

GERMANY'S PROGRES TREATING RARE

BY NORBERT FUCHS AND SYBILLE BECK

THE START OF THE GERMAN HEALTH CARE SYSTEM is originally associated with the introduction of the statutory health insurance under Chancellor Otto von Bismarck in 1883. Understanding its complexities and structure requires awareness of the sociopolitical priority to have an inclusive system with insurance for all and especially the working population. Societal changes and scientific developments since the 19th century have driven a dynamic process to reform and improvement resulting in a (patient) population predisposed to regular and even fundamental change.

The current situation...

One of the most remarkable characteristics of the German system is the strict distinction between outpatient and inpatient treatment, whereby the outpatient treatment is—historically and politically—the one to be preferred. As a result the financial resources allocated to the two sectors are strictly separated as well, and the options of hospitals to treat patients on an outpatient basis were traditionally very limited. Medical and scientific progress made it obvious that for certain diseases a special form and a special infrastructure had to be found to provide patients with more complex, serious and often chronic disease care from one source.

The Health Modernization Act in 2004 allowed hospitals to apply for a special status, which would allow them—among other things—to treat patients in well-defined clinical areas. This new approach was further strengthened with the enhancement of Paragraph 116b SGB V (Code of Social Law V) in 2007. Table 1 gives a full list of the diagnosed conditions to which Paragraph 116b SGB V specifically applies and which are classified as follows:

- Diseases requiring highly specialized treatment;
- Rare diseases; and
- Diseases with special course of disease.

Table 1

DISEASES REQUIRING HIGHLY SPECIALIZED TREATMENT	RARE DISEASES	DISEASES WITH SPECIAL COURSE OF DISEASE
1. CT/MRT-based interventional pain-related performances	1. Cystic Fibrosis	1. Oncological diseases
2. Brachytherapy	2. Hemophilia	2. HIV/AIDS
	3. Patients with dysplasia, congenital deformity of the skeletal system	3. Serious courses of rheumatic diseases
	4. Severe immunological diseases, e.g. PID	4. Serious heart failure
	5. Biliary cirrhosis	5. Multiple Sclerosis
	6. Primary sclerosing cholangitis	6. Epilepsy
	7. Wilson's Disease	7. Cardiological diseases in children
	8. Transsexualism	8. Premature babies with secondary damages
	9. Children with specific inherited metabolic diseases	9. Paraplegia with complications requiring interdisciplinary care
	10. Marfan syndrome	
	11. Pulmonary hypertension	
	12. Tuberculosis	
	13. Neuromuscular Diseases	

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SIVIVE APPROACH TO DISEASES

The Joint Federal Committee has identified the scope, i.e. the indications, which fall under this regulation and critically reviews the list bi-annually. The Committee has also defined a number of prerequisites, which have to be fulfilled precisely in order to get approval of the authority responsible for hospital planning in that respective State. This approval grants the hospital cost-covering treatment of patients with such diseases from highly qualified, specialized and experienced physicians and medical staff. Primary immunodeficiencies exemplify best the great benefit and purpose of the Paragraph 116b SGB V legal provision. The unspecific heterogeneous symptoms presented by primary immunodeficiency disease (PID) patients typically result in a long period prior a conclusive PID diagnosis. The well documented patient histories show their long ordeal often start with the general practitioner and then may lead onto the Ear-Nose-Throat-specialist, or the pulmonologist, the gastroenterologist etc. during which time the patient continues in poor health. None of these experts has the appropriate qualifications, skills, appropriate diagnostic tools, or experience to diagnose PID. They will go on “mistreating” a patient suffering from a primary immunodeficiency.

The Future...

Paragraph 116b SGB V was opposed by the general practitioners and in particular by the specialists in private practice as they fear “losing” their patients and the related funding to the specialized

treatment centers. They also regard the introduction of the “new” Paragraph 116b SGB V as competition with unfair measures. The most common argument is that hospitals can usually rely on financing through the provider, the health insurers and the state, whereas the physician in private practice bears the full financial risk; plenty of lawsuits have been conducted – so far without any tangible success or clarity.

The new German government consisting from the Christian-Democrats and the Liberals has announced their intention to carry out another fundamental health care reform, which will also impact Paragraph 116b SGB V. The Liberals in particular who provide the Health Minister are traditionally the party of the medium-sized businesses and the self-employed including physicians in private practice, hence, reforming Paragraph 116b SGB V will be welcomed by the natural constituency. Although patients and stakeholders have been reassured that the regulation as such will not be eliminated, it will certainly be amended. It is not pessimistic to expect that such an amendment might lead to a non-applicability, hence, quasi-elimination. The various stakeholder groups in these discussions—patients, physicians and PPTA—will be working to maintain the provisions of Paragraph 116b SGB V as they are to ensure optimal diagnosis and treatment for patients requiring more than standard care particularly PID patients and people with hemophilia. ☺

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Pictured here: Berlin, Germany