p. 5). In general, it is to be seen critical that a situation is created in which the health insurance companies gain such profound power over the living conditions of patients. One could acknowledge the legislator that he has deleted this formulation. However now remains open which consequences threaten the patients, should they not receive a positive judgement of the MD over the supply at the place of the service provision. Thus, a legally unclear situation was created, which can harm especially the patients, who are now dependent on the "favour" of the health insurance companies to lead a life according to their wishes.

The second problem created by the introduction of § 37c (2) is the authority of health insurers to deny benefits to insureds in places referred to in Section 37c (2) Number 3 or 4 (dwelling units, the insured's own household, or any other suitable place) if insureds or their authorized representatives refuse the MD access to the dwelling units. On the one hand, this is part of the problem mentioned above, but on the other hand, it presents its own problem. For example, the SoVD can understand the intention of the regulation, "since the health insurance funds must be granted access to the premises for on-site inspections and require the consent of the owner of the house rights for this" (Sozialverband Deutschland (SoVD), 2020, p. 8), but doubts that the "connection between refusal of access and denial of benefits at the place of benefit requested by the person concerned is proportionate and purposeful" (Sozialverband Deutschland (SoVD), 2020, p. 8). "State interventions in fundamental rights must [however] be constitutionally justified and are subject to the requirement of proportionality" (Deutscher Bundestag, 2020, p.3). It is doubtful whether § 37c (2) GKV-IPReG does not actually interfere with the inviolability of the home secured by Article 13 of the Constitution, and whether it is proportionate. In fact, this regulation seemingly grants police powers to the MD.

Third, the insured may face an enormous burden in having to undergo an annual audit. The impact of the review on the living conditions of the insured is considerable. Thus, according to critics, an annual review with an uncertain outcome can cause great uncertainty on the part of the insured and their relatives. The Federation of German Consumer Organisations notes that patients and their families "live in constant uncertainty as to whether they will have to leave the place they have chosen for themselves and move into a care facility" (Verbraucherzentrale Bundesverband, 2020, p. 5). It is questionable whether it is in the spirit of the legislator to expect the insured to do so. Especially since the annual review is probably not useful in some cases. The Patient Protection Foundation, for example, draws attention to patient groups for whom ventilator weaning (part of the annual review is to assess patients for ventilator potential) is not possible. For these groups, the regulation would be "unsustainable" (Deutsche Stiftung Patientenschutz, 2020, p. 6). The Bundesvereinigung Lebenshilfe e.V. and the BAG Selbsthilfe call for an exemption for this patient group (Bundesarbeitsgemeinschaft SELBSTHILFE von Menschen mit Behinderung, chronischer Erkrankung und ihren Angehörigen e.V. (BAG SELBSTHILFE), 2020, p. 10; Bundesvereinigung Lebenshilfe e. V., 2020, p. 4). The G-BA, which is responsible for the design of the guidelines, has reacted to these demands and declared a single test for ventilator weaning to be sufficient. In addition, there are concerns about whether patients will in future draw attention to care problems within their homes, as this could lead to a transfer to an inpatient facility (Bundesarbeitsgemeinschaft SELBSTHILFE von Menschen mit Behinderung, chronischer Erkrankung und ihren Angehörigen e.V. (BAG SELBSTHILFE), 2020, p. 6; Deutsche Stiftung Patientenschutz, 2020, p. 6; Sozialverband Deutschland (SoVD), 2020, p. 6; Sozialverband VdK Deutschland e. V., 2020, p. 6). The threatened sanctions restrict the personal rights of insured persons.

Furthermore, it is difficult to understand why it is envisaged that in the event of a deficit in care in an outpatient form of housing, the insured person is to be transferred to an inpatient facility. It is repeatedly emphasized that it is a fallacy to assume that inpatient facilities "automatically" have a higher quality of care (Sozialverband Deutschland (SoVD), 2020, p. 7; Sozialverband VdK Deutschland e. V., 2020, p. 7). On the contrary, massive quality deficits and cases of fraud come to light time and again, even, or especially, in inpatient facilities (Dowideit, 2018; Keller et al., 2021). Accordingly, the Social Association VdK demands that inpatient facilities must also demonstrate that they can ensure quality care (Sozialverband VdK Deutschland e. V., 2020, p. 6).

Basically, it can be said that outpatient care meets the social and personal needs of the insured rather than inpatient care. Many insured persons also pursue professional, honorary, scientific, or other activities despite their limitations, which can be managed well in a home environment set up according to their needs. Inpatient facilities are usually not able to tailor their care to the needs of these patients. There is a suspicion that the legislator is demanding sacrifices from the insured for financial reasons (since fewer staff can be deployed for more patients in inpatient facilities, these are cheaper due to lower staff costs), which should not be demanded of this particularly vulnerable group or any other citizen (Deutsche Stiftung Patientenschutz, 2020, p. 5; Sozialverband VdK Deutschland e. V., 2020, p. 7). Instead, in the event of outpatient misuse, it should be ensured that this is provided in accordance with current standards (Deutsche Stiftung Patientenschutz, 2020, p. 5). If this is not the case, the paradigm "outpatient before inpatient", which is valid in the German health care system and has been repeatedly confirmed by supreme court rulings, is reversed.

In summary, it can be said that the criticism of § 37c (2) GKV-IPReG, on the part of the stakeholders of the patients, is justified. The uncertainty about the consequences in the case of a negative decision of the MDs, the annual review, and the possibility to reduce the benefit in a place of residence of their choice creates on the one hand great uncertainty on the part of those affected. On the other hand, the power of the health insurance companies over the place of residence of the insured is a violation of Article 19 of the UN Convention on the Rights of Persons with Disabilities,(außerdem Grundgesetz Artikel 3(3), Grundgesetz AArtikel 13). Although this power is less explicit in the GKV-IPReG than it was in its draft, it is still clear enough. The proposals of the stakeholders were given little attention.

Instead, it seems as if the legislator had deliberately left a regulatory gap open. In § 37c (2) GKV-IPReG, on the one hand, all places of residence are listed on an equal footing, but on the other hand, the MD is to check annually whether and how medical and nursing care is ensured at the place of the service according to sentence 1. Except for cases in which the MD is denied access to the premises of an insured person, in which he is referred to inpatient facilities, the legislature does not explicitly clarify what happens in a case of medically and nursing poor care. Thus, the legislator leaves the decision to the respective decision maker mentioned. That is in mentioned case the MD, and by its role the health insurance company, with the crucial task to pay the cost-intensive care of the patients. The overwhelming majority of patients are thus deprived of almost any decision-making competence regarding their local whereabouts. Accordingly, the legislator can be accused of creating a constitutionally highly vulnerable legal situation (Bundesarbeitsgemeinschaft SELBSTHILFE von Menschen mit Behinderung, chronischer Erkrankung und ihren Angehörigen e.V. (BAG SELBSTHILFE), 2020, p. 5), which, contrary to its intention, endangers the safety of the insured.

Chapter 4 – The Design of the Guidelines

In another part of the GKV-IPReG, it becomes clear how problematic this transfer of decision-making authority can be. In the amendment of the SGB V to include the extension of § 37c Out-of-hospital intensive care, insured persons "with a particularly high need for medical treatment care" are granted a claim to out-of-hospital intensive care. Insured persons have a particularly high need for medical treatment care "if there is the constant presence of a suitable nursing specialist for individual control and readiness for use or a comparably intensive use of a nursing specialist". The legislator fails to define the service "out-of-hospital intensive care" beyond this formulation. Instead, the legislator delegates this task to the Joint Federal Committee (G-BA) with reference to § 92 SGB V.

The G-BA is the highest decision-making body of the joint self-administration in the German health care system. In the form of guidelines, the G-BA determines which medical services the insured can claim. The G-BA is composed of an impartial chairperson, two other impartial members, and the four major self-governing organizations in the health care system. The total of 13 voting members is made up as follows.

The Kassenärztliche Bundesvereinigung (KBV), the umbrella organization of the seventeen associations of panel doctors, which organizes "nationwide outpatient health care close to home and represents the interests of panel doctors and contract psychotherapists at the federal level" (Kassenärztliche Bundesvereinigung (KBV), 2022), as well as the Kassenzahnärztliche Bundesvereinigung (KZBV), the umbrella organization of the seventeen Kassenzahnärztliche Vereinigungen für Zahnärztinnen und Zahnärzte, and the Deutsche Krankenhausgesellschaft (DKG), the federal association of 28 member associations of hospital owners, which represents hospital interests at the federal level, together have 5 votes. The Spitzenverband Bund der Krankenkassen (GKV-Spitzenverband), the central representative body of the statutory health and long-term care insurance funds, has 5 votes. The impartial chairman, as well as the two other impartial members, each have one vote. Patient interest groups are regularly invited to the negotiating table, as is ALS-mobil e.V. in the case of the GKV-IPReG, but they have no voting rights. Furthermore, a permanent representation of the interests of nursing services is not part of the G-BA.

The G-BA is empowered to adopt "the guidelines necessary to ensure the provision of medical care and to guarantee sufficient, appropriate and economic care for the insured" (§ 92 SGB V). In simple terms, the guidelines laid down by the G-BA determine which services insured persons can make use of. Until now, the service of out-of-hospital intensive care, now newly included in the Fifth Book of the Social Code, was to be found in the guideline on the prescription of home nursing care (Home Nursing Guideline) drawn up by the G-BA under the service description "Patient observation, special". It includes the "continuous observation and intervention with the necessary medical-nursing measures" (G-BA guideline, no.24), the "documentation of vital functions such as: Pulse, blood pressure, temperature, skin, mucous membrane" (guideline G-BA, nr.24), as well as "all nursing measures occurring during this period" (guideline G-BA, nr.24), means all other services specified in the Home Nursing Guideline. Persons in need of care who were entitled to benefits according to this guideline are, by definition, intensively cared for.

Since the redefinition of the content and scope of benefits envisaged by the legislature, as well as various requirements, will have far-reaching consequences for the entire community of insured persons, the legitimacy and independence of the G-BA should be established at this point. Such a determination could possibly become the subject of a stand-alone paper, which is why only the essential problems are to be identified and substantiated here. These are, first, the appointment of impartial members, second, the current impartial members, and third, the composition of the G-BA.

For the appointment of the impartial chairperson of the G-BA, its member organisations each agree on a proposal in accordance with § 91 (2) of the German Social Code, Book V. This proposal is submitted to the Federal Ministry of Health. This is submitted to the Federal Ministry of Health, which in turn forwards the proposal to the Health Committee of the German Bundestag. Should the independence of the nominated chairperson be established in a non-public hearing, the Health Committee of the German Bundestag can object to his or her appointment with a two-thirds majority. The only legal criterion for exclusion is the activity of the nominated member in one of the organisations represented in the G-BA, with their members, with associations of their members, in a hospital, or as a panel doctor, panel dentist, or as a panel psychotherapist.

Effectively, this means that the organizations represented in the G-BA determine the impartial members, as well as the impartial board itself. Even with the twelve-month ban, there is the suspicion that the impartiality of the chairman is not given. Beyond that it is precarious that its hearing in the committee for health of the German Bundestag is not public. Especially regarding the enormous consequences of the decisions for the insured community, which the G-BA makes, the appointment and hearing of its board can be classified as a process of public interest. The appointment of an impartial chair and impartial members is non-transparent and possibly interest-driven, thus casting doubt on impartiality.

A look at the curriculum vitae of the impartial members also casts doubt on their impartiality. Professor Josef Hecken has been chairman of the G-BA since 2012. He has been a member of the CDU since 1978. His impartial colleague Karin Maag has been a member of the CDU since 1989, was a member of the Bundestag for her party from 2009-2021, and also the health policy spokesperson for the CDU/CSU Bundestag faction from 2017. While there is a twelve-month bar on non-partisan members regarding their activities in the health sector, their impartiality does not appear to be compromised for lawmakers if they are or were in the governing party. The GKV-IPReG brought on the way by the Federal Ministry for Health, by the former Minister of Health and CDU member Spahn, contains in the case of the extension of § 37 SGB V by the article § 37c SGB V only legal basic conditions of the requirements of intensive care. The exact content and scope of the services, as well as various requirements, are to be determined by the service providers organized in the G-BA, and the impartial members organized in the majority in the same party, which drafted the law.

Finally, the composition of the G-BA casts doubt on its legitimacy. Among the 13 voting members, apart from the possibly impartial members, there are exclusively the four large self-governing organisations or service providers in the health care system. Patient representatives have the right to participate in consultations and to submit proposals, but do not have the right to vote. As described in more detail elsewhere, the provision of the new guideline on entitlement to out-of-hospital intensive care has an impact on the right of self-determination of those affected. It does not follow why service recipients represented by a qualified participant, such as ALS-mobil e.V. in this case, do not have a right to vote, especially since the insured community jointly finances the health care system.

Furthermore, nurses are also not represented in the Joint Federal Committee. This is particularly problematic in light of the fact that this group makes up a very significant part of the health care system. Nurses have the most regular contact with patients. In comparison with physicians, therapists, or workers of the health insurance, they have thereby a more personal relationship to the patients and thus, often know better what lies in their interest. It is also the nurses, in addition to the therapists, for example, who implement the measures decided by the doctor, and help to execute the essential daily needs that intensive care patients have. Nurses can therefore make an important contribution to the legislative process through the experience they have gained in this process.

The expansion of the Fifth Book of the Social Code to include § 37c Out-of-hospital intensive care is intended to enable insured persons "with a particularly high need for medical treatment care" (§ 37c (1), p.9) to claim out-of-hospital intensive care. Details on the scope and content of the services, as well as the requirements, are determined by the G-BA. In principle, the delegation of the task of defining the framework of a law to a body with the necessary expertise is to be welcomed. However, a closer examination of the G-BA reveals that it probably does not work in the interest of the entire community of insured persons and cannot do so at all due to its legally defined composition. Significant groups of the insured community, such as service users and caregivers, have no voting rights in it, or are not represented at all. The lack of a definition of "out-of-hospital intensive care" and the planned process for determining the scope, content and requirements of this new service must therefore be viewed critically and raise doubts about the justness of the GKV-IPReG, and the institution of the Federal Joint Committee.

Chapter 5 – Is the GKV-IPReG a Just Law?

So far, this paper has presented a law that fundamentally reorganizes out-of-hospital intensive care in the German health care system, identified the problems that patients see in said reorganization, and analyzed an institution that is significantly involved in shaping the reorganization for its problems. It was determined that the GKV-IPReG, is a highly problematic law from the point of view of the patients, and that the power of the Join Federal Committee in its current form is not fairly distributed. Thus, a situation arises, which asks whether injustice is possibly done to the patients with the GKV-IPReG. The immediate outcry of those affected after the publication of the GKV-IPReG, and their ongoing preoccupation with it, gives at least the appearance that a situation has arisen here that Amartya Sen would describe as so unjust that it is impossible to remain silent about it (Sen, 2010, p. 1). Answering the question of whether or not the GKV-IPReG is a just law for the critical care patients it affects is the subject of this chapter.

The theoretical basis for this is Amartya Sen's theory of justice, from his work The Idea of Justice. This theory is particularly appropriate for this work for two reasons. First, because in it, instead of possible questions about "perfectly just institutions or situations, the focus is on promoting justice” (Sen, 2010, p. 9). It deals with concrete, identifiable problems, and asks for reality-based comparisons that focus on the advancement or retreat of justice (Sen, 2010, p. 8). This makes Sen's theory of justice very practical and well applicable to a real existing problem, like that of the GKV-IPReG. At best, this can lead to an agreement, based on public reasoning, on rankings of alternatives that can be realized (Sen, 2010, p. 17). This is particularly related to the fundamental question of the justice of the GKV-IPReG, as its answer can clarify whether or not its continued existence, in its current form, is an appropriate alternative. The goal of Sen's theory of justice is not to imagine the perfect world, but to actually make the world a bit less unjust (Sen, 2010, p. 25).

Sen combination of this approach, with the argument that justice cannot be indifferent to the lives that people can actually lead (Sen, 2010, p. 18), represents the second reason. While he considers institutions to be an important influencing factor of what happens in the world, he emphasizes that “the realized actuality goes well beyond the organizational picture” (Sen, 2010, p. 18). Indeed, it also includes the lives that people manage or not manage to lead (Sen, 2010, p. 18). However, for Sen, the focus is not only on the interest in things that we actually succeed in doing, but above all on “the freedoms that we actually have to choose between different kinds of lives” (Sen, 2010, p. 18). According to Sen, this freedom can have a decisive influence on our well-being, but furthermore, it also represents an important aspect in itself (Sen, 2010, p. 18).

“Being able to reason and choose is a significant aspect of human life” (Sen, 2010, p. 18). The GKV-IPReG is a regulation created by institutions that has a concrete impact on people's lives. It has been established in the course of this work that the concerns of those affected by the policy are about the possible restriction of their freedoms (especially that of choice), and the possibilities for shaping their lives. Through this aspect, the question of the fairness of the GKV-IPReG takes on a concrete form. Does it make the lives of those in need of care more just, or not?

First, it shall be examined whether or not the GKV-IPReG makes life more just for those in need of long-term care. The following issues have been identified in the course of this work. First, the requirements of the guidelines must be met in order to be eligible for intensive outpatient care. This may transfer the freedom of choice about where care is provided out of the hands of the patient, and into the hands of the health insurance. Second, if the MD is denied access to a patient’s premises, he or she loses the entitlement to outpatient care. If patients wish to retain that entitlement, they must grant access to the MD. Third, the annual repetition of the audit, with uncertain outcome, can lead to increased psychological stress for patients, as they constantly fear being torn from their environment. Fourth, in the Federal Joint Committee, which is responsible for shaping the guidelines, neither patients nor caregivers have a vote. Thus, despite having a say, they effectively have no opportunity to participate in decision-making about the guidelines that affect them. All the above problems share one characteristic; the freedom of affected patients is restricted in order to achieve the goals designated by the legislature.

In Sen's theory of justice, accessing our lives plays an important role. This also means, instead of looking only at our means of living, we must also look at the life we can actually lead (Sen, 2010, p. 227). This stems from the fact that our means of living have no value in themselves, but only a conditional value in that they help us to achieve our goals, for example, to live a life we consider worth living (Sen, 2010, p. 226). There are good reasons, therefore, not to confuse our means with ends.

Intensive care is merely a means to an end, to achieve two main goals. First, it is to keep the person being cared for alive. As mentioned earlier, intensive care patients are characterized by the fact that they cannot survive without the necessary care. The second goal is to ensure and promote the patient's quality of life. Of course, this means that a minimum standard of care must be provided to keep the patient alive. Without this, almost all other things in life valued by the patient would be unattainable. However, what is understood by quality of life can vary greatly from person to person. The ranking of the different aspects of quality of life can also vary greatly. Furthermore, everyone has different ways, or opportunities, of realizing these ideas. For example, a person may associate being with his family with a high quality of life, and gives a higher priority to it than, say, being able to receive higher quality care. He may even consciously accept a shorter life caused by inadequate care in order to remain with his family. While another person may not value this togetherness and gives higher priority to a higher standard of care. Both can claim to be correct in this assessment from their respective standpoints, and it would not be possible for an outsider to doubt their respective justifications based on "objective" truths. “We have different types of competing reasons of justice, and it may be impossible to reject them all with the exception of just one set of complementary principles that cohere nicely and entirely with each other" (Sen, 2010, p. 201). Thus, although intensive care plays an important role in the lives of those in need of it, it does so only by enabling them to achieve other goals.

Maria-Cristina Hallwachs, a woman dependent on intensive care, puts it this way; "I need out-of-hospital intensive care to survive. Yes, that is true. But I also need intensive care in order to be able to participate in social life, it is only the basis for participation and inclusion in my life, for me it means freedom and not restriction. And that's how it is for others, an estimated 30,000 people in Germany: we don't just want to survive, we want to live!" (Hallwachs, 2022, p. 17)

In fact, the statements of the affected people's associations, as well as Hallwachs' statement, reflect the argument Sen makes in his theory of justice. Namely, that "in assessing our lives, we have reason to be interested not only in the kind of lives we manage to lead, but also in the freedom that we actually have to choose between different styles and ways of living" (Sen, 2010, p.227). For Hallwachs, out-of-hospital intensive care is a means to participate in social life. Out-of-hospital intensive care thus enables her to make decisions that affect her way of life. Out-of-hospital intensive care means freedom for her, and others in its need.

This freedom is a requirement of justice, and valuable for at least two reasons. The first reason is that "freedom gives us more opportunity to pursue our objectives - those things that we value” (Sen, 2010, p. 228). In doing so, it can help us live the life we choose or promote the things we value (Sen, 2010, p. 228). Does the GKV-IPReG basically give people in need of intensive care the possibility to participate in social life, because it is made possible for them to be cared for on an outpatient basis, or is this possibility taken away from them? This "possibility aspect" of freedom is directly related to our ability to achieve what we value, regardless of the process by which we achieve those things (Sen, 2010, p. 228).

The GKV-IPReG allows individuals to choose a place of care of their choice. While the criteria that must be met in order to comply with this request greatly interferes with the process that allows individuals to actually receive care in that location, meeting the criteria does not fundamentally remove their ability to receive care in a location of their choice. In a sense, part of this process is that individuals must undergo annual reviews and allow the MD access to their home. The specification of the guidelines by the Federal Joint Committee is also part of this process but does not per se deprive patients of the possibility of being cared for in a place of their choice. The "possibility aspect" of freedom is preserved in this specific point by the GKV-IPReG.

Freedom, secondly, is also valuable because we may value having a choice in the first place, rather than being forced by others into a situation that is repugnant to us (Sen, 2010, p. 228). Should an affected person choose the option of ambulatory intensive care attributed to him by the legislator, the implementation of this choice presupposes the meeting of various requirements. He must meet the required criteria of the guidelines. He must undergo the annual audit. He must allow the MD access to his home. He must accept the adopted guidelines without ever having had an effective choice in their adoption. The GKV-IPReG thus contributes to the creation of a situation in which patients, through the coercion of the legislator, find themselves in situations that might be repugnant to them, for example, when they want to exercise their constitutionally given right to the inviolability of the home, but thereby lose their right to ambulatory intensive care. Accordingly, it can certainly be argued that the "process aspect" of the freedom of those affected is massively violated by the GKV-IPReG.

Sen sees the distinction between the "possibility aspect" and the "process aspect" as significant and far-reaching (Sen, 2010, p. 228,229). To illustrate this, let us compare two possible scenarios. Scenario A is set in a time before the GKV-IPReG came into force. In this scenario, a person in need of intensive care decides to receive ambulatory care in his own home. The health insurance company grants him this, and he is henceforth cared for at home. Scenario B takes place in a time after the GKV-IPReG has come into force. In this scenario, a person in need of intensive care decides to receive ambulatory care in his own home. The health insurance company grants him this for one year after a detailed examination. The examination is repeated annually from then on and decides on the continuation of the possibility of outpatient care for the person concerned. The result of both scenarios is that the person concerned receives care in his own home, paid for by the health insurance. So, can it be argued that both scenarios are the same because they both have the same outcome?

Obviously not. It has already been argued that the "possibility aspect", regarding the choice of the place of care, is not compromised. However, this argument turns out to be true only if we define the "possibility aspect" to be narrowly defined in regards to the culmination of outcomes, to what people end up with, i.e. the receipt of ambulatory care in this case. Should we limit ourselves to this restricted definition, the existence of other options and freedom of choice becomes, in a sense, irrelevant (Sen, 2010, p. 230).

Alternatively, however, we can define the possibility aspect more broadly, in which we also include the possibilities that exist for a person in the realization of his goals (Sen, 2010, p. 230). Is it his own choices that lead to the desired outcome or those of others? Legislators seem to argue from a narrow perspective, while affected persons argue from a broader one, which Sen says is more plausible (Sen, 2010, p. 230). Should we focus on this, broader, definition, it becomes clear that the "possibility aspect", of patients affected by the GKV-IPReG is also negatively affected.

As both the "possibility aspect" and the "process aspect" of individuals' freedoms are affected by the GKV-IPReG, their respective abilities to live a life they personally consider worth living also decline. In Sen's theory of justice, assessing individual benefits based on abilities to do things that a person values serves as an informal focus that helps us evaluate whether something is just or unjust (Sen, 2010, p. 231). Should affected persons have more advantages through the GKV-IPReG, in the realization of their goals, their abilities increase, and vice versa. Since the focus is on the actual freedoms that individuals have, to achieve their goals, and not on what is achieved in the end, the concept of capability is directly related to the possibility aspect (Sen, 2010, p. 232).

The capability approach focuses on human life, and not only on detached objects of convenience that people may possess. Intensive care itself, as noted earlier, is merely a means to an end, but need not in itself be a top priority in the lives of those in need of intensive care, or in the analysis of their quality of life. "The various attainments in human functioning that we may value are very diverse, varying from being well nourished or avoiding premature mortality to taking part in the life of the community and developing the skill to pursue one’s work-related plans and ambitions. The capability that we are concerned with is our ability to achieve various combinations of functioning’s that we can compare and judge against each other in terms of what we have reason to value" (Sen, 2010, p. 233). The GKV-IPReG diminishes the freedoms, and abilities of those affected for the reasons stated. From the viewpoint of the persons concerned it can be plausibly justified thus that the GKV-IPReG is an unjust law, which contradicts the interests of the patients.

Conclusion

As a result of this investigation, it can be stated that the GKV-IPReG is not a law in the sense of the affected people in need of intensive care. The reason for this are serious errors in the law, as well as in the legislative process. The GKV-IPReG endangers the right of self-determination of an already vulnerable group. Their stakeholders had the opportunity to comment but were ignored on key points. Why this might be the case was shown by the process of determining the new guidelines, from the G-BA, which accompany the GKV-IPReG. A closer look reveals an extreme imbalance of power and the associated decision-making competencies within the insured community. Several conclusions can be drawn from the perspective examined here.

First, it is expected that insured persons will appeal against the GKV-IPReG to the Constitutional Court. Several interest groups noted in their comments on the draft law that it does not respect the "human rights obligations to which the Federal Republic of Germany has committed itself" (Interessenvertretung Selbstbestimmt Leben in Deutschland e.V. - ISL, 2020, p. 2), and that therefore "a constitutionally highly attackable change compared to the [previous] legal situation" (Bundesarbeitsgemeinschaft SELBSTHILFE von Menschen mit Behinderung, chronischer Erkrankung und ihren Angehörigen e.V. (BAG SELBSTHILFE), 2020, p. 5) was created. It remains to be seen how the Constitutional Court will judge the GKV-IPReG.

Secondly, thought should be given to whether and how certain groups in the German social security system can have more say. The constitutionally vulnerable situation need not have been created. Particularly on the core problems of those most affected by the law, little was changed in the legislative process. The problems concerned however mainly evenly the said rights them by the constitution, and other binding right, like the UN-Behindertenrechtskonvention, are guaranteed. According to Article 20 of the Basic Law, the Federal Republic of Germany is a democratic and social state. The GKV-IPReG and the existing structures in the German social security system do not reflect this.

Third, the GKV-IPReG represents a deeply unjust law. It seems that the legislator made the mistake of not considering out-of-hospital intensive care as a means to the end of achieving a high quality of life for patients. Instead, it is clear that out-of-hospital intensive care has been viewed either as an end in itself, or, and this would be of great concern, as a means to be sacrificed in the name of "allocation of resources. In this case, neither the special needs of the patients nor their human dignity would be met.

Against this background, all stakeholders should consider how a humane future of out-of-hospital intensive care in Germany can look. The problems expressed in the comments on the GKV-IPReG are so weighty that the law itself can hardly be regarded as part of such a future. This paper also comes to a similar conclusion. Compared to the situation that is now emerging, out-of-hospital intensive care was previously only legally anchored on the basis of often repeated, well established processes, but did not so obviously overlook the needs and demands of those affected. It is doubtful that the GKV-IPReG represents an improvement in the lives of intensive care patients. Other solutions must be found.

Part of these solutions would also be a structural change of the Joint Federal Committee. The power imbalances in the committee are too strong, and the insured community is too dependent on the good will of the interest groups with voting rights in the committee. Those affected should not only be heard, but should also have the right to vote. The democratization of the Joint Federal Committee is a must.

The German healthcare system is affected by a number of problems. One of these is the increasing importance of intensive care, as identified by legislators. Several factors, such as the acute shortage of skilled workers, are causing difficulties in coping with the tasks ahead. It is in the interest of all citizens that the legislator deals with adequate solutions to the problems and that these are implemented by capable people and institutions. In the course of this work, it was determined that the GKV-IPReG cannot be part of these solutions and is not in the interest of the patients affected by it.

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