

AKG Transparency Rule

§ 28 Transparency

Transparency is an indication of fair business practice. From 2016, all cash-equivalent benefits in connection with training or continuing education events pursuant to § 19, any other unilateral benefits and any benefits granted to members of the health professions or health organisations on the basis of reciprocal agreements are to be published in an annual list which is available to the general public, beginning with the data for calendar year 2015. Publication shall comply with the statutory data protection regulations as amended from time to time.

The list is to be broken down into the categories (a) research and development, (b) donations and other unilateral cash or non-cash benefits, (c) cash-equivalent benefits in connection with training or continuing education events and (d) service and consultancy fees. Publication in the research and development category is to be in the form of an aggregated list. Publication in the other categories will generally enable allocation of the entry to individuals. In case of any legal grounds or grounds relating to the individual company that preclude individual publication, publication shall be in the form of an aggregated list.

The list can be published on the company's website and can also take the form of a reference to other publications.

The member companies are entitled to make exceptions for minor benefits. Further details are stated in the "Transparency" guidelines issued by the Board.

§ 22 Para. 2 is unaffected by this section.

Arzneimittel und Kooperation im Gesundheitswesen AKG e. V.

Where can I find out more about the transparency rule?

Contact:

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Link to the transparency guidelines and additional helpful tools available for download: www.ak-gesundheitswesen.de/akg-transparenzregelung/vorlagen/

Link to the "at a glance" guide: www.ak-gesundheitswesen.de

You should also know:

Section 4, Para. 1 of the Federal Data Protection Act (BDSG)

The processing and use of personal data shall be admissible only if this Act or any other legal provision permits or prescribes them or if the data subject has consented.

Section 28, Para. 1 of the Federal Data Protection Act (BDSG)

The storage, modification or communication of personal data or their use as a means of fulfilling one's own business purposes shall be admissible

- in accordance with the purposes of a contract or a quasi-contractual fiduciary relationship with the data subject,
- in so far as this is necessary to safeguard justified interests of the controller of the data file and there is no reason to assume that the data subject has an overriding legitimate interest in his data being excluded from processing or use, or
- if the data can be taken from generally accessible sources or the controller of the data file would be entitled to publish them, unless the data subject clearly has an overriding legitimate interest in his data being excluded from processing or use.

When personal data are collected, the purposes for which the data are being processed or used must be specifically defined.

AKG Transparency Rule

§ 28 AKG Code of Conduct (Codex)

10 Questions

10 Answers

"Transparency creates trust"



This information brochure is intended to give an overview of key elements of the AKG transparency rule. Additional details can be found in the guidelines for this rule, which are available separately.

1. What is the AKG transparency rule?

In 2014, the AKG rules of conduct, the codex, were expanded by the addition of a new transparency rule, §28. This rule encourages AKG members to disclose the cash-equivalent benefits that they provide to people and institutions in the health care industry. Implementation of the transparency rule is voluntary and is not enforced by sanctions.

2. Why was the transparency rule passed?

With this transparency rule, the AKG wants to increase the public's trust in the integrity of the health system and in the fairness of competition. The transparency rule is thus a building block that forms part of the AKG's voluntary commitments and compliance measures.

3. Time, duration and place of publication:

- **2015:** The first reporting period
- **No later than 30 June 2016:** Initial publication of data for the 2015 reporting period
- In **following years**, the data will be published annually, **no later than 30 June**.
- The published data shall be accessible for **three years**.
- Should be in a public, easy-to-read form (i.e. on the company's home page)
- It must be ensured that data can be removed or corrected at any time.

4. What recipient groups are covered by the requirement to disclose cash-equivalent benefits?

Healthcare professionals (HCPs), for example:

- Practicing physicians, dentists, pharmacists, and healthcare and nursing professionals or other persons who prescribe, procure, deliver or administer prescription medications (according to § 48 AMG).
- Health care organizations (HCOs), for example: Hospitals, clinics, universities, medical service centres, continuing education and training institutes, professional associations.

5. What are cash-equivalent benefits?

Cash-equivalent benefits are direct or indirect payments or the provision of benefits that have monetary value.

6. What must not be disclosed?

- The transfer of product samples, training materials or brochures
- Food and drink
- Discount and bonus regimes
- Minor benefits of minimal value (promotional articles and gifts)
- Passive participation, as long as no costs are covered, such as travel and/or lodging costs

7. What information should be disclosed?

- The recipient of the benefit
- Their address
- The value of the benefit
- The category

8. What categories should cash-equivalent benefits be grouped into?

Category (a)

- Research and development (data will only be published in aggregated form)

Category (b)

- Donations or gifts (in money or in-kind)
- Other unilateral cash or in-kind benefits

Category (c)

- Sponsoring of training or continuing education events or measures
- Payment of participant fees or of travel or lodging expenses in connection with such events

Category (d)

- Honoraria for consulting services, speeches, expert opinions, etc.
- Travel and lodging expenses in connection with such services

9. What must be taken into consideration when disclosing personal data?

- Written permission is required from the person in question
- Data must be deleted promptly if permission is withdrawn, followed by disclosure in aggregate form

10. Should data be disclosed in individualised or aggregate form?

- The publication of individualised data is preferable to the publication of aggregate data
- However, if legal grounds or grounds related to the individual company preclude the publication of individualised data, aggregate data should be disclosed.