Defence
Safety Authority

DSA02.DMSR

Healthcare Regulations

Version Record

Version 1.0
Version Date: 21 Dec 2018.
Version changes: document created

Version 2.0
Version Date: 13 Jan 2023.
Version changes: revised RAs with support of New DCOPS

Version 2.1
Version Date: 9 Feb 2024.
Version changes: Updated to use new DSA Regulation Template and addition of accountable person definition

Version 3.0
Version Date: 24 Feb 2025.
Version changes: incorporation of Autism Training, Volunteers and Visitors post H&SCA amendments

Version 4.0
Version Date: 11 Mar 2025.
Version changes: incorporation of 1000 series Registration regulations

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DMSR's Safety Message

The regulations set out in this document are the minimum standards to be adopted for Healthcare Safety; they are mandatory and full compliance is required. It is the responsibility of those planning, managing, supporting or undertaking activity within the scope of these regulations to ensure that personnel, including contractors, involved in the conduct of Defence activities are fully aware of their responsibilities.

The DMSR team is committed to enhancing the safe delivery of medical capability and the continuous improvement of the DMSR through a focus on improved safety and quality management. Key to this is the continued development of a widespread engaged safety culture.

To enable the DMSR's vision "to grow the DMSR, as the independent regulator, to being recognised as integral to effective Defence medical capability, providing essential safety oversight of Defence delivered healthcare. Where DMSR interventions are embraced as opportunities to cultivate safety and performance, enhanced by increased transparency, inclusion and just accountability," we must continue to engage with the Regulated Community and other regulatory bodies to ensure that our regulatory activity remains effective, relevant and proportional.

Air Cdre Bradley
Head Defence Medical Services Regulator
Defence Safety Authority
Feb 2025

Contents

Chapter 1

DMSR's Regulation Policy Overview

Authority

1. The MOD has a duty to protect its employees, other personnel and the environment, from the effects of its activities. Effective management of Health, Safety and Environment matters is crucial to force protection and maximising operational capability. The MOD's commitment to Health, Safety and Environment is set within the Secretary of State (SofS) for Defence policy statement.

2. On behalf the SofS for Defence, the DSA is established through the DSA Charter, empowering it as an independent regulator, investigator and assurer for Health, Safety and Environmental Protection within Defence. In accordance with the DSA Charter and letter of delegation from DG DSA, Hd DMSR has been authorised to regulate healthcare activity across Defence where there are Disapplications, Exemptions or Derogations (DEDs) from statutory requirements, or where there is no statutory requirement or where assurance of specific hazardous activities is required.

3. The DMSR Regulatory Articles (RAs) provide a framework for ensuring that acceptable levels of healthcare safety are being achieved and maintained. The DMSR RA are intended for all those engaged in healthcare activities, including support, facilitation, assurance, management and leadership of healthcare.

4. These RAs apply to all staff responsible for delivery of Defence healthcare services worldwide, including all members of the Armed Forces, Civilian employees and others, including contractors.

5. These regulations do not replace legislative obligations and full reference is to be made to national and international regulation and legislation; and, where applicable, Host Nation (HN) requirements.

6. Defence Regulations and UK legislation are to be compared with the HN requirements and the more stringent standards are to be applied.

Citation

7. These regulations shall be referred to as DMSR RAs.

Interpretation

8. The key definitions that apply to the implementation of Defence Healthcare Regulations:

   a. **Must.** Describes an action that is mandatory in order to comply with UK legislation.

   b. **Shall.** Describes an action that is mandatory in order to comply with Defence regulations.

c. **Should.** Describes an action that is not a compulsory requirement but is considered best practice to comply with regulation. However, alternative approaches will be considered.

d. **As Low As Reasonably Practicable (ALARP).** A risk is ALARP when it has been demonstrated that the cost of any further Risk Reduction, where the cost includes the loss of Defence capability as well as financial or other resource costs, is grossly disproportionate to the benefit obtained from that risk reduction.

e. **Patient.** A person who receives Defence healthcare services.

f. **Relevant Person.** A person using a Defence healthcare service and/or any person lawfully acting on their behalf in the following circumstances:

(1) When the patient dies.

(2) Where the patient is under 16 and not competent to make a decision in relation to their care or treatment.

(3) Where the patient is 16 or over and lacks capacity to make decisions.

Examples of relevant persons include, but are not limited to, the patient, spouse, parents, guardians, carers, Next of Kin, 'Power of Attorney' holders and healthcare providers.

g. **Medical Services.** Any part of the system designed to deliver MOD healthcare capability, where the output and the activity is not more appropriately regulated by a Statutory Regulator or another Defence Regulator. This includes:

(1) Medical materiel, medical infrastructure, medicines and medical information systems.

(2) People as an element of the healthcare system function.

(3) Management and assurance of healthcare.

The determination of whether a medical system primarily impacts on another Regulator should be discussed and agreed with the relevant domain regulator.

h. **Registered Activities**. Healthcare services delivered by Defence.

i. **Provider.** An accountable organisation that carries out Defence healthcare activities. The Provider will include the four levels of Responsible Person who are registered with the DMSR.

j. **Responsible Persons (RP).** In the context of Defence Healthcare Regulations, the RPs are responsible for compliance with statute and Defence regulations. This includes a duty of care for all people, including contractors and members of the public, who come within their AoR. This duty of care extends to environmental protection not just within their AoR, but also for other areas affected by activities in their AoR. All RPs are accountable for ensuring that safety risks from activities are reduced to a level that is ALARP and tolerable, and that risks to the environment are appropriately managed. The defined responsibilities of the RP should be identified within TORs. Defence Healthcare Regulations recognises four levels of RP which, are defined as follows:

(1) **Level 1.** This function relates to the senior responsible appointment within either the Top Level Budget (TLB) or Higher Level Budget (HLB) organisation which carries out Defence delivered healthcare activities (e.g. Commander Defence Primary Healthcare).

(2) **Level 2.** This function relates to the responsible appointment within the TLB/HLB organisation. They are subordinate to the Level 1 RP but have command responsibility for the Level 3 RP (e.g. Regional Clinical Director).

(3) **Level 3.** This function relates to the senior appointment at Unit/Facility level and is responsible for the functional delivery of healthcare (e.g. Senior Medical Officer).

(4) **Level 4.** This function relates to a recognised appointment at Unit/Facility level and is responsible to the Level 3 RP (e.g. Practice Manager).

k. **Accountable Person (AP).**[1] Enforcement Action (EA) should be directed to an individual who is to be held accountable to the Regulator for reducing risk of harm and, where applicable, those responsible for complying with Defence Regulations. This person is referred to as the AP. The AP should hold the authority and resource to carry out any improvements required. The AP may also be the RP.

Enforcement Action

9. Failure to comply with any regulation set out in this regulatory document may result in enforcement action which may be applied incrementally. The full DMSR Enforcement Policy can be found in DMSR Guide - Corrective Action and Enforcement.[2] The DMSR spectrum of action is listed below:

a. Advice and Guidance.

b. Corrective Action Requirements (CARs).

c. DMSR Enforcement Notices.

(1) Improvement Notice (IN).

(2) Urgent Improvement Notice (UIN).

(3) Prohibit Notice (PN).

10. The Appeals process is detailed in DMSR Guide - Corrective Action and Enforcement[3].

11. **Operational Imperative**. Where the Regulator has issued a PN, or the Duty Holder has identified that they are unable to deliver the required operational effect in a compliant manner, it may not be appropriate for the activity to cease immediately if there is an operational imperative. However, the following shall be considered:

[1] JSP815_Vol2_Element5.pdf (sharepoint.com) Accountable Person pg6. Dated Sep 24.
[2] Defence Intranet link only.
[3] Defence Intranet link only.

a. Where it is judged that the operational benefits gained from a specific operational act outweigh the high risks to patients and healthcare staff safety which cannot be mitigated to ALARP and tolerable, an operational commander[4] may decide to continue with the activity. In arriving at such a decision, where time and security constraints permit, the assessment of the risk, its mitigation and justification of the benefits should be made in written consultation with the appropriate RP or AP, Duty Holder (DH) where relevant, and discussion with the Hd DMSR.

b. It might also be appropriate for a DH, when preparing force elements for a specific operation, to make such a judgement. This judgement should be made in discussion with the Hd DMSR and future operational commander to ascertain whether the output of the force preparation activity is essential to the operational capability required for that specific operation, and to consider alternative means of delivering that operational capability.

Regulatory Waivers and Exemptions

12. There may be occasions when the regulated community is unable to comply with DMSR regulations. In such circumstances, a regulatory waiver or exemption may be applied for to grant a temporary waiver or enduring exemption, from extant Regulations. When granting a waiver or exemption, the Regulator needs to be satisfied that any risk associated with non-compliance has been fully considered by the DH or AP as appropriate. When the need for a regulatory waiver or exemption is identified, the case is to be developed and submitted in accordance with the procedures detailed in DMSR SOP 2.[5]

How to use this Defence Regulatory Publication

13. The DSA02.DMSR sets out the Defence Medical Regulations. They are designed to be used by staff responsible for medical services.

14. Guidance for the regulated community can be found in DSA03.DMSR – Defence Codes of Practice (DCOP) for Healthcare.

15. Due to the enabling nature of Defence healthcare activity, full consideration shall be given to other relevant Defence regulations. An example of this is the requirements of DSA02 Defence Land Safety Regulator Regulations when storing medical gases.

Coherence with other Defence Authority Policy and Guidance

16. These Regulations should be read with reference to the following documents:

a. JSP 815: Defence Safety Management System, which provides a framework for defence organisations' safety management systems (SMS) and contains two volumes; Volume 1: Defence SMS Framework and Volume 2: Defence SMS Direction and Guidance.

b. JSP 816: Defence Environmental Management System: Defence Environmental Management System, which contains two volumes; Volume 1: Defence EMS Framework and Volume 2: Defence EMS Direction and Guidance.

[4] As authorised in a CDS Operational Directive.
[5] Defence Intranet link only.

c. DSA 01.1 - Regulations, which explains how the DSA sets regulations.

d. DSA 01.2 - Assurance, which explains how the DSA conducts assurance.

e. DSA 01.3 - Enforcement, which explains how the DSA conducts enforcement against regulations.

f. DSA 01.4 - Investigations, which explains how the DSA conducts safety inquiries.

g. DSA 01.5 – Analysis, which explains how the DSA conducts analysis.

17. Where applicable, DSA02.DMSR and DSA03.DMSR contain links to relevant JSPs and regulatory documents, some of which may be published by different Defence Authorities.

Further Advice and Feedback - Contacts

18. For further information on any aspect of this document, areas not addressed within the subsequent sections, or to provide feedback (including proposed amendments on the content), contact DMSR's regulation and compliance team:

Email: DSA-DMSR-Gp@mod.gov.uk

Disclaimer

19. Nothing contained in the DMSR suite of publications removes the requirement for personnel to comply with all applicable legislation, other Defence Regulations, Defence Policy or the SofS policy statement.

20. This regulatory document is **not** intended to:

a. Address hazards associated with enemy or hostile action.

b. Address the requirements to put in place safe systems of work to manage residual risk in the workplace - that is managed in accordance with Joint Service Publications and TLB procedures.

c. Address Sustainable Development (SD). SD is important in protecting the environment, but it is not governed by the environmental protection elements of this regulatory document.

d. Be used for contracting purposes in its own right. Contracting for safety is to be in accordance with Defence Standards; however, specific Defence Regulations could be included within contracts as appropriate.

Chapter 2

Regulatory Articles Index

DMSR Regulatory Article 1001 Command Intent, Direction and Compliance

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act. This disapplication results in the Care Quality Commission (Registration) Regulations 2009 being inapplicable to Defence.

Command Intent, Direction and Compliance

1. The identified Level 1 Responsible Person (RP) shall have processes to demonstrate their command intent and direction[1] to safely deliver Defence healthcare in accordance with these regulations. This shall contain:

a. the intent of the Provider in carrying out the activity;

b. the list of all healthcare services provided and the range of patients' needs which those services are intended to meet. These will be known as 'registered activities';

c. the organisational structure to which the capability is aligned and any appropriate dependencies;[2]

d. the operating status of the capability;[3] and,

e. an assessment that the capability is safe to deliver the registered activities and is compliant with Defence Healthcare Regulations and applicable legislation.[4]

For further guidance see DSA03.DMSR DCOP 1001

[1] Op Order, Op Directive or statement from the Responsible Person to provide chain of command intent and direction on how services are to be delivered by the organisation.
[2] Dependencies may be defined as (but not limited to) Service Level Agreements, Memorandums of Understanding, Joint Business Agreements or Operational Orders.
[3] Operating state e.g. open/closed/combined/networked, or readiness state/deployed.
[4] Through the organisational identified first and second Lines of Defence (1LOD and 2LOD) processes.

DMSR Regulatory Article 1002 Requirements of Responsible Person

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act. This disapplication results in the Care Quality Commission (Registration) Regulations 2009 being inapplicable to Defence.

Requirements of Responsible Person (RP)

1. The RP shall:

   a. be issued Terms of Reference which should include: job specification, responsibility and accountability, SQEP requirements, risk management responsibility, governance and assurance structures;

   b. be able to properly perform tasks that are intrinsic to their role; and,

   c. have the necessary skills, qualifications, experience and competence to carry out the registered activities or supervise their management.

For further guidance see DSA03.DMSR DCOP 1002

DMSR Regulatory Article 1003 Management of Change

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act. This disapplication results in the Care Quality Commission (Registration) Regulations 2009 being inapplicable to Defence.

Management of Change

1. The Provider shall have a system in place to identify, record, and manage change/s in order to maintain safety including when:

a. the Responsible Person (RP) changes;

b. any absences of 28 days or more of an RP, and how the registered activities will be managed during their absence;

c. there is a change to the registered activities of the service;

d. there is a change to the registered details of the service;

e. there is a change to the operating status of the capability; and,

f. there is a change to the assurance grading/validation status which adversely affects the capability to operate safely.

For further guidance see DSA03.DMSR DCOP 1003

DMSR Regulatory Article 1004 Notification of Incidents

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act. This disapplication results in the Care Quality Commission (Registration) Regulations 2009 being inapplicable to Defence.

Notification of Incidents

1. The Provider shall have systems in place to immediately report the incidents specified below as they occur during the provision of healthcare services, or as a consequence of the carrying out a healthcare activity. The report should be made using the specified reporting tool indicated below:

a. through the Automated Significant Event Reporting (ASER) system using a Sentinel Report and to the Defence Accident Investigation Branch (DAIB) all Service deaths;

b. through the ASER system using a Sentinel Report to the DAIB in the event of the death of a non-serving patient or member of staff;

c. through the ASER system any unauthorised absence of a person in any location who is liable to be detained under the Mental Health Act 1983;

d. through the ASER system and report to DAIB any injury to a patient which, in the reasonable opinion of a health care professional, has resulted in (or may result in):

(1) an impairment of the sensory, motor or intellectual functions of the patient which is not likely to be temporary;

(2) changes to the structure of a patient's body;

(3) the patient experiencing prolonged pain or prolonged psychological harm; or,

(4) the shortening of the life expectancy of the patient.

e. through the ASER system any injury to a patient which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent:

(1) the death of the patient; or

(2) an injury to the patient which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph d.

f. through the ASER system and Safeguarding system any abuse or allegation of abuse in relation to a patient;

g. through Reporting of Injuries, Diseases and Dangerous Occurrences Regulations and the ASER system any incident which is reported to, or investigated by, the police;

h. through the ASER system any occupational duty of care events; and,

i. through the ASER system any event which prevents, or threatens to prevent, the ability to continue to carry on the registered activity safely, including:

(1) an insufficient number of suitably qualified and experienced persons available for the purposes of carrying on the regulated activity;

(2) an interruption in the supply to premises owned or used by the service provider for the purposes of carrying out the regulated activity. This could include MedIS connectivity, electricity, gas, water or sewerage where that interruption has lasted for longer than a continuous period of 24 hours;

(3) physical damage to premises owned or used by the service provider for the purposes of carrying on the regulated activity which has, or is likely to have, a detrimental effect on the treatment or care provided to patients;

(4) the failure, or malfunctioning, of fire alarms or other safety devices in premises owned or used by the service provider for the purposes of carrying on the regulated activity where that failure or malfunctioning has lasted for longer than a continuous period of 24 hours; and,

(5) any placement of a service-user under the age of eighteen in a psychiatric unit whose services are intended for persons over that age where that placement has lasted for longer than a continuous period of 48 hours.

2. The Provider shall report to DMSR without delay any issue of a Regulation 28 under the Coroners and Justice Act 2009 regarding the provision of healthcare services, or as a consequence of the carrying on of a healthcare activity.

3. Using the Sentinel Report, the Provider shall report without delay any ‘Never Event’. See DCOP 1004 for a list of Never Events.

4. For the purposes of this regulation “abuse” in relation to patients means:

a. sexual abuse;

b. physical or psychological ill treatment;

c. theft, misuse or misappropriation of money or property, or;

d. neglect and acts of omission which cause harm or place at risk of harm.

5. For the purposes of this regulation:

   a. “prolonged pain" and "prolonged psychological harm" means pain or harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days, and;

6. a sensory, motor or intellectual impairment is not temporary if such an impairment has lasted, or is likely to last, for a continuous period of at least 28 days.

For further guidance see DSA03.DMSR DCOP 1004

DMSR Regulatory Article 2001 Person Centred Care

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Person Centred Care

1. The care and treatment of patients shall:

    a. be appropriate;

    b. meet their needs; and,

    c. reflect their preferences.

2. But paragraph 1 does not apply to the extent that the provision of care or treatment would result in a breach of DSA02 DMSR Regulation 2003 (need for consent).

3. Without limiting paragraph 1, the things which a provider shall do to comply with that paragraph include:

    a. carrying out, collaboratively with the relevant person, an assessment of the needs and preferences for care and treatment of the patient;

    b. designing care or treatment with a view to achieving patients' preferences and ensuring their needs are met;

    c. enabling and supporting relevant persons to understand the care or treatment choices available to the patient and to discuss, with a competent health care professional or other competent person, the balance of risks and benefits involved in any particular course of treatment;

    d. enabling and supporting relevant persons to make, or participate in making, decisions relating to the patient's care or treatment to the maximum extent possible;

    e. providing opportunities for relevant persons to manage the patient's care or treatment;

    f. involving relevant persons in decisions relating to the way in which the regulated activity is carried on in so far as it relates to the patient's care or treatment;

    g. providing relevant persons with the information they would reasonably need for the purposes of sub-paragraphs 3c to f;

    h. where meeting a patient's nutritional and hydration needs, having regard to the patient's well-being; and,

i. align visitation and accompanianment for Defence delivered secondary healthcare with Defence compassionate policy.

4. Paragraphs 1 and 3 apply subject to paragraphs 5 and 6.

5. If the patient is 16 or over and lacks capacity in relation to a matter to which this regulation applies, paragraphs 1 to 3 are subject to any duty on the Provider under the Mental Capacity Act 2005 in relation to that matter.

6. But if Part 4 or 4A of the Mental Health Act 1983 (2007) applies to a patient, care and treatment must be provided in accordance with the provisions of that Act.

For further guidance see DSA03.DMSR DCOP 2001

DMSR Regulatory Article 2002 Dignity and Respect

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Dignity and Respect

1. Patients shall be treated with dignity and respect.

2. Without limiting paragraph 1, the things which a provider is required to do to comply with paragraph 1 include:

a. ensuring the privacy of the patient;

b. supporting the autonomy, independence and involvement in the community of the patient; and,

c. having due regard to any relevant protected characteristics (as defined in section 149(7) of the Equality Act 2010) of the patient.

For further guidance see DSA03.DMSR DCOP 2002

DMSR Regulatory Article 2003 Need for Consent

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Need for Consent

1. Care and treatment of patients shall only be provided with the consent of the relevant person.

2. Paragraph 1 is subject to paragraphs 3 and 4.

3. If the patient is 16 or over and is unable to give such consent because they lack capacity to do so, the Provider must act in accordance with the Mental Capacity Act 2005.

4. But if Part 4 or 4A of the Mental Health Act 1983 (2007) applies to a patient, care and treatment must be provided in accordance with the provisions of that Act.

5. The Responsible Person must make sure that staff who obtain the consent of patients are familiar with the principles and codes of conduct associated with the Mental Capacity Act 2005, and are able to apply those when appropriate, for any of the patients they are caring for.

For further guidance see DSA03.DMSR DCOP 2003

DMSR Regulatory Article 2004 Safeguarding

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Safeguarding

1. Patients shall be protected from abuse and improper treatment in accordance with this regulation.

2. Systems and processes shall be established and operated effectively to prevent abuse of patients.

3. Systems and processes shall be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse.

4. Care or treatment for patients shall not be provided in a way that:

   a. includes discrimination against a patient on grounds of any protected characteristic (as defined in section 4 of the Equality Act 2010) of the patient;

   b. includes acts intended to control or restrain a patient that are not necessary to prevent, or not a proportionate response to, a risk of harm posed to the patient or another individual if the patient was not subject to control or restraint;

   c. is degrading for the patient; or,

   d. significantly disregards the needs of the patient for care or treatment.

5. A patient shall not be deprived of their liberty for the purpose of receiving care or treatment without lawful authority.

6. For the purposes of this regulation “abuse” means:

   a. any behaviour towards a patient that is an offence under the Sexual Offences Act 2003;

   b. ill-treatment (whether of a physical or psychological nature) of a patient;

   c. theft, misuse or misappropriation of money or property belonging to a patient; or,

   d. neglect of a patient.

7. For the purposes of this regulation, a person controls or restrains a patient if that person:

   a. uses, or threatens to use, force to secure the doing of an act which the patient resists; or,

b. restricts the patient's liberty of movement, whether or not the patient resists, including by use of physical, mechanical or chemical means.

For further guidance see DSA03.DMSR DCOP 2004

DMSR Regulatory Article 2005 Meeting Nutrition and Hydration Needs

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Meeting Nutrition and Hydration Needs

1. The nutritional and hydration needs of patients shall be met.

2. Paragraph 1 applies where:

    a. care or treatment involves:

        (1) the provision of accommodation by the Provider; or,

        (2) an overnight stay for the patient on premises used by the service for the purposes of carrying on a regulated activity; or,

    b. the meeting of the nutritional or hydration needs of patients is part of the arrangements made for the provision of care or treatment by the Provider.

3. But paragraph 1 does not apply to the extent that the meeting of such nutritional or hydration needs would:

    a. result in a breach of DSA02-DMSR regulation 2003, (need for consent); or,

    b. not be in the patient's best interests.

4. For the purposes of paragraph 1, “nutritional and hydration needs” means:

    a. receipt by a patient of suitable and nutritious food and hydration which is adequate to sustain life and good health;

    b. receipt by a patient of parenteral nutrition and dietary supplements when prescribed by a health care professional;

    c. the meeting of any reasonable requirements of a patient for food and hydration arising from the patient's preferences or their religious or cultural background; and,

    d. if necessary, support for a patient to eat or drink.

For further guidance see DSA03.DMSR DCOP 2005

DMSR Regulatory Article 2006 Receiving and Acting on Complaints

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Receiving and Acting on Complaints

1. Any complaint received shall be investigated, and necessary and proportionate action shall be taken in response to any failure identified by the complaint or investigation.

2. The Provider shall establish and operate effectively an accessible system for identifying, receiving, recording, handling and responding to complaints by patients and other persons in relation to the carrying on of the regulated activity.

For further guidance see DSA03.DMSR DCOP 2006

DMSR Regulatory Article 2007 Fit and Proper Persons Employed

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act. Note that Hd DMSR has reviewed amendment No.2 2023 (Volunteers) to this act and has assessed that it is not applicable to Defence healthcare. The requirement for checks of employment history shall remain in accordance with extant Defence security policy.

Fit and Proper Person Employed

1. Persons employed for the purposes of delivering Defence healthcare shall:

    a. be of good character;

    b. have the qualifications, competence, skills and experience which are necessary for the work to be performed by them; and,

    c. be able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the work for which they are employed.

2. Recruitment procedures shall be established and operated effectively to ensure that persons employed meet the conditions in paragraph 1.

3. Persons employed shall be registered with the relevant professional body where such registration is required by, or under, any enactment in relation to:

    a. the work that the person is to perform; or,

    b. the title that the person takes or uses.

4. Where a person employed by Defence no longer meets the criteria in paragraph 1, the Chain of Command shall:

    a. take such action as is necessary and proportionate to ensure that the requirement in that paragraph is complied with; and,

    b. if the person is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question.

For further guidance see DSA03.DMSR DCOP 2007

DMSR Regulatory Article 2008 Duty of Candour

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Duty of Candour

1. Personnel delivering Defence healthcare shall act in an open and transparent way with relevant persons in relation to care and treatment provided to patients in carrying on a regulated activity.

2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred the Provider shall:

   a. notify the relevant person that the incident has occurred in accordance with paragraph 3; and,

   b. provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

3. The notification to be given under paragraph 2a shall:

   a. be given in person by one or more representatives of the Provider;

   b. provide an account, which to the best of the Provider's knowledge is true, of all the facts the Provider knows about the incident as at the date of the notification;

   c. advise the relevant person what further enquiries into the incident the Provider believes are appropriate;

   d. include an apology; and,

   e. be recorded in a written record which is kept securely by the Provider.

4. The notification given under paragraph 2a shall be followed by a written notification given or sent to the relevant person containing:

   a. the information provided under paragraph 3b;

   b. details of any enquiries to be undertaken in accordance with paragraph 3c;

   c. the results of any further enquiries into the incident; and,

   d. an apology.

5. But if the relevant person cannot be contacted in person or declines to speak to the representative of the Provider:

   a. paragraphs 2 to 4 are not to apply, and

b. a written record is to be kept of attempts to contact or to speak to the relevant person.

6. The Provider shall keep a copy of all correspondence with the relevant person under paragraph 4.

7. In this regulation:

"apology" means an expression of sorrow or regret in respect of a notifiable safety incident;

"moderate harm" means:

a. harm that requires a moderate increase in treatment; and,

b. significant, but not permanent, harm;

"moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

"prolonged pain" means pain which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days;

"prolonged psychological harm" means psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days;

"severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the patient's illness or underlying condition.

8. In relation to a health service body, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a patient during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in:

a. the death of the patient, where the death relates directly to the incident rather than to the natural course of the patient's illness or underlying condition; or,

b. severe harm, moderate harm or prolonged psychological harm to the patient.

9. In relation to any other provider, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a patient during the provision of a regulated activity that, in the reasonable opinion of a health care professional:

a. appears to have resulted in:

(1) the death of the patient, where the death relates directly to the incident rather than to the natural course of the patient's illness or underlying condition;

(2) an impairment of the sensory, motor or intellectual functions of the patient which has lasted, or is likely to last, for a continuous period of at least 28 days;

(3) changes to the structure of the patient's body;

(4) the patient experiencing prolonged pain or prolonged psychological harm; or,

(5) the shortening of the life expectancy of the patient; or,

b. requires treatment by a health care professional in order to prevent:

(1) the death of the patient, or

(2) any injury to the patient which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph 9a.

For further guidance see DSA03.DMSR DCOP 2008

DMSR Regulatory Article 3001 Safe Care and Treatment

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Safe Care and Treatment

1. Care and treatment shall be provided in a safe way for patients.

2. Without limiting paragraph 1, the things which a provider shall do to comply with that paragraph include:

a. assessing the risks to the health and safety of: staff delivering care or treatment; and patients receiving care or treatment;

b. doing all that is reasonably practicable to mitigate any such risks;

c. ensuring that persons providing care or treatment to patients have the qualifications, competence, skills and experience to do so safely;

d. ensuring that the premises used by the Provider are safe to use for their intended purpose and are used in a safe way;

e. ensuring that the equipment used by the Provider for providing care or treatment to a patient is safe for such use and is used in a safe way;

f. where equipment or medicines are supplied by the Provider, ensuring that there are sufficient quantities of these to ensure the safety of patients and to meet their needs;

g. the proper and safe management of medicines;

h. assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated; and,

i. where responsibility for the care and treatment of patients is shared with, or transferred to, other persons, working with such other persons, patients and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the patients.

For further guidance see DSA03.DMSR DCOP 3001

DMSR Regulatory Article 3002 Good Governance

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Good Governance

1. Systems or processes shall be established and operated effectively to ensure compliance with the requirements in this Part.

2. Without limiting paragraph 1, such systems or processes shall enable the Provider, in particular, to:

a. assess, monitor and improve the quality and safety of the services provided (including the quality of the experience of patients);

b. assess, monitor and mitigate the risks relating to the health, safety and welfare of patients, staff and others who may be at risk which arise from the carrying on of the regulated activity;

c. maintain securely an accurate, complete and contemporaneous record in respect of each patient, including a record of the care and treatment provided to the patient and of decisions taken in relation to the care and treatment provided;

d. maintain securely such other records as are necessary to be kept in relation to:

(1) persons employed in the carrying on of the regulated activity, and

(2) the management of the regulated activity.

e. seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services;

f. evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs 2a to e.

For further guidance see DSA03.DMSR DCOP 3002

DMSR Regulatory Article 3003 Staffing

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Staffing

1. Providers shall adequately staff healthcare capabilities with suitably qualified and experienced personnel to enable them to meet the care and treatment needs of patients and the other regulatory requirements.

2. Staff involved in the provision of a regulated activity shall:

   a. receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform;

   b. be enabled where appropriate to obtain further qualifications appropriate to the work they perform; and,

   c. where such persons are health care professionals, social workers or other professionals registered with a health care or social care regulator, be enabled to provide evidence to the regulator in question demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise or a requirement of their role.

For further guidance see DSA03.DMSR DCOP 3003

DMSR Regulatory Article 4001 Premises and Equipment

Provenance

Regulation required due to Defence disapplication from the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See Schedule 2 para 10 of Act.

Premises and Equipment

1. All premises and equipment used by the service provider shall be:

    a. clean;

    b. secure;

    c. suitable for the purpose for which they are being used;

    d. properly used;

    e. properly maintained; and,

    f. appropriately located for the purpose for which they are being used.

2. The Provider shall, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used.

For further guidance see DSA03.DMSR DCOP 4001