

2 WHAT IS AN ORGAN DONATION IN-HOUSE COORDINATOR?

Organ Donation In-House Coordinators have an important position in the overall organ donation process. They are the persons professionally responsible for the organ donation process in the respective donation hospitals, and fulfil key functions in this capacity.

Following the amendment of the Transplantation Act, all donation hospitals are obliged by federal law to appoint at least one Organ Donation In-House Coordinator.

In fulfilling their tasks, they report directly to the medical management of the donation hospital and are to be released from their normal duties to the extent necessary for correct performance of their tasks. Organ Donation In-House Coordinators are usually doctors from the field of intensive-care medicine. Nursing personnel working in intensive care can also be commissioned with this function in individual cases. The details are determined by the Länder.

Among other things, Organ Donation In-House Coordinators are responsible for ensuring that the relatives of donors are given appropriate support, that the competencies and procedures for fulfilling the statutory obligations in the donation hospitals are defined, and that the medical and nursing personnel in the donation hospitals are regularly informed about the importance and the process of organ donation.

3 WHAT HAS CHANGED AS REGARDS DATA PROTECTION?

In keeping with the specifications of EU law, the regulation on data protection existing in the Transplantation Act has been expanded in order to permit the use of personal data for research purposes in the interests of advancing transplantation medicine. This applies to the own research projects of the doctors and other scientific personnel of the donation hospital, the coordination agency or the allocation agency. The existing requirements of data protection law must be fulfilled in the event of disclosure of personal data to third parties for a specific research project. Therefore, either the data have to be made anonymous, or the con-

sent of the affected person has to be obtained. Only if none of these requirements can be met may the data be disclosed to third parties if the public interest in implementation of the research project outweighs the interests of the affected person meriting protection and the research objective cannot be achieved in any other way.

Insofar as possible in accordance with the research objective, and provided that it does not require an unreasonable effort in relation to the targeted purpose of protection, the personal data must at all events be made anonymous. If this is not yet possible, pseudonyms must be used.

III. Changes resulting from another statutory amendment introduced with effect from 1 August 2013.

1 WILL MANIPULATIONS OF PATIENT RECORDS BE PUNISHED?

The further statutory amendment taking effect on 1 August 2013 also stipulates the legal consequences of manipulations of patient records, which have occurred at individual transplantation centres. Incorrect collection, incorrect documentation and reporting of an incorrect state of health with the aim to give preference to particular patients on the waiting list are now also punishable as a criminal offence in terms of falsification of documents. A violation of this prohibition under the Organ Transplantation Act is punishable by up to two years of imprisonment or a fine, depending on the gravity of the offence.

2 HOW IS IT GUARANTEED THAT THE GERMAN MEDICAL ASSOCIATION'S GUIDELINES FOR THE STATE OF KNOWLEDGE OF MEDICAL SCIENCE REGARDING ORGANS ARE TRANSPARENT AND VERIFIABLE?

From now on, the guidelines of the German Medical Association have to be accounted for and are subject to approval by the Federal Ministry of Health. These measures make the guidelines transparent and verifiable.

FURTHER INFORMATION ...

... on organ and tissue donation is available on the website of the Bundeszentrale für gesundheitliche Aufklärung (BZgA): → www.organspende-info.de

NEW STATUTORY REGULATIONS

in the Transplantation Act

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parties.

The Act Amending the Transplantation Act and the Act Regulating the Decision Solution in the Transplantation Act contain important innovations. An overview of the most important changes is given below.

I. Changes resulting from the Act Regulating the Decision Solution in the Transplantation Act, entering into force on 01/11/2012:

1 WHAT DOES THE IMPLEMENTATION OF THE DECISION SOLUTION MEAN FOR THE PUBLIC?

The (statutory) health insurance funds provide their insureds over the age of 16 with education material on organ and tissue donation, as well as organ donor cards, at the time of issuing the electronic health card to their insureds. The (private) health insurance companies provide their insureds with these documents at the time of sending them their premium notification. If provision in conjunction with the mailing of the electronic health card or the premium notification is initially not possible, the health insurance funds and health insurance companies send their insureds the aforementioned education documents separately, together with the organ donor card. At the time of being provided with the education material and the organ donor card, the insureds are called upon to document a declaration regarding organ and tissue donation. This declaration is made on a voluntary basis and can be documented on the organ donor card provided. The health insurance funds and health insurance companies give their insureds the names of professionally qualified contacts to deal with any enquiries on the subject of organ and tissue donation.

2 IS A DECLARATION REGISTERED BY THE HEALTH INSURANCE FUNDS OR HEALTH INSURANCE COMPANIES?

No. The health insurance funds and health insurance companies merely request their insureds to make a declaration regarding their personal willingness to donate organs and tissues. This declaration is recorded neither by the health insurance funds, nor by the health insurance companies. There is also **no other** register in which people's declarations are recorded. In the long term, there are plans for members of the statutory health insurance scheme to be able to store their declaration for or against organ and tissue donation on their electronic health card, if they so wish.

3 DO YOU HAVE TO MAKE A DECLARATION?

No. There is no obligation to make a declaration regarding organ and tissue donation. Making such a declaration is entirely voluntary. However, everyone should be aware of the fact that failure to make a declaration regarding organ and tissue donation means that, if the worst comes to the worst, the immediate relatives will face the burden of deciding whether or not they should consent to organ or tissue donation.

4 WHAT HAS TO BE BORNE IN MIND AS REGARDS A DECLARATION REGARDING ORGAN AND TISSUE DONATION WHEN DRAWING UP AN ADVANCE DIRECTIVE?

An advance directive can be used to document a decision for or against organ and tissue donation. The following wording is recommended in this respect:
I consent to removal of my organs for transplantation purposes following my death (if applicable: I have completed an organ donor card). If, according to a medical assessment, I am open

to consideration as an organ donor in the event of impending brain death, and if this necessitates medical interventions that I have excluded in my advance directive, then (alternatives):

- *my declared willingness to donate organs shall take priority.*
 - *the provisions of my advance directive shall take priority.*
- or
- *I reject removal of my organs and tissues for transplantation purposes following my death.*

Further information on advance directives can be found in the brochure "Advance directive. Suffering – Sickness – Death. How do I determine the medical action to be taken if I am incapable of making a decision?" Published by the Federal Ministry of Justice: (<http://www.bmj.de/SharedDocs/Downloads/DE/pdfs/Patientenverfuegung.html>).

II. Changes resulting from the Act Amending the Transplantation Act, entering into force on 01/08/2012:

1 HOW ARE LIVING DONORS COVERED UNDER INSURANCE LAW?

The Act Amending the Transplantation Act clearly regulates and greatly improves the insurance cover of living organ donors. Health insurance law now expressly stipulates that, regardless of their own insurance status, living organ donors have a direct claim to treatment on the statutory health insurance fund of the organ recipient. This includes the outpatient and inpatient treatment of the donors, medically necessary preoperative and postoperative care, medical rehabilitation benefits, as well as sickness benefits and necessary travel expenses. Moreover, in addition to the care of patients before and after organ transplantations, the care of living organ donors will in future also belong to the field of so called specialist care. This makes it possible to guarantee high-quality, specialised diagnosis and treatment, as well as structured aftercare.

In the case of living organ donations to persons having private health insurance, the private health insurance company of the organ recipient guarantees to cover the donors (where

appropriate, another insurance institution, e.g. the office of health insurance for civil servants, also pays part of the costs). In a voluntary commitment dated 9 February 2012, all the member companies of Germany's Association of Private Health Insurers agreed to pay the expenses incurred by the donors (outpatient and inpatient treatment, rehabilitation measures, travel expenses, suffered loss of earnings). This ensures a standardised coverage of the living organ donors, regardless of the insurance status of the organ recipients.

The Act Amending the Transplantation Act of 01/08/2012 additionally stipulates that temporary incapacity for work as a result of organ donation also constitutes blameless incapacity for work. Consequently, the affected employees are entitled to continue to receive their regular pay for six weeks. The employer has a claim to reimbursement on the statutory health insurance fund or private health insurance company (where appropriate, on the health insurance scheme for civil servants for part of the costs) of the organ recipient. After expiry of the six weeks, or if no claim to pay continuation exists, the claim to sickness benefit on the health insurance fund of the organ recipient takes effect, or the private health insurance company of the organ recipient pays for the loss of earnings suffered.

Improved insurance cover also exists in the field of statutory accident insurance: the accident insurance cover extends to all damage to health in connection with organ donation. This includes damage to the health of the donor that goes beyond the impairments regularly occurring as a result of donation and demonstrates a causal relationship. The occurrence of this kind of damage to health is rated as a fictitious event insured under the accident insurance scheme. The length of time between donation and occurrence of the damage to health is irrelevant. A – refutable – statutory presumption exists as regards the causality. For the time after entry into force of the Act Amending the Transplantation Act, this extended accident insurance cover for living organ donors also extends to damage to health occurring in donors after introduction of the Transplantation Act in 1997 and before entry into force of the extended accident insurance cover.