

NEW COMPLIANCE MANAGEMENT SYSTEM OF THE UNIVERSITY HOSPITAL FRANKFURT, GERMANY

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I. COMPLIANCE

The meaning of Corporate Governance is all values and principles guiding or regulating good and responsible business management.

Clearly defined roles and responsibilities for managing compliance, risks and checks is the prerequisite for the latter.

For that reason, a compliance management system was set up at the University Hospital Frankfurt in 2015.

The management system “*Recht im Betrieb*” assists the Management Board, senior executives and officers in charge of various delegated statutory tasks facing the executives and officers in charge (*Betriebsbeauftragte*) to identify, monitor and verifiably delegate or fulfill their statutory obligations, as well as monitor, update and document them.¹

The purpose of a compliance management system consists in fulfilling the legal obligations. As at every other company, the members of the Hospital Management also need to conduct themselves in a legally compliant manner and ensure that all the employees likewise conduct themselves in a legally compliant manner.²

For the University Hospital Frankfurt 5,570 legal obligations have been ascertained. The Management Board is not in a position to fulfill over 5,500 obligations of the hospital personally. It needs to be ensured by means of organizational steps that the company and its employees operate in accordance with the legal framework. This obligation to ensure legal compliance at the company by means of organizational steps is the responsibility of the Commercial and Medical Directors. They are liable for any loss caused through their organizational fault.

There are six tasks that need to be fulfilled in order to avoid organizational fault. How a company, and thus also the University Hospital, is to be organized can be seen from the new ISO 19600 standard.³ It has been applicable since 15/12/2014 as a set of new, interna-

¹ ISO 19600 „Compliance-Management-System-Guidelines“ published 12/15/2014; Manfred Rack, *CB-Test: Die rechtlichen Voraussetzungen für ein Compliance-Management-System*, COMPLIANCE BERATER, 279 (2014).

² ANNEMARIE MATUSCHE-BECKMANN, DAS ORGANISATIONSVERSCHULDEN, 143 (2001); GERALD SPINDLER, UNTERNEHMENSORGANISATIONSPFLICHTEN, 760 (2002); TIM NEELMEIER, ORGANISATIONSVERSCHULDEN PATIENTENFERNER ENTSCHEIDER UND EINRICHTUNGSBEZOGENE AUFKLÄRUNG, 64 (2014); Jürgen Klauber et al., *Schwerpunkt Patientensicherheit*, in *Krankenhaus-Report 2014* 3 (Jürgen Klauber et al. eds., 2014).

³ ISO 19600 “Compliance-Management-System-Guidelines“ published 12/15/2014.

tional self-regulatory provisions for compliance management. Whoever complies with these rules on corporate governance will avoid being accused of organizational fault.

- a. All the obligations of a company are to be ascertained. Ignorance is no protection against punishment. For the University Hospital Frankfurt a total of 5,579 pertinent obligations have been ascertained, based on 1,100 relevant regulations, which have in turn been sifted out by the database from an aggregate corpus of more than 15,000 regulations. As further, specific types of regulations and sources of legal obligations, the recommendations of the Robert Koch Institute, S3 guidelines, Guidelines of the Federal German Medical Association (*Bundesärztekammer*), Guidelines of the Joint Federal Committee (GBA) and Court judgments taken from medical legislation and hospital legislation have been analyzed, searching for legal obligations. The compliance of legal obligations serves the purpose of averting risk still prior to it being able to cause any damage.
- b. The **second** organizational obligation consists of delegating these obligations to the 6,000 employees of the University Hospital Frankfurt. No obligation may remain without anyone being responsible for it. The legal obligations are to be delegated to the departments of the hospital in which the risk to be averted is caused. All officers having a staff function, including the Quality and Compliance Officers, need to co-operate in complying with any legal obligations, in particular the Management Board and senior executives have to provide advice, inform the employees of the hospital about their obligations, and monitor their compliance. They are subject to officers' liability, and may be held responsible based on aiding and abetting. All things considered, after delegating all obligations ascertained the "*Recht im Betrieb*" management system offers one-click information on which hospital employees are required to fulfill which obligations in which department and in what period of time.
- c. All the legal obligations need to be updated. On average around 400 legal obligations are amended every month, out of which, on average, only 40% are relevant at a given company. The 400 amended, new or repealed legal obligations are automatically sifted out by the database of the "*Recht im Betrieb*" management system. Sixty per cent of the usual effort is saved through the digitalized filter.
- d. All the legal obligations need to be fulfilled. In order to avoid directors' and officers' liability and liability of authorized representatives, as well as officers' liability, all the employees of the hospital need to be interested in fulfilling their obligations - the Management Board, the executives who are line managers and the Quality and Compliance Officers having a staff function.
- e. The fulfillment of all obligations is to be monitored. The Management Board is obliged to carry out superintendence. This task cannot be delegated. It will remain exclusively the management's responsibility. In the Compliance manage-

ment system, the superintendence can be attended to using a single user interface. The respective current process status can be retrieved. The digitalized Compliance management system allows for checking compliance at a glance. The officers responsible for the obligations that are overdue and have not been fulfilled can be notified about it from the user interface by e-mail, and have it brought to their attention.

- f. As a **sixth point**, all the organizational procedures are automatically documented in the system. The reversal of the burden of proof applies. Should patients suffer loss or damage, the hospital - and not the patient affected - needs to provide evidence that the obligations were known and fulfilled. Should losses occur at the hospital, it must not be the result of poor organization. The University Hospital Frankfurt has, for the first time, deployed a digitalized Compliance management system that has been tried and tested at several hundred industrial companies over the past 20 years. The organizational obligations are the same. Only the applicable legal obligations are different, that avert typical risks at a clinic.

II. CONCLUSION

Through the digitalization of the Compliance Management System “*Recht im Betrieb*”, the effort required for compliance management has been considerably reduced. Patient safety is increased. The D&O liability, as well as the representatives’ liability of the other executives, and the officers’ liability is reduced. The potential for conflict between patient safety due to medical services provided to the highest standard and simultaneous compliance with the efficiency rule in accordance with the Social Security Code (SGB) and the regulations of the Joint Federal Committee (GBA) becomes transparent, and enables targeted solutions. Especially conflicts between the doctors carrying out the treatment and the Hospital Management, which is remote from the patient, are avoided through compliance with all the organizational obligations. Medical malpractice due to organizational defects can be avoided. Through efficient compliance management, the Management Board, senior executives and all the doctors carrying out the treatment, and ultimately the patients treated, whose protection from damage due to organizational malpractice is the issue, benefit.