Regulations of 21 December 2001 No. 1477

Regulations on the collection and processing of personal health data in the Cancer Registry of Norway (Cancer Registry Regulations)
Chapter 1  General provisions

Section 1-1 (Establishment of the Cancer Registry)
These Regulations provide for the establishment of a national Cancer Registry. The Regulations lay down rules for the collection and processing of personal health data in the Registry.

The collection and processing of personal health data in the Cancer Registry may be done manually and by electronic means.

Section 1-2 (Contents of the Cancer Registry)
The Cancer Registry shall contain personal health data relating to all persons in Norway who have or have had cancer. The Cancer Registry shall contain personal health data on precancerous conditions and benign tumours in the central nervous system.

The Cancer Registry may also contain personal health data relating to affected relatives of persons in Norway shown by documentary evidence to be predisposed to or to have hereditary cancer that may be made the object of unsolicited contact and disclosure, if the relative concerned, after having received information about the way such data is processed in the Cancer Registry, does not object thereto.

The Cancer Registry may furthermore contain personal health data relating to persons who have participated in screening programmes for early diagnosis and control of cancer. For negative findings; data that directly identify a natural person may only be recorded permanently by consent. Data that directly identify a natural person may, however, be stored temporarily so that the quality of the data may be assured.

Section 1-3  (Purpose of the Cancer Registry)
The purpose of the Cancer Registry is to:
1. collect and, within the scope of the Regulations, process data relating to cases of cancer and cancer studies in Norway in order to document the distribution of cancer in the country and describe changes over time,
2. conduct, promote and provide a basis for research to develop new knowledge of the causes, diagnosis, natural course and effects of treatment of cancer in order to improve and enhance the quality of preventive measures and medical assistance that are offered or provided to combat cancer, including the follow-up of individual patients and groups of patients,
3. provide advice and counselling on medical assistance to combat cancer,
4. provide advice and information to other public administrative bodies and the population at large on measures that may prevent the development of cancer.
In addition to such purposes, mentioned in the first paragraph, data in the Cancer Registry may be processed for the following purposes: management, planning and quality assurance of public health services and the public health administration, for the preparation of statistics and for research.

Section 1-4 (*Prohibition against misuse*)
Data in the Cancer Registry may not be used for purposes that are incompatible with section 1-3.
Data relating to individuals that have come to light in connection with the processing of personal health data pursuant to these Regulations may not be used for insurance purposes even if the data subject consents thereto.

Section 1-5 (*Data controller*)
The Cancer Registry shall be the data controller (as defined in the Health Registry Act) for the collection and processing of personal health data in the Cancer Registry.

Section 1-6 (*Data processor*)
The Cancer Registry may enter into a written agreement with a data processor concerning the collection and processing of personal health data in the Cancer Registry, including monitoring and research, cf. section 1-3, the operation and quality assurance of the Registry, and the disclosure of data to users.

Section 1-7 (*Data relating to cancer cases in the Cancer Registry*)
The Cancer Registry may without consent contain the following data relating to persons who have or have had cancer, precancerous conditions, or benign tumours in the central nervous system to the extent that these data are necessary in order to achieve the purpose of the Registry:
1. personal data:
   1.1. name and personal identity number,
   1.2. address and municipality of residence,
   1.3. marital status,
2. administrative data:
   2.1. institution/enterprise/unit where the medical assistance is offered and provided,
   2.2. the name and address of the physician responsible for treatment, and of the physician responsible for the patient, if different,
   2.3. admission to a health institution, date of admission, date of discharge, and out-patient consultations, if any,
3. medical data:
   3.1. relating to the reason why the public health services were contacted, the time and evolution of symptoms, diagnosis, treatment, follow-up consultations and relapses, if any,
   3.2. relating to the cancer
      3.2.1. the site of origin of the cancer,
      3.2.2. disease category,
      3.2.3. morphological diagnosis,
      3.2.4. spread at the time of diagnosis,
      3.2.5. metastases,
      3.2.6. relapses,
   3.3. relating to the basis for diagnosis:
      3.3.1. clinical findings,
      3.3.2. pictorial diagnostics,
3.3.3. histopathological examination,
3.3.4. cytological material,
3.3.5. other type of examination

3.4. cancer treatment received by the data subject (patient), indications and contra-
indications for treatment, method of treatment, as well as any complications or side-
effects,

3.5. information relating to any residual tumour after treatment.

If, after having received information as to how such data are processed in the Cancer
Registry, the data subject does not object thereto, the Cancer Registry may contain data
relating to the data subject’s
1. occupational conditions,
4. smoking habits,
5. any other known risk factors for cancer.

Section 1-8 (Data relating to affected relatives of persons who have hereditary cancer)

Subject to such conditions as are mentioned in section 1-2, second paragraph, the
Cancer Registry may contain the following data relating to affected relatives of persons in
Norway shown by documentary evidence to be predisposed to or to have hereditary cancer
that may be made the object of unsolicited contact and disclosure:
1. personal data:
   1.1. name and national identity number,
   1.2. address and municipality of residence,
   1.3. marital status,
2. administrative data:
   2.1. enterprise/unit, hospitalisation, if any,
   2.2. time of the follow-up consultations (date and year),
   2.3. time of planned follow-up,
3. relevant medical data:
   3.1. basis for diagnosis,
   3.2. diagnosis,
4. background for the examination.

Section 1-9 (Data relating to persons who have participated in programmes for the early
diagnosis or control of a specific cancer)

With the exceptions that follow from the second paragraph, the Cancer Registry may
contain the following data relating to persons who have participated in a screening
programme for the early diagnosis and control of cancer:
1. personal data:
   1.1. name and personal identity number,
   1.2. address and municipality of residence,
   1.3. marital status,
2. administrative data:
   2.1. enterprise/unit, hospitalisation, if any,
   2.2. time of the check-up (date and year),
   2.3. time of planned follow-up,
3. relevant medical data:
   3.1. basis for diagnosis,
   3.2. diagnosis,
4. background for the examination:
   4.1. screening programme,
4.2. other background.

In the event of a negative finding, such personal data as are mentioned in the first paragraph, sub-paragraph 1, shall be erased after the quality of the data has been assured and not later than six months after the data were collected, unless the data subject (patient) has consented to the permanent recording of the data. If the data subject (patient) so requests, the Cancer Registry shall record data relating to name, personal identity number and address in a separate register for data subjects who have reserved consent to the disclosure of their personal health data.

Section 1-10 (Data relating to cause of death)

The Cancer Registry may contain personal health data relating to cause of death, autopsy, date of death, time, month and year for all the persons registered in the Registry.

Section 1-11 (Coding and classification of the data in the Cancer Registry, documentation requirements)

The data controller for the Cancer Registry shall be able to document which classifications or coding systems have been used for every entry in the Registry.

The Ministry may issue further provisions regarding which national or international coding system and classifications shall be used when recording data in the Cancer Registry.

Chapter 2 Reporting of personal health data to the Cancer Registry, quality control, etc.

Section 2-1 (Duty of health care personnel to document and report data)

Clinicians, pathologists, radiologists and other laboratory physicians who provide medical assistance in connection with cancer shall without regard to their duty to adhere to the rules of confidentiality, report such data as are mentioned in section 1-7, first paragraph, to the Cancer Registry. Data regarding occupational conditions, smoking habits, etc. as mentioned in section 1-7, second paragraph, shall be reported if the data subject (patient) does not object thereto.

Clinicians, pathologists, radiologists and other laboratory physicians who examine patients for possible cancer, cf. section 1-2, third paragraph, shall in the event of a negative finding report such data as are mentioned in section 1-9, first paragraph, to the Cancer Registry without regard to their duty to adhere to the rules of confidentiality. The report shall indicate whether the data relating to the person’s identity shall be registered permanently or erased after the quality of the data has been assured.

Such reports as are mentioned in the first and second paragraphs shall be sent on an ongoing basis and not later than two months after the data have been documented in accordance with sections 39 and 40 of the Health Care Personnel Act.

Section 2-2 (Reporting form, requirements relating to the form of reporting, etc.)

Such data as are mentioned in section 2-1, first and second paragraphs, shall be reported in a form or in another manner determined by the Ministry.

The Ministry may give orders concerning the use of specified classification systems and coding systems when recording the data, and give orders concerning the use of standardized reporting formats when transmitting the data.

Section 2-3 (Duties of the enterprise)
Health institutions, out-patient departments, health centres, pathology laboratories, x-ray laboratories, clinical-chemical laboratories or other enterprises that are responsible for recording data that are to be reported to the Cancer Registry, cf. sections 1-7 and 1-9, are responsible for ensuring that the duties mentioned in sections 2-1 and 2-2 are fulfilled, and shall see to it that there are routines to ensure such fulfilment, cf. sections 4-2 and 4-3 of the Regulations.

Section 2-4  (Recipient’s responsibility for quality control)

The data controller for the Cancer Registry shall ensure that personal health data that are collected and processed by the Cancer Registry are correct, relevant and necessary for the purposes for which they are collected, cf. section 1-3. As part of the quality control process, the data may routinely be linked with the National Registrar and the Causes of Death Registry.

If the reporting form is inadequately filled in, the person who sent the form shall be notified, cf. section 9, second paragraph, second sentence, of the Personal Health Data Filing Systems Act. If the form is still inadequately filled in, the Norwegian Board of Health shall be notified.

Chapter 3  Processing of personal health data in the Cancer Registry

Section 3-1  (Linkage of data for the production of statistics)

Data in the Cancer Registry may be linked with data in the Medical Birth Registry, the Causes of Death Registry, the System of Notification of Infectious Diseases, the Central Tuberculosis Surveillance Registry and the System for Immunization Surveillance and Control, if it is done by the data controller for one of the aforementioned filing systems or an enterprise decided by the Ministry, and the result of the linkage appears in an anonymised form.

The data controller shall normally execute requests for statistical data from the public administration and researchers not later than 60 days from the day the order was received. If special circumstances make it impossible to execute the request within the time limit, execution may be postponed until it is possible to fulfil the request. In such case, the data controller shall give a provisional reply with information as to whether the request can be executed, the reason for the delay and when the order is likely to be executed.

Personal health data that are received for the production of statistics pursuant to the first paragraph shall be erased as soon as the production of statistics has been carried out satisfactorily.

Section 3-2  (Linkage of data from the Cancer Registry with data in other filing systems for research, etc.)

The data controller for the Cancer Registry may link data in the Cancer Registry with data in such personal health data filing systems as are mentioned in section 3-1, first paragraph, for explicitly stated purposes, consistent with the purposes of the filing systems, cf. section 1-3 of the Regulations, if this is ethically unobjectionable and the data processor (researcher) shall only process de-identified data.

Linked personal health data may not be stored until the name, date of birth and personal identity number have been erased or encrypted. Data directly identifying a natural person (name and national identity number) that are received for processing shall be erased as soon as the linkage has been carried out satisfactorily.

All data involved in the processing pursuant to the first and second paragraphs shall be erased upon conclusion of the project.
Section 3-3  *(Disclosure of linked data files for research, etc.)*

Upon application, such de-identified data as are mentioned in section 3-2, first paragraph, shall be made available and disclosed for research, or possibly for another explicitly stated purpose consistent with the purpose of the Registry, cf. section 1-3 of the Regulations, if
- the recipient shall only process de-identified data,
- processing of the data is ethically unobjectionable and
- the data are linked and arranged by the data controller for one of the filing systems whose data are processed, or in an enterprise decided by the Ministry.

Section 3-2, second paragraph, shall apply correspondingly.

The data controller shall disclose or transfer necessary and relevant data to the person responsible for the stated project not later than 60 days from the date on which the application was received. The legal basis for processing the data shall be stated in the application, cf. first paragraph.

If special circumstances make it impossible to respond to the application within the stated time limit, response may be postponed until it is possible to effect it. In such case, the data controller shall give a provisional reply with information as to whether the inquiry can be followed, the reason for the delay and when the application is likely to be executed.

All data involved in processing pursuant to this section shall be erased or returned upon conclusion of the project.

Section 3-4  *(Duty to disclose data for research, etc. without linkage to other data sources)*

Upon inquiry from the public administration and researchers, the data controller for the Cancer Registry shall disclose statistical data from the Cancer Registry not later than 30 days from the date on which the inquiry was received.

The data controller for the Cancer Registry shall upon application disclose de-identified data from the Cancer Registry if
- the data are to be used for an explicitly stated purpose consistent with the purpose of the Registry,
- the recipient shall only process de-identified data and
- the processing of the data is ethically unobjectionable.

The data controller shall disclose or transfer necessary and relevant data to the person responsible for the stated project not later than 30 days from the day on which the application was received. The legal basis for processing the data shall be stated in the application.

Section 3-3, fourth and fifth paragraphs, shall apply correspondingly.

Section 3-5  *(Disclosure and other processing of data in the Cancer Registry)*

Data in the Cancer Registry that identify a natural person may, unless otherwise provided by these Regulations, only be processed (aligned, disclosed, etc.) with the permission of the Data Inspectorate and in accordance with the general rules regarding the duty to adhere to the rules of confidentiality.

The Norwegian Directorate for Health and Social Affairs shall reply to inquiries regarding the disclosure of data that identify a natural person for use in explicitly stated research projects not later than 30 days from the day on which the inquiry was received. If special circumstances make it impossible to reply to the inquiry within the stated time limit, the reply may be postponed until it is possible to give a reply. In such case the Norwegian Directorate for Health and Social Affairs shall give a provisional reply with information as to the reason for the delay and when a reply is likely to be given.
Section 3-6 (Information strategy targeting user groups)

In order to promote the use of data from the Cancer Registry and to build up information and knowledge, cf. section 1-3 of the Regulations, the data controller for the Cancer Registry shall develop an active information strategy and information plan targeting the public health administration, public health services and other public administrative bodies as well as researchers in medical research, health care research and social research.

Section 3-7 (Costs)

The data controller for the Cancer Registry may charge payment for the processing and arrangement of data pursuant to sections 3-1 to 3-5. Payment may not exceed the actual costs of such processing and arrangement of the data.

Section 3-8 (Overview of disclosures)

The data controller for the Cancer Registry shall keep a record of the persons who receive disclosures of data from the Cancer Registry and the legal basis for the disclosures. The record shall be stored for at least three years after disclosure has taken place.

Chapter 4 Duty of confidentiality, data security, internal controls

Section 4-1 (Duty of confidentiality)

Any person who processes personal health data pursuant to these Regulations has a duty to adhere to the rules of confidentiality pursuant to sections 13 to 13 e of the Public Administration Act, as well as pursuant to the Health Care Personnel Act.

The duty of confidentiality pursuant to the first paragraph also applies to the patient’s place of birth, date of birth, personal identity number, pseudonym, nationality status, marital status, occupation, residence and place of work.

Pursuant to section 13 b, subsections 5 and 6, of the Public Administration Act, data may only be given to other public administrative bodies when this is necessary to facilitate the fulfilment of tasks pursuant to these Regulations, or to prevent significant danger to life or serious injury to a person’s health.

Section 4-2 (Data security)

By means of planned, systematic measures, the data controller for the Cancer Registry and the data processor shall ensure satisfactory data security as regards confidentiality, integrity, quality and accessibility in connection with the processing of personal health data pursuant to these Regulations, cf. section 16 et seq. of the Personal Health Data Filing Systems Act.

Where processing of personal health data takes place wholly or partly by electronic means, the provisions regarding data security in sections 2-1 to 2-16 in the Personal Data Regulations shall apply.

Section 4-3 (Responsibility to establish internal controls)

The data controller for the Cancer Registry shall establish internal controls in accordance with section 17 of the Personal Health Data Filing Systems Act. The systematic measures shall be adapted to the nature, activities and size of the enterprise to the extent that is necessary in order to comply with requirements laid down in or pursuant to the Personal Health Data Filing Systems Act, with particular emphasis on provisions laid down pursuant to section 16 of the said Act.

Data processors who process personal health data on behalf of the data controller shall process data in accordance with routines established by the data controller.
Section 4-4 *(Content of the internal controls)*

Internal controls imply that the data controller shall have knowledge of current rules regarding the processing of personal health data and adequate, up-to-date documentation for the implementation of routines, and have the said documentation available for those concerned. The internal controls shall, *inter alia*, comprise:

1. an overview of the way the enterprise is organized,
2. an overview of responsibilities and authority,
3. an overview of the requirements laid down in and pursuant to the Personal Health Data Filing Systems Act which apply to the enterprise,
4. routines followed by the enterprise in order to ensure compliance with the requirements, including routines for:
   4.1. fulfilment of requirements that data identifying a natural person are only to be processed when this is necessary to promote the purpose of the data processing, and in line with current provisions regarding the duty to adhere to the rules of confidentiality, cf. sections 11 and 15 of the Personal Health Data Filing Systems Act,
   4.2. documentation and quality control of personal health data, cf. sections 1-11 and 2-4 of these Regulations,
   4.3. fulfilment of requests for information and right of access, cf. sections 21 to 25 of the Personal Health Data Filing Systems Act, and section 5-1 of these Regulations,
   4.4. the way in which the enterprises comply with the provisions regarding access to personal health data filing systems, cf. sections 3-1, 3-3, 3-4 and 3-5,
   4.5. compliance with the rules regarding the duty to notify the Data Inspectorate, cf. section 29 of the Personal Health Data Filing Systems Act,
5. routines followed by the enterprise if violations of regulations occur and information as to who is responsible,
6. routines followed by the enterprise in order to prevent the recurrence of violations of regulations and information as to who is responsible,
7. routines for the way the enterprise systematically and regularly reviews its internal controls in order to check that the activities and the results thereof are in accordance with the system established by the enterprise, and whether it leads to compliance with the legislation on personal health data filing systems,
8. routines for how the enterprise ensures that all relevant and only valid routines are used, and
9. routines for how the enterprise ensures that the employees have sufficient competence to comply with the requirements laid down by these Regulations.

Written documentation shall at least comprise documentation of such routines as are mentioned in the first paragraph, nos. 1 to 8. The supervisory authorities may issue orders regarding additional written documentation if it deems this to be necessary. The supervisory authorities may grant exemptions from all or parts of this chapter under special circumstances.

**Chapter 5 The rights of the data subject to information and access**

Section 5-1 *(The right of the data subject to information and access)*

Data subjects are entitled to information concerning the Cancer Registry and access to the processing of personal health data relating to themselves in accordance with sections 22 to 25 of the Personal Health Data Filing Systems Act.
Access to personal health data relating to oneself, cf. section 22, second paragraph, of the Personal Health Data Filing Systems Act, shall preferably be provided through the physician and health institution who last treated the data subject. The information shall be provided in a comprehensible form.

Section 5-2 (Information and access when the data subject is a minor)
Parents and other persons with parental responsibility are entitled to access pursuant to rules corresponding to those laid down in section 3-4 of the Patients’ Rights Act.

Section 5-3 (Time limit for replying to inquiries regarding access)
Requests for access pursuant to section 5-1 shall be replied to without undue delay and not later than 30 days from the day the inquiry was received, cf. section 19 of the Personal Health Data Filing Systems Act.
If special circumstances make it impossible to reply to the inquiry within 30 days, implementation may be postponed until it is possible to reply. In such case the data controller shall give a provisional reply with information as to the reason for the delay and when a reply is likely to be given.

Chapter 6 Storage of personal health data in the Cancer Registry

Section 6-1 (Storage of personal health data)
Data in the Cancer Registry shall be stored indefinitely, unless otherwise provided by these Regulations or section 26 or section 28 of the Personal Health Data Filing Systems Act.

Chapter 7 Penalties

Section 7-1 (Penalties)
Any person who wilfully or through gross negligence breaches provisions laid down in section 2-1, section 2-3 and sections 4-2 to 4-4 of these Regulations shall be liable to fines or imprisonment for a term not exceeding one year or both.
An accomplice shall be liable to similar penalties.

Chapter 8 Concluding provisions

Section 8-1 (Commencement)
These Regulations shall enter into force on 1 January 2002.