
EXPLANATORY NOTE

(This note is not part of the Regulations)

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (“the Regulations”) make new arrangements for the notification and consideration of and response to concerns notified by persons in respect of services provided by or under arrangements with the National Health Service in Wales.

A concern is defined as a complaint, a notification of an incident concerning patient safety or, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation.

The Regulations also introduce the concept of “redress”. They place an obligation on a Welsh NHS body to consider, when it is notified of a concern that alleges harm has or may have been caused, whether or not there is a qualifying liability.

Part 7 of the Regulations contains provisions detailing how the redress arrangements will operate when a Welsh NHS body enters into arrangements with an NHS body in England, Scotland or Northern Ireland.

The redress elements of the Regulations do not apply to primary care providers or independent providers.

The Regulations replace the existing arrangements for the making and consideration of complaints which are contained in three separate sets of Directions. The Regulations revoke the Directions, subject to transitional provisions, and make, in Schedule 2, consequential amendments to the relevant terms of service for primary care providers in Wales.

PART 1

General

The Regulations apply to services provided as part of the health service in Wales.

Parts 1 to 6 and 8 to 10 of the Regulations come into force on 1 April 2011. Part 7 of the Regulations comes into force on 1 October 2011.

Regulation 2 defines terms used in the Regulations. Key definitions include the definition of “complaint”, “concern”, “primary care provider”, “qualifying liability in tort”, “qualifying services” and “responsible body”.

Regulation 3 establishes the general principles which must be followed when handling and investigating concerns under the Regulations.

PART 2

Duty to Make Arrangements for the Handling and Investigation of Concerns

Regulation 4 provides that a responsible body must make arrangements, in accordance with these Regulations, for the handling and investigation of concerns.

Regulation 5 provides that arrangements for handling concerns must be published in accordance with the provisions of that regulation.

Regulation 6 stipulates that a responsible body is required to designate a person to be responsible for the oversight of its operation of the arrangements under the Regulations. Regulation 7 provides that a responsible officer must be designated to take responsibility for the day to day operation of the process to ensure concerns are dealt with in an integrated manner.

Changes to legislation: *There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Regulation 8 requires a responsible body to designate a senior investigations manager who will oversee the handling and consideration of concerns.

Regulation 9 provides that a responsible body must ensure that its staff receive appropriate training to enable them to comply with the requirements of the Regulations.

PART 3

Nature and Scope of the Arrangements for Handling Concerns

Regulation 10 provides that a responsible body must handle concerns in accordance with the arrangements for handling concerns set out in the Regulations. Regulation 10 is expressed to be subject to regulation 14 which sets out which matters and concerns are excluded from consideration under the Regulations.

Regulation 11 provides that a concern may be notified in writing, electronically or verbally. If a concern is notified verbally a written record of the concern must be prepared and a copy provided to the person who notified the concern.

Regulation 12(1) sets out who may notify a concern under the Regulations. Regulation 12(2) provides that a representative may notify a concern on behalf of a person who is receiving or has received services where that person has died, is a child, lacks capacity or has simply requested a representative to act on his or her behalf. Regulation 12(3) deals with the notification of concerns by a representative on behalf of a child. Pursuant to regulation 12(4) a responsible body must provide a child who notifies a concern with such assistance as the child may reasonably require to pursue the concern. Regulations 12(5) and (6) deal with the consideration of concerns notified on behalf of children and persons who lack capacity where the responsible body is of the opinion that the representative who notified the concern is not a suitable person to act as a representative or who is not pursuing the concern in the best interests of the child or person who lacks capacity. Regulation 12(7) deals with concerns that are reported by a member of staff of a responsible body and sets out when a patient must be informed of and involved in the investigation of such concerns. Regulation 12(8) sets out the circumstances in which a responsible body may form the opinion that a patient should not be informed of and involved in the investigation of such concerns.

Regulation 13 sets out the matters in respect of which concerns may be notified. A concern may be notified to: a Local Health Board or a National Health Service Trust managing a hospital or other establishment wholly or mainly in Wales about any matter connected with the exercise of its functions; to a primary care provider (which is defined in regulation 2 to be limited to primary care providers in Wales providing services pursuant to the National Health Service (Wales) Act 2006) about the provision of services by it under a contract or arrangements with a Welsh NHS body; or an independent provider in Wales about the provision of services by it under arrangements with a Welsh NHS body. Provided the requirements of regulation 18 are met, a person may also notify a concern to a Local Health Board about any matter connected with the provision of services by a primary care provider under a contract or arrangement with the Local Health Board.

Regulation 14(1) sets out the matters and concerns which are excluded from the scope of the arrangements under the Regulations. Regulation 14(2) provides that a responsible body must, as soon as reasonably practicable, notify in writing the person who notified the concern if it is of the opinion that the matter or concern relates to an excluded matter or concern and provide the reason for its decision.

Regulation 15 sets out the time limits for the notification of concerns under the Regulations.

Regulation 16 provides that a concern may be withdrawn at any time by the person who notified the concern. The withdrawal may be notified in writing, electronically or verbally. Regulation 16(3) provides that even if a concern is withdrawn, a responsible body may continue to investigate any issues raised by a concern if it considers that it is necessary to do so.

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PART 4

Concerns which involve other Responsible Bodies

Regulation 17 deals with concerns involving more than one responsible body. It places a duty on responsible bodies to co-operate for the purposes of co-ordinating the handling and investigation of the concern notified and must ensure that the person who notified the concern receives a co-ordinated response.

Regulations 18, 19, 20 and 21 deal with concerns about primary care providers which are notified to the Local Health Board with whom the primary care provider, who is the subject of the concern, has entered into a contract or arrangement. Regulation 19 deals with the action that a Local Health Board must take when it receives a concern notified by or on behalf of a person who is receiving or has received services from a primary care provider. Regulation 20 deals with the action that a Local Health Board must take when it receives a concern notified by a primary care provider. Both regulations 19 and 20 require a Local Health Board to consider whether or not it is appropriate for it to consider the concern or whether it is more appropriate for the primary care provider who is the subject of the concern to consider it. Regulation 21 deals with notification by a Local Health Board of the decision made under regulation 19 or 20. It sets out the relevant time limit for making a decision and the duty on the Local Health Board to give a reason for the decision.

PART 5

Handling and Investigation of Concerns

Regulation 22 provides that unless specified exceptions apply, a responsible body must notify receipt of a concern not later than two working days after receipt. A responsible body must also offer to discuss with the person who notified the concern matters relating to the investigation of the concern outlined in regulation 22(4). Pursuant to regulation 22(6) a responsible body must send a copy of the notification of a concern to the person who is the subject of the concern unless it is of the view that provision of a copy would, in its reasonable opinion, prejudice its consideration of the matters raised by the concern.

Regulation 23 provides that a responsible body must investigate the matters raised by a concern in the manner which appears to that body to be the most appropriate. It must have particular regard to the matters raised in regulation 23(1). Regulation 23(1)(i) provides that where a Welsh NHS body receives notification of a concern which includes an allegation that harm has or may have been caused it must consider the likelihood of any qualifying liability; the duty to consider redress in accordance with the provisions of regulation 25; and, where appropriate, consideration of the additional requirements set out in Part 6.

Regulation 24 sets out the requirements for a response to an investigation under regulation 23. Regulation 24 does **not** apply where a Welsh NHS body considers that there is or there may be a qualifying liability. In those circumstances an interim report under regulation 26 must be produced. In all other circumstances, a response under regulation 24 must be prepared. Regulation 24(1) prescribes the content of a response under regulation 24. Regulation 24(3), (4) and (5) prescribe the timescales for sending a response to the person who notified the concern. Regulation 24(3) places a duty on Welsh NHS bodies to provide reasons if, in relation to a concern that alleges harm has been or may have been caused, they come to the decision that there is no qualifying liability and the redress arrangements in Part 6 will not be triggered.

PART 6

Redress

The duty to consider redress under Part 6 only applies to Welsh NHS bodies, which are defined in regulation 2 as Local Health Boards and National Health Service Trusts managing a hospital or other establishment or facility wholly or mainly in Wales. It does not apply to primary care providers or independent providers.

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Regulation 25 provides that where a Welsh NHS body determines during the course of an investigation in accordance with regulation 23 that a qualifying liability exists or may exist, it must determine whether or not an offer of redress should be made to the patient. Regulation 25(2) makes it clear that an offer of redress may be made by a Welsh NHS body where it is established that there is a qualifying liability.

Regulation 26 states that where a Welsh NHS body is of the opinion, following an investigation under regulation 23, that there is or there may be a qualifying liability it must produce an interim report. Regulation 26(1) prescribes the content of the interim report. Regulation 26(2), (3) and (4) set out the timescales for sending the interim report to the person who notified the concern. Regulation 26(5) and (6) prescribe the timescale for sending the person who notified the concern, or his or her legal representative, a copy of the investigation report referred to in regulation 31.

Regulation 27 sets out the form that redress may take under the Regulations.

Regulation 28 provides that redress is not available in relation to a liability that is or has been the subject of civil proceedings and if civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of redress must stop and the person who notified the concern must be so advised.

Regulation 29 sets the limit for the financial compensation element of redress at £25,000. This is for special and general damages. Regulation 29(2) provides that if, on investigation, it transpires that the financial quantum of the claim exceeds £25,000, redress, in accordance with the Regulations, must not be offered. However, regulation 29(3) provides that if the financial limit will be exceeded, a Welsh NHS body may give consideration to making an offer of settlement outside the provisions of these Regulations. The regulation provides that the value of any compensation awarded will be assessed on the common law basis. The Welsh Ministers also have the power to issue a compensation tariff.

Regulation 30 deals with suspension of the relevant limitation periods during the period in which a liability is the subject of an application for redress under Part 6 of the Regulations.

Regulation 31 provides that the findings of an investigation of a concern must be recorded in an investigation report. Regulation 31(2) sets out what must be included in an investigation report. Regulation 31(3) provides that unless the provisions of regulation 31(4) apply, a Welsh NHS body must provide the person who is seeking redress under Part 6 of the Regulations, or his or her legal representative, with a copy of the investigation report.

Regulation 32 provides that where a Welsh NHS body has determined that a qualifying liability exists or may exist it must ensure that legal advice is available, in accordance with the provisions of this regulation. It must also ensure that if medical experts need to be instructed, they are instructed jointly by the Welsh NHS body and the person who notified the concern. Regulation 32(2) provides that legal advice can only be sought from firms of solicitors who have at least one partner or employee who is a member of either the Law Society Clinical Negligence Panel or the Action Against Medical Accidents Clinical Negligence Panel. Regulation 32(3) sets out the matters in respect of which legal advice, without charge to the person who notified the concern, must be made available. Regulation 32(4) provides that the cost of such legal advice and costs arising from the instruction of medical experts must be borne in their entirety by the Welsh NHS body.

Regulation 33 prescribes the time limits that apply to the making of offers of redress; the communication of decisions not to make offers of redress; the time limits for considering offers and refusals to make offers and extensions to such time limits. Regulation 33(e) provides that any offer of settlement will be by way of formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates. Regulation 33(g) provides that where a settlement is subject to court approval, the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

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PART 7

Requirements for NHS Bodies, other than Welsh NHS Bodies, to Consider Redress and Procedure to be Followed by a Welsh NHS Body when it Receives Notification of a Concern in Accordance with the Provisions of this Part.

Part 7 deals with how redress is to be provided where Welsh NHS bodies enter into arrangements with NHS bodies in England, Scotland or Northern Ireland. Primary care providers and independent providers are excluded from the scope of the arrangements under Part 7.

Regulation 34 defines terms that are used in Part 7.

Regulation 35 places a duty on an “English NHS body”, which is a term defined in regulation 34, that receives notification of a concern or a complaint about a service which it has provided or arranged for the provision of under arrangements with a Welsh NHS body, to consider, when investigating the complaint or concern, whether or not a qualifying liability exists or may exist.

Regulation 36(1) provides that if an English NHS body concludes that such a liability exists or may exist it must take the steps outlined in regulation 36(2).

Regulation 36(2) places a duty on an English NHS body to notify the Welsh NHS body with whom it has entered into an arrangement if it is of the view that a qualifying liability exists or may exist. It must then, after obtaining the appropriate consents from the patient or, in certain cases his or her representative, provide the Welsh NHS body with the information and documentation outlined at paragraphs (a) to (f).

Regulation 37 prescribes the action that a Welsh NHS body must take when it receives notification from an English NHS body in accordance with regulation 36.

Regulation 38 prescribes the action that a Welsh NHS body is required to take if it receives a notification from a Scottish NHS body or a Northern Irish NHS body that there is, or there may be, a qualifying liability.

Regulation 39 places a duty on Welsh NHS bodies to conduct an investigation on receipt of a notification from an English NHS body, a Scottish NHS body or a Northern Irish NHS body. Regulation 39(2) places a duty of co-operation on Welsh NHS bodies and English NHS bodies.

Regulation 40 provides that if after conducting an investigation in accordance with regulation 39 a Welsh NHS body is of the opinion that there is or there may be a qualifying liability, the Welsh NHS body must produce an interim report. Regulation 40(1) prescribes the content of the report. Regulation 40(3) and (4) prescribe the timescales for sending the interim report to the person who notified the concern. Regulation 40(4) prescribes the timescale for sending the person who notified the concern a copy of the investigation report referred to in regulation 46.

Regulation 41 prescribes the action that a Welsh NHS body must take when, following an investigation in accordance with the provisions of regulation 39, it decides that a concern notified by an English NHS body in accordance with regulation 36 or a Scottish NHS body or Northern Irish NHS body (in accordance with provisions in a commissioning contract) does not involve a qualifying liability.

Regulation 42 sets out the form that redress may take under Part 7 of the Regulations.

Regulation 43 provides that redress is not available in relation to a liability that is or has been the subject of civil proceedings and if civil proceedings are issued during the course of a Welsh NHS body’s consideration of redress, the Welsh NHS body’s consideration of redress must stop and the Welsh NHS body must notify the person who notified the concern and the English NHS body, Scottish NHS body or Northern Irish NHS body as appropriate.

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Regulation 44 sets the limit for the financial element of redress at £25,000. This is for special and general damages. Regulation 44(2) provides that if, on investigation, it transpires that the financial quantum of the claim exceeds £25,000, redress, in accordance with the Regulations, must not be offered. The regulation provides that the compensation awarded will be assessed on the common law basis. The Welsh Ministers also have the power to issue, a compensation tariff.

Regulation 45 deals with the suspension of the relevant limitation periods during the period in which a liability is the subject of an application for redress under Part 7 of the Regulations.

Regulation 46 provides that the findings of an investigation of a concern must be recorded in an investigation report. Regulation 46(2) sets out what must be included in an investigation report. Regulation 46(3) provides that unless the provisions of regulation 46(4) apply, a Welsh NHS body must provide the person who is seeking redress under Part 7 of the Regulations, or his or her legal representative, with a copy of the investigation report.

Regulation 47 replicates the provisions in regulation 32 save that regulation 47(4) makes reference to the fact that a Welsh NHS body may have rights to recover the cost of any expenditure related to redress from an English NHS body.

Regulation 48 prescribes the time limits that apply to the making of offers of redress; the communication of decisions not to make offers of redress; the time limits for considering offers and refusals to make offers and extensions to such time limits. Regulation 48(e) provides that any offer of settlement will be by way of formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates. Regulation 48(g) provides that where a settlement is subject to court approval the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

PART 8

Learning from concerns

Regulation 49 provides that each responsible body must ensure that it has processes in place to ensure that any deficiencies in its actions or service provision that are identified as part of an investigation of a concern in accordance with these Regulations are acted upon and monitored.

PART 9

Monitoring the Process

Regulation 50 prescribes the matters a responsible body must keep a record of in order to monitor the operation of the arrangements for dealing with concerns under the Regulations.

Regulation 51 provides that a responsible body must prepare an annual report. Regulation 51(1) prescribes the content of the annual report. Regulation 51(2) and (3) together provide that an independent provider, a primary care provider or a NHS Trust managing a hospital or other establishment wholly or mainly in Wales must if it agrees to provide services under an arrangement with a Local Health Board, send a copy of its annual report to that Local Health Board.

PART 10

Transitional and Consequential Provisions and Revocations

Regulation 52 contains transitional provisions.

Regulation 53 revokes the Directions specified in paragraphs (a) to (c).

Regulation 54 gives effect to Schedule 2.

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Changes and effects yet to be applied to :

- Sch. 2 para. 2 revoked by S.I. 2013/898 Sch. 8 para. 25
- reg. 1(2) words substituted by S.I. 2011/1706 reg. 2(1)
- reg. 2(1) word omitted by S.I. 2023/281 reg. 2(2)(a)(i)
- reg. 2(1) words inserted by S.I. 2023/274 reg. 14(2)
- reg. 2(1) words inserted by S.I. 2023/281 reg. 2(2)(a)(ii)
- reg. 2(1) words inserted by S.I. 2023/281 reg. 2(2)(b)
- reg. 12(1)(a) words substituted by S.I. 2023/281 reg. 2(4)(a)
- reg. 12(7) substituted by S.I. 2023/274 reg. 14(3)
- reg. 12(8) words omitted by S.I. 2023/274 reg. 14(4)
- reg. 12(9) words inserted by S.I. 2023/281 reg. 2(4)(b)
- reg. 14(1) word omitted by S.I. 2023/281 reg. 2(5)(d)
- reg. 14(1)(c) words inserted by S.I. 2023/281 reg. 2(5)(a)
- reg. 14(1)(f) words omitted by S.I. 2023/281 reg. 2(5)(b)
- reg. 14(1)(i) words inserted by S.I. 2023/281 reg. 2(5)(c)
- reg. 22(1) word substituted by S.I. 2023/274 reg. 14(5)(a)
- reg. 22(6) words substituted by S.I. 2023/274 reg. 14(5)(b)
- reg. 25(2) words inserted by S.I. 2023/281 reg. 2(6)
- reg. 34 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 34(1)(a)(b) omitted by S.I. 2013/235 Sch. 2 para. 162(1)(a)
- reg. 34(1)(a)(b) omitted by S.I. 2013/235 Sch. 2 para. 162(2)(a)
- reg. 35 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 36 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 37 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 38 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 39 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 40 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 41 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 42 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 43 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 44 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 45 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 46 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 47 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 48 coming into force by S.I. 2011/704 reg. 1(2)
- reg. 52(5) words substituted by S.I. 2011/1706 reg. 2(2)

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- reg. 3(1) reg. 3 renumbered as reg. 3(1) by S.I. 2023/281 reg. 2(3)(a)
- reg. 3(2)(3) inserted by S.I. 2023/281 reg. 2(3)(b)
- reg. 14(1)(k) and word inserted by S.I. 2023/281 reg. 2(5)(e)
- reg. 22(7) inserted by S.I. 2023/274 reg. 14(5)(c)
- reg. 34(1)(ca)-(cc) inserted by S.I. 2013/235 Sch. 2 para. 162(1)(b)
- reg. 34(1)(ca)-(cc) inserted by S.I. 2013/235 Sch. 2 para. 162(2)(b)
- reg. 34(1)(ca) substituted by S.I. 2022/634 reg. 52(2)

– reg. 34(1)(ca) substituted by [S.I. 2022/634](#) reg. 53(2) (Amendment to Welsh text)