# Information to patients and relatives after a reported serious adverse event

The Norwegian Board of Health Supervision has received a report about a serious adverse event (according to the Specialized Health Services Act, Section 3-3a)

> ***Section 3-3a Reporting of serious adverse events to the Norwegian Board of Health Supervision***
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> *"In order to ensure that serious adverse events are followed up by the supervisory authorities, health trusts, and organizations that have a contract with a health trust or regional health authority, shall immediately report serious adverse events to the Norwegian Board of Health Supervision. A serious adverse event is defined as death or serious injury to a patient when the result is unexpected in relation to the expected risk."*

The health service has the main responsibility for taking care of you after the event, and giving you the information you need. They will assist you and answer your questions about what has happened.

The aim of the reporting system is to ensure that serious adverse events in health services are followed up by the supervision authorities, to ensure that the event is well documentated without delay, and therefore to ensure that the time taken to deal with the case is short. Patients and relatives shall be given the possibility to give their version of what happened, since it is important to obtain a correct picture of the event.

## The right to be given information

The health service shall ensure that you as a patient or relative are given adequate and sound information. The information shall be given in an appropriate way. If there are language problems, the health trust shall consider using an interpreter.

The type of information you have the right to be given when you yourself or a relative of yours is injured as a result of treatment, is laid down in the Patients' and Consumers' Rights Act, Sections 3-2 and 3-3.

### The rights of the patient

As a patient you have the right to be given information as soon as possible about injury or serious complications that have occurred as a result of treatment. This is the case independently of whether the health care provided by the hospital was sound and adequate or not.

### The rights of the relatives

As a relative, you will also have a need to know as much as possible if your relative has been injured. The type of information you have the right to be given is laid down in the Patients' and Consumers' Rights Act, Section 3-3. In some cases, a patient does not wish their close family to know about the circumstances surrounding what has happened. The hospital must respect the patients wishes, and must take these into account when providing information to the relatives.

### The right to appeal against the decision of the hospital

As a patient or relative, you can always appeal if the hospital makes the decision not to give you information, or not to give you copies of important documents, such as the patient records. You can then appeal directly to the hospital. If the hospital does not reverse their decision, they will send your complaint on to the Office of the County Governor.

## What does the Norwegian Board of Health Supervision do when they receive a report about an adverse event?

We investigate all the serious adverse events that are reported to us. Serious adverse events are events in which a patient has died or been seriously injured as a result of treatment provided in a hospital. We always collect information from the hospital, and then assess how we shall follow up the incident.

- In some cases we ask the hospital to investige the event themselves, sometimes by asking the hospital to give us a written report.
- Some of the cases are dealt with by the Office of the County Governor.
- In some cases we carry out local supervision, by visiting the hospital.

You cannot appeal against our decision about how a serious adverse event shall be followed up (but see below: your right to appeal to the Office of the County Governor).

### Local supervision

In some cases, we visit the hospital to carry out local supervision. The aim of supervision is to assess the event in detail, analyse what has happened, and then identify whether the hospital has failed to provide adequate and sound health care. In this way we aim to help to prevent the same mistakes happening again. In addition, the legislation allows us to give sanctions against the organization and/or the health care personnel who were involved in the incident.

We give you the opportunity to have a meeting with us, so that we can hear how you experienced the event. This can provide additional information about the event. You may ask for asssistance from a lawyer, the Health and Social Services Ombudsman, or someone else. We also obtain information from all the people who have been directly involved in the event. We ask for a copies of the hospital's written procedures, patient records and other relevant documentation. You are not regarded as a formal partner in the case, but you can be given copies of correspondance and patient records in the case (with some exceptions). In addidtion, you have the right to give a statement. After all information has been collected, we write a report about the

event. Even though we carry out an investigation, the hospital shall also investigate what has happened and deal with the case with the aim of preventing similar events happening in the future.

### The right to complain

You always have the right to send a complaint to the Office of the County Governor if you believe that you or your relatives have not received adequate and sound treatment, and to ask the supervision authorities to assess the case, according to the Patients' and Consumers' Rights Act, Chapter 7. The Health and Social Services Ombudsman can help you to do this.

# Extract from the Patients' and Consumers' Rights Act

### § 3-2 Patient's and Consumers right to be informed

The patient shall have the information that is required in order for him to gain insight into his medical condition and the contents of the medical treatment given to him. The patient shall also be informed of possible risks and side effects involved.

Information shall not be given against the expressed will of the patient, unless it is necessary in order to prevent harmful affects due to the health care given, or it is determined in or pursuant to law.

Information may be omitted if it is absolutely necessary to prevent endangering the patient's life, or to prevent serious damage to the patient's health. Information may also be omitted if, due to persons who are close to the patient, it would be clearly inadvisable, to disclose such information.

If injury or serious complications are inflicted upon the patient, the patient shall be informed thereof. The patient shall at the same time be made aware of his right to apply for compensation through The Norwegian System of Compensation for Injuries to Patients, and that they can request the supervision authorities to assess whether there has been a breach of the Patients' and Consumers' Rights Act, Section 7-4.

If, after the treatment has been completed, it is discovered that the patient may have suffered considerable injury as a result of the health care rendered, the patient shall, if possible, be informed thereof.

Consumers shall be given the information that is necessary in order to gain sufficient insight in the services that are available and to be able to ensure their rights.

### § 3-3 Information to the patient's next of kin

If the patient gives his consent thereto, or circumstances justifies it, the patient's next of kin shall receive information relating to the patient's medical condition and the treatment that is being provided.

If the patient is above 16 years of age and clearly incapable of managing his own affairs for reasons of physical or mental disorder, dementia or mental disability, both the patient and his next of kin are entitled to receive information pursuant to the provisions of Section 3-2.

## § 3-4 Information when the patient is a minor

If the patient is below 16 years of age, both patient and the parents or others holding the parental responsibility shall be informed.