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Legal implications of the stratification of the insured clientele according to § 25b SGB V - requirements for patient information and the use of AI

Since 2024, there has been a new health and long-term care insurance benefit: these can carry out data-based analyses to identify rare diseases, cancers, vaccination indications and a need for long-term care that has not yet been determined (Section 25b (1) SGB V). If one of these analyses identifies a specific health risk, the specific risk of an illness or need for care or the existence of an indication for vaccination, the insured person must be informed of this immediately (Section 25b (4) sentence 1 SGB V). Two questions arise from this task of health and long-term care insurers: What legal requirements must be placed on the stratification of the insured clientele and the decision to (not) inform certain insured persons? And what are the resulting legal requirements for the use of artificial intelligence (AI) in stratification?

>> The content and legal requirements of the social insurance regulations were determined by applying the legal methods of interpretation, in particular the interpretation according to thewording1 and thetelos2 as well as thehistorical3 andconstitutional4 interpretation. The same methodology was used to determine the constitutional requirements for stratification. The legal databases Beck-Online and Juris were used to search for publications on the provisions analysed. Finally, the legal requirements determined in this way were summarised, interpreted and conclusions were drawn from the perspective of both welfare and jurisprudence.

Results

The health and long-term care insurance funds store a large amount of health data relating to insured persons. In order to improve the utilisation of this wealth of data, the legislator has, in the course of the

Health Data Utilisation Act (Gesundheitsdatennutzungsgesetz) and decided that health and long-term care insurance funds can analyse this data (Section 25b (1) sentence 1 SGB V).

Legal implications of the stratification of the insured clientele according to Section 25b SGB V – Requirements for patient information and AI use

Statutory health and long-term care insurance may analyse insurance data. The data analysis can result in various information obligations. Firstly, they exist when a specific health risk to the insured person is recognised. This presupposes that there is a sufficient probability of damage to health. They must also provide information if they recognise through their data analysis that there is a foreseeable future possibility (not probability) of illness or a need for long-term care arising from the individual (life) circumstances of a single insured person. Whether these thresholds are reached in each case is ultimately determined by medical science and healthcare research.
Statutory health and long-term care insurance must always be able to justify in a comprehensible manner how they arrived at their results and why they made which information decision. These legal requirements limit the use of artificial intelligence insofar and as long as it cannot make its procedures and results transparent and comprehensible.
Violations of these requirements can result in claims for information and damages against the health and care insurance fundss.

Keywords

Health insurance companies, stratification, insured clientele, Section 25b SGB V, patient information, AI use

1 Social law requirements for stratification

Health and long-term care insurance funds are corporations under public law (Section 4 (1) SGB V/Section 46 (2) SGB XI) and as such are public authorities. As such, they are comprehensively bound by law (Article 20 (3) of the Basic Law [Grundgesetz - GG]).

When analysing data in accordance with Section 25b para. 1 sentence 1 SGB V, they have a discretionary power5, i.e. they can decide whether or not to carry out these data analyses at all. Reasons for a so-called reduction of discretion to zero6, i.e. an obligation to analyse data for the reason that all other official decisions would be unlawful, are not apparent as a matter of law. This is because the legislator has deliberately left the 'whether' of data analysis to the discretion of the health and long-term care insurance funds.

However, if a health or long-term care insurance fund analyses data and identifies a specific health hazard, a specific risk of illness or need for long-term care or the existence of an indication for vaccination, it must inform the insured person concerned immediately (Section 25b (4) sentence 1 SGB V). While there was still a discretionary power with regard to data analysis, this does not exist with regard to informing the insured person. The health and long-term care insurance funds are obliged to provide this information. The law further specifies how this information is to be provided, thereby concretising the discretionary power, i.e. the 'how' of the information7. According to Section 25b (5) SGB V, the data basis of the information provided must also be publicised.

However, information does not have to be provided on every result, but only when the threshold for a 'concrete' risk of illness or care is exceeded or a vaccination indication is recognised. This is because the law itself specifies how high the probability of harm to the insured person must be in order to exceed the threshold for the obligation to provide information, thus enabling reassurance

from medicine and healthcare science. Section 25b (4) sentence 1 SGB V requires a 'specific health risk' or the 'specific risk of illness or a need for care' or the 'existence of an indication for vaccination'. The terms 'specific danger' and 'specific risk' were not further explained by the legislator.

However, the term 'concrete danger' is known in various areas of law: A danger is a sufficient probability of damage to a protected legal interest (in police law, for example, public safety or order, here health, as the law is based on a 'concrete health risk').

The question now is what constitutes a specific danger. It would be obvious to think that a concrete danger is more likely than an abstract danger. The Federal Administrative Court makes a different differentiation and believes that abstract and concrete danger do not differ according to the degree of probability of a damaging event.8 Rather, it believes that the 'mere probability' of the occurrence of damage would also belong to both the abstract and the concrete danger; 'both concepts of danger impose the same requirements of probability as far as the expected occurrence of damage is concerned. '9 According to the Federal Administrative Court, the difference lies 'only in the approach, with the concrete danger 'concrete', i.e. related to the individual case, with the abstract danger 'abstract-general', i.e. related to the typical case'.10 A concrete danger therefore exists,

'if, in the specific individual case to be assessed, the occurrence of damage must be expected with sufficient probability at some point, albeit in the foreseeable future; an abstract danger is given if a general-abstract consideration for certain types of behaviour or conditions leads to the conclusion that damage is sufficiently likely to occur in the individual case'.11

The case law of the courts still follows this today and believes that even the 'remote possibility of damage occurring is sufficient to assume a concrete danger. '12

As we have seen, the legislator of SGB V did not bother to define the term 'specific health risk'. The administrative law concept of 'concrete danger' at least implies that there must be a concrete threat of harm to a specific person in the 'foreseeable future' in such a way that there is a 'sufficient probability' of harm occurring.

Health services research and medicine can build on this. If the thresholds of concrete danger or vaccination indication are not reached from the perspective of medicine and healthcare research, then the information for insured persons is neither required nor permitted.

This applies all the more as the economic efficiency requirement of Section 25b para. 4 SGB V, the economic efficiency requirement of Section 12 SGB V and Section 29 SGB XI also applies.13 According to this, all services must be sufficient, appropriate and economical in the narrower sense; they must not exceed what is necessary. Insured persons cannot claim non-essential or uneconomical services and health and long-term care insurance funds may not authorise them.14

This means that if there is insufficient evidence from a medical point of view, it is not only possible, but even necessary, to refrain from informing the insured person.

In this respect, the law follows medicine and healthcare research. For example, informing a very old man about the presence of prostate cancer may be medically unreasonable if and because another disease is highly likely to lead to death beforehand - if the treatment is therefore not necessary in terms of the economic efficiency requirement, the patient information is also not necessary and can be omitted. Consequently, health insurance fund directors are liable with their private assets if they should have known that the health insurance fund was providing an uneconomical service (Section 12 (3) SGB V).

Pursuant to § 25b Para. 4 S. 1 SGB V, there is also an obligation to provide information if there is a specific risk of illness or a need for long-term care. The legislator has not further defined this term either. The term 'specific risk' is also unknown to legal databases. It is not clear from the explanatory memorandum to the law whether the legislator really wanted to make a distinction here between danger and risk.

A risk is less than a danger, i.e. an event that is even less probable than the reasonable probability of the occurrence of an illness or need for care. A risk is what a society is prepared to accept when it authorises potentially dangerous activities; the law only intervenes when the threshold of 'danger' is exceeded. However, the legislator now wants a warning to be issued as soon as a specific risk exists.

With regard to the term 'concrete' as opposed to 'abstract' risk, please refer to the distinction made by the Federal Administrative Court. Since the risk must be specific and not the illness, it is not important that a specific illness can be imminent; at the same time, the risk must exist for the specific individual case for the specific insured person - hardly a meaningful distinction.

At the same time, the legislator not only differentiates between 'risk' and 'danger', but also in the second element of the offence: the danger (specifically: endangerment) should exist for 'health', while the risk must exist with regard to the occurrence of an 'illness' or 'need for care'.

Although the wording suggests otherwise, there seems to be no reason to differentiate between the two in view of the telos, i.e. the meaning and purpose of the regulation pursued by the legislator. Ultimately, the constituent elements of the specific risk of an illness or need for long-term care must be understood to mean that health and long-term care insurance funds are obliged to pay benefits upon recognising a foreseeable future possibility (not probability) of an illness or need for long-term care arising from the individual (life) circumstances of a single insured person.

2. requirements of constitutional law for stratification

In addition to the requirements of ordinary law, i.e. SGB V, for health and long-term care insurance funds, constitutional law must also be taken into account and analysed to determine which fundamental rights may be affected and whether, and if so in what form, this also results in requirements for health and long-term care insurance funds with regard to stratification, the use of artificial intelligence and the decision to inform insured persons.

Data analysis and the provision of information to insured persons affect several fundamental rights of insured persons:

(a) General principle of equality of Article 3(1) of the Basic Law

The general principle of equality in Art. 3 Para. 1 of the Basic Law requires an authority to treat essentially equal facts equally and essentially unequal facts unequally. It is therefore not only a prohibition of unequal treatment, but also a requirement of it.15

This first requires the formation of comparative groups16 that hardly differ in factual terms. Only when the circumstances within a comparison group are treated unequally is the application of the general principle of equality even possible. In concrete terms, this means that the general principle of equality can only be violated in the context analysed here if, for example, in the case of two insured persons with an identical 'risk' or an identical identified 'hazard' identified by stratification, one of the two insured persons is informed about the 'risk' or the 'hazard', while the other is not.

It follows that health and long-term care insurance funds do not have to provide information about all risks identified during the data analysis in order to comply with the general principle of equality under Article 3 (1) of the German Basic Law. As shown above, the question of when information must be provided and how high and specific the risks are is determined by healthcare research and medicine. If a risk is largely negligible from a medical-scientific perspective, then it is not necessary to inform insured persons with an existing but negligible risk.

However, the general principle of equality requires that the risk requirements with regard to information be applied equally to all insured persons. Therefore, if there is an existing but negligible risk for several insured persons, some of the insured persons may not be informed about this and others not. Conversely, information about a specific risk must always be provided to all insured persons for whom such a risk has been identified.

Ultimately, however, the equal treatment of substantially unequal circumstances or the unequal treatment of substantially equal circumstances can also be justified, so that even in this case there is no violation of fundamental rights. Case law and legal scholarship have developed several models for this, ranging from a pure review of the arbitrariness of the official decision to a strict proportionality test.17

In the context of the strict proportionality test, unequal treatment of substantially equal circumstances or equal treatment of substantially unequal circumstances is only justified if the unequal treatment or equal treatment pursues a legitimate purpose, is appropriate, necessary (in the sense of the absence of less (in)equal but equally effective administrative action) and proportionate in the narrower sense of a prohibition of excessiveness. Whether the stricter standard of the proportionality test should be applied or whether the authority has more leeway is now determined by whether the official measure is linked to personal characteristics, whether fundamental freedoms are affected and to what extent the person concerned has the opportunity to influence the realisation of the differentiation criteria through their behaviour.18 In this context, the state has more leeway when granting (voluntary) benefits than when encroaching on the legal positions of citizens (e.g. in police law).

In the present case, there is much to be said in favour of applying the stricter standards of the proportionality test to any decisions made by health and long-term care insurance funds in the context of stratification on the one hand and information for insured persons on the other. This is because once a health and long-term care insurance fund has decided to analyse data, it is obliged to provide information. In addition, this involves personal characteristics - namely illnesses, personal dispositions, etc. - and the individual is not in a position to adjust their behaviour towards the health or long-term care insurance fund in such a way that they could influence whether or not they are informed.

Whether the general principle of equality is possibly violated by a lack of or inadequate information if the health or long-term care insurance fund treats essentially identical facts (results of data analyses/insured persons, decisions to provide information or not) unequally is therefore determined by whether the decision of the health or long-term care insurance fund is based on the following criteria

- whether the decision of the health or long-term care insurance fund pursues a legitimate purpose (this may well be administrative simplification or cost savings);
- whether the health or long-term care insurance fund is taking a step towards achieving this goal by not informing the insured person in question;
- whether there are simpler means for the health and long-term care insurance fund to achieve this goal than not providing information (in the case of the goal of administrative simplification, for example, digital information for insured persons) and
- whether the desired simplifications on the part of the health and long-term care insurance fund are in proportion to the disadvantages for the insured person.

In view of the fact that the insured person faces specific health risks, the hurdles for the latter decision are particularly high. Which - to stay with the example - administrative simplification can outweigh a concrete health risk to an insured person?

Only if all of these requirements are cumulative would the decision of the health or long-term care insurance fund not to provide information be justified under the general principle of equality in Article 3 (1) of the Basic Law and therefore legal, even though information is (has been) provided in comparable circumstances.

b) Fundamental right to life and physical integrity - Art. 2 para. 2 sentence 1 Basic Law

Fundamental rights are first and foremost rights of defence against intrusive state measures.19 However, fundamental rights can - as an exception - also have the character of a right to benefits. Almost 90% of the population are insured under the statutory health insurance scheme, most of them as compulsory members. Their financial resources are usually not sufficient to take out full private health insurance. Under certain circumstances, this can mean that the legal content of the fundamental right to life and physical integrity, in part together with the welfare state principle of Art. 20 Para. 1 of the German Basic Law, is affected by the incorrect or inadequate provision of benefits by statutory health insurance.

It is at least recognised that the state has a duty to create a sustainable health and health insurance system.20

However, specific benefits are not derived from the Basic Law21;

a well-known exception is the Federal Constitutional Court's so-called St Nicholas decision, according to which there would be a direct entitlement to benefits in the case of life-threatening or serious illnesses.22 Otherwise, ordinary law - in this case Section 25b (1), (4) SGB V - specifies the rights of insured persons and the obligations of health and long-term care insurance and thus the content of the fundamental right.

The health and long-term care insurance funds therefore do not interfere with the fundamental right to life and physical integrity under Art. 2 para. 2 sentence 1 GG by failing to provide information or providing incorrect information.

Even if one were to assume that the simple legal concretisation of the information obligations of the health and long-term care insurance funds would also lead to a fundamental right obligation to the same extent - which is by no means obvious - the statements made above apply: If the threshold of a concrete health risk (or a 'simple' vaccination indication) is not reached from a medical-scientific point of view, the health and long-term care insurance funds do not have to provide information, there is neither a simple legal nor even a constitutional right to this.

c) Fundamental right to data transparency - Article 19 (4) of the Basic Law

It has already become clear from the above that the health or long-term care insurance fund must be able to justify how it carries out the stratification and how it has made its decisions.

Legally, this is also required by the fundamental right to data transparency (Art. 19 para. 4 GG).

According to established case law and the prevailing view in legal research, it is now recognised that it follows from Article 19(4) of the Basic Law that a person subject to the law has a fundamental right to be able to fully review state measures in legal and factual terms.23

The transparency requirement was initially developed by the Federal Constitutional Court in the context of state surveillance measures. According to this, the principle of proportionality places requirements on transparency, individual legal protection and supervisory control of data processing.24 The transparency of data processing should help to create trust and legal certainty and ensure that the handling of data remains part of a democratic discourse. At the same time, it enables citizens to behave accordingly.

It also forms the prerequisite for effective legal protection vis-à-vis data subjects. By providing them with knowledge of the data processing that affects them, it enables them to have the lawfulness of the relevant measures reviewed - if necessary also in court - and to assert any rights.25 This is because in the case of data processing with an impact on fundamental rights - as is the case here - the data used must be preserved at least to the extent that the data subject retains judicial review of the measure.

It is rightly assumed that a request for legal protection can only be examined by courts in a truly comprehensive and independent manner in legal and factual terms if the facts of the case are open to scrutiny.26 This is a precursor to the guarantee of legal protection.27 A court must be able to review executive acts - such as decisions by health and long-term care insurance funds - completely on its own authority.28

These legal rights of insured persons derived from the Basic Law have a direct impact on the official decision-making processes in the health and long-term care insurance funds and on the use of artificial intelligence.

Artificial intelligence can only be used if its methodology, the sources it uses, the calculations and weightings are transparent and comprehensible. The currently known AI models offer the possibility of checking results, highlighting them and jumping to specific results from imported sources. However, the solution and research paths are partially unknown; in some cases, only the AI developers know them and they are not disclosed to the users. Negative results and the reasons why the AI does not produce them (e.g. why no vaccination recommendation is given or why no warning is issued for a specific disease) also remain partially unknown.

This means that all positive and negative results of the use of artificial intelligence must ultimately be checked by humans using comprehensible, documented criteria. For legal reasons, the use of AI that is not individually verified for the respective result can only be considered if the AI's solution has been documented and verified - especially with regard to the decision not to inform certain insured persons - and this can be reproduced.

3 Recognition and consequences of legal violations

Under German law, a legal violation alone is not sufficient to be able to defend oneself against it. Rather, the norm violated by the authority must not only serve the public interest, but also the interest of the individual (so-called protective norm theory, see Section 42 VwGO). Lawyers must therefore analyse whether the standard is also intended to serve the interests of the individual insured person. This is clearly the case with Section 25b (4) SGB V. This is because the legislator has placed the health interests of the individual insured person at the centre and protective purpose of the provision.

If information is provided in accordance with Section 25b (4) SGB V, the insured person or their representative is entitled to know the basis of the data in accordance with Section 25b (5) SGB V. This can enable a review of false-positive reports.

In addition, all health and long-term care insurance funds are subject to the respective freedom of information laws of the federal states or (the funds under federal supervision) the Federal Freedom of Information Act (IFG), which means that there is an abstract right to information about the conditions and the way in which data is analysed. According to Section 1 (1) of the Federal Freedom of Information Act, everyone has the right to access official information. According to Section 2 No. 1 IFG Bund, official information is all records that serve official purposes, regardless of how they are stored. This also includes the plans and measures for implementing Section 25b (1) SGB V, i.e. stratification.

Insured persons can also request information from the respective health and long-term care insurance fund about the purposes for which their data is processed (Art. 15 para. 1 lit. a) General Data Protection Regulation [GDPR]). These purposes also include processing activities such as the data analysis possible under Section 25b (1) SGB V29 and also whether the health or long-term care insurance fund uses AI applications. For 'automated decision-making '30, Art. 15 para. 1 lit. h) GDPR in conjunction with Art. 22

GDPR expressly provides for a right to information, which also includes 'meaningful information on the logic involved and the scope and intended effects of such processing for the data subject'.

Both the abstract information claims under the freedom of information laws and the specific information about the data processing of the respective insured person can be enforced in court (before the administrative or social courts).

In practice, it is conceivable that insured persons may learn through third parties - other insured persons, self-help groups, etc. - that they and their data have been treated differently, for example that they have not received certain information from the health and long-term care insurance fund in accordance with Section 25b (4) SGB V (false negatives), which may indicate unequal treatment or errors in the evaluation process (whether it is AI-based or not).

As described above, Section 25b (4) SGB V protects third parties, i.e. the individual insured person can invoke the standard and demand its application. Insofar as insured persons were unlawfully not informed, they can assert this so-called primary claim - i.e. information from the health or long-term care insurance fund. This is aimed at simple administrative action, the provision of information or justification as to why the insured person did not need to be informed. Here, too, it becomes clear that the health and long-term care insurance fund itself must know at all times how it came to the respective decision. The following also applies here: If the health or long-term care insurance fund cannot justify its processes and decisions on the basis of medical science, it will lose. These claims can be enforced in court before the social courts.

If the insured person receives information from their health or long-term care insurance fund too late in accordance with Section 25b (4) SGB V and suffers causal damage to health as a result, the insured person can claim damages by way of official liability (Section 839 of the German Civil Code [BGB], Art. 34 GG). For example, damage to health due to delayed treatment or omitted vaccinations with the realisation of the health risk against which the vaccination should have protected.

However, it is likely to be extremely difficult for the insured person to prove the causality between the omitted or delayed information by the health or long-term care insurance fund and the respective damage to health, as it seems difficult to imagine that there were no more obvious indications of these health risks than the data available from the respective health or long-term care insurance fund. However, if he succeeds in doing so, the damages that can be compensated include loss of earnings, illness-related additional expenses, claims for damages for pain and suffering, etc. These can be asserted in court before the regional courts.

Discussion and conclusion

Health and long-term care insurance funds can carry out data-based analyses. An obligation to provide information initially exists when a specific health risk to the insured person is recognised. This presupposes that there is a sufficient probability of damage to health. At the same time, the legislator has demanded in a barely comprehensible form that health and long-term care insurance funds must provide information if there is a concrete risk of illness or a need for long-term care. It remains unclear whether the requirements for the likelihood of damage occurring for the insured person are really different from those for the first offence. If one wishes to differentiate, one can assume that health and long-term care insurance funds must provide information when they recognise a foreseeable future possibility (not probability) of an illness or need for long-term care arising from the individual (life) circumstances of an individual insured person.

Whether these thresholds are reached in each case is ultimately determined by medical science and healthcare research. If the danger or risk is not great enough from a medical point of view, there is also no legal reason to inform the insured person.

In addition, information must be provided if a vaccination indication for a STIKO vaccination is recognised. It is clear that the legal formulation and differentiation is neither congruent nor consistent.

By law, health and long-term care insurance funds must be able to justify in a comprehensible manner how they came to their conclusions and why they made which information decision. These legal requirements arise from the general principle of equality in Article 3 (1) of the German Basic Law, but also

from the fundamental right to data transparency. However, these requirements also arise from the burden of proof regulations of the respective procedural law, as the health and long-term care insurance funds would lose both the primary claim (request for information) and the secondary claim (claim for damages) in court if they were unable to justify their decisions.

These legal requirements limit the use of artificial intelligence to the extent that and as long as it cannot make its procedures and results transparent and comprehensible, especially its decisions not to categorise certain constellations as a 'specific risk' for an insured person. Only when artificial intelligence fulfils these requirements can it also be used for stratification in accordance with Section 25b (1) SGB V and the decision on insured person information in accordance with Section 25b (4) SGB V. <<

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