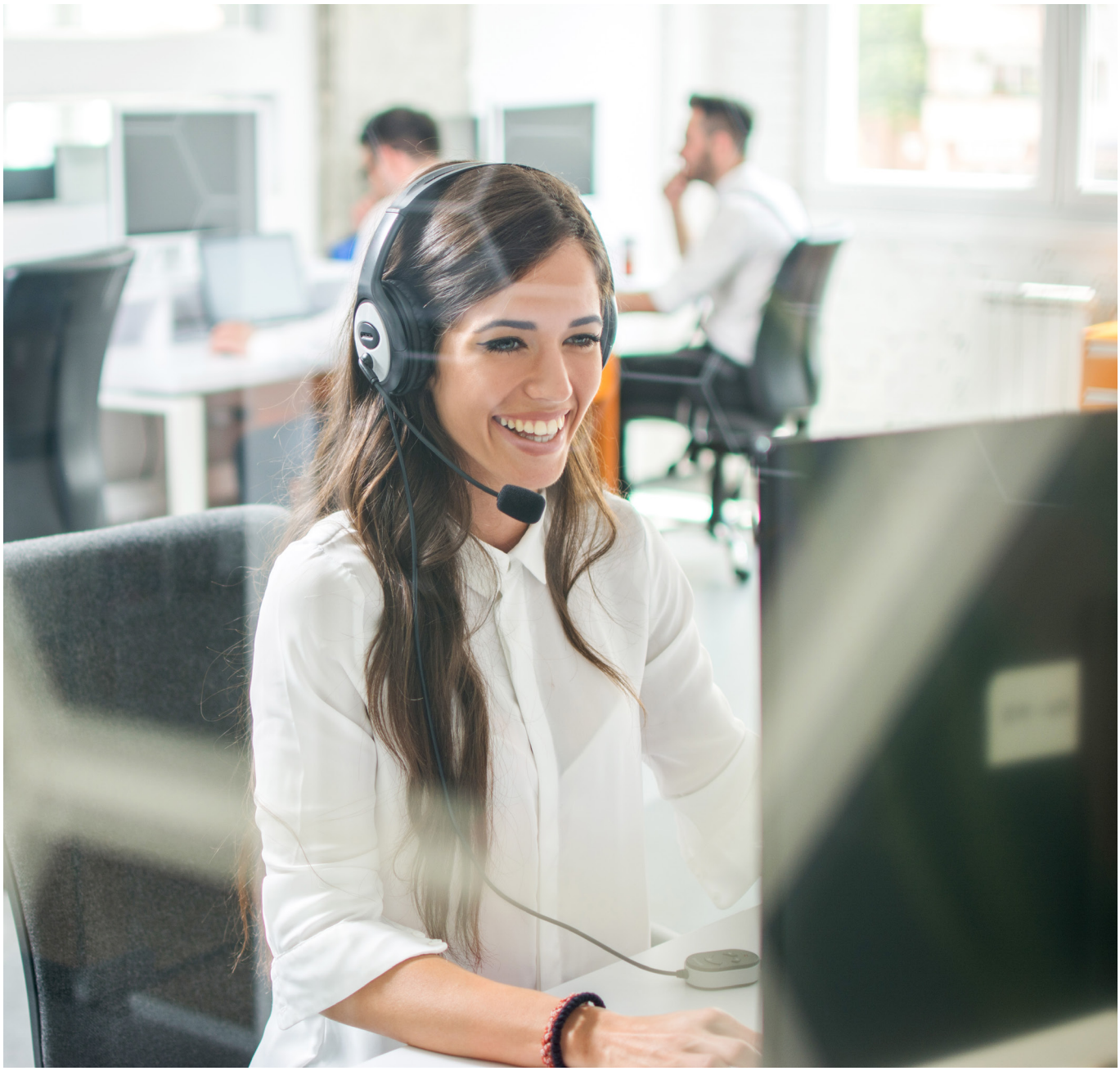
UTA | UROLOGY TRADE ASSOCIATION

SIACA CHOICE ASSURED

BHTA British Healthcare Trades Association

Dispensing Appliance Contractors – DAC Code of Ethical Business Practice



Contents

Introduction

Dispensing Appliance Contractors (DACs) are an integral part of the Health Service across the UK providing Part IX Drug Tariff products, stoma, continence, laryngectomy appliances and wound care dressings, and services to approximately 375,000 patients with long-term conditions.

This code sets out the minimum standards appropriate to the various services carried out by the members of the BHTA, SIACA and UTA. This code is not intended to replace national regulations, laws, or current Codes of Practice, whether they be from trade associations or individual companies rather it aims to strengthen them and as a result encourage industry-wide best practice and an ethical approach to appliance dispensing.

Member companies should ensure that if any third-party organisations are contracted, they are responsible for ensuring their adherence to this code and such members will be liable for the activities of their contractors.

The following regulations[1] are in place for Dispensing Appliance Contractors and all companies should abide by these regulations:

- The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 with particular reference to Schedule 5 terms of service and the clinical governance requirements with these regulations.
- The NHS Conflicts of Interest Guidance 2017.
- Specification of requirements for Dispensing and Supply of stoma appliances to patients in the community for NHS Scotland.
- The NHS (Pharmaceutical Services) (Scotland) Regulations 2009.
- National Health Service (Pharmaceutical Services) (Wales) Regulations 2020; and
- Pharmaceutical Services Regulations (Northern Ireland) 1997.

If a Dispensing Appliance Contractor also employs specialist nurses[2], the following codes apply:

- Nursing and Midwifery Council: The Code (https://www.nmc.org.uk/standards/code/)

All member organisations should follow national and international legislation that are in place, some of which are highlighted below for reference:

- Medical devices and supply regulations.
- Data Protection laws.
- Anti-corruption laws.
- Competition and Markets law.
- Environmental Health and Safety laws; and
- Advertising and Promotion laws.

1. Government regulations may change at any time, and you should refer to the regulatory frameworks.

2. As defined by the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, a "specialist nurse" means a person who is—
   (a) registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(f) (establishment and maintenance of register); and
   (b) employed or engaged by any pharmacy contractor or appliance contractor for the purposes of conducting a review of a person's use of specified appliances

Aims and principles

To maintain a consistent approach, by all member companies, ensuring patient centred care and the best patient experience is the purpose and outcome of all the services and activities DACs provide.

To partner with the relevant health care organisations, across all four nations, with the aim of improving communications between the contractor and the relevant healthcare professional or organisation to ensure value for money for the NHS.

To uphold the integrity of Dispensing Appliance Contractors who are named on the pharmaceutical list to provide high quality and compliant services to patients and their regulators and not to bring the industry into disrepute.

To follow prescribing guidelines as published by the PIPs forum and PrescQIPP and, when required, to highlight potential outliers and signpost the patient, with their consent, to an NHS Clinician or their prescriber.

Ensure all conflicts of interest are mitigated no matter what the DAC business structure is to ensure all services are in the best interest of the patient.

Benefits DACs deliver to patients

DACs provide many services to patients that are not included within the scope of the regulations. These additional services often result in improved patient experiences and underpin the strong collaborative links between DACs and the NHS, on whose behalf they provide services. Some examples of these services are detailed below:

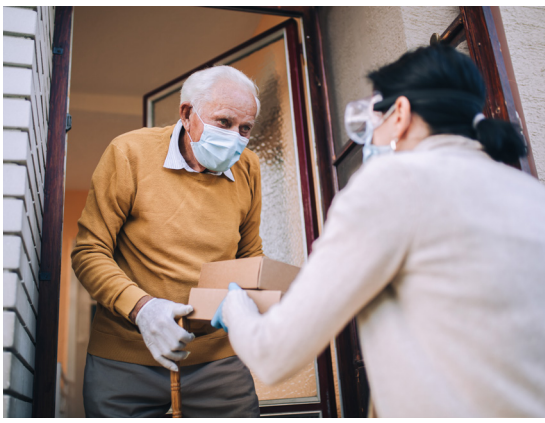
DAC/clinician collaboration
When a DAC interaction with a patient highlights a potential need to change a product to improve a patient's health and to enhance the patient's quality of life, the DAC will contact the patient's specialist nurse[3], if known, or their GP, and request approval to change the patient's product. There are over 375,000 stoma, continence and laryngectomy long-term patients and they are not all seen by or even know their specialist nurse, so the DAC can be a support bridge for patients in the community.

Patient support
DAC staff are available for patients to call, even if the subject matter is not about their next appliance prescription. DAC staff are a source of information for the patient, when required, and can ascertain when a patient is struggling to manage their condition or have other wellbeing challenges.

The DAC staff can contact the patient's GP or clinician, after getting consent, and explain their concerns. Signposting, such as this, allows other NHS services to be involved in the patient's care and potentially prevent hospital admissions or address other mental or physical health issues. Signposting to patient associations and other organisations is used in order to support the patient with their quality of life and ongoing interaction with patient communities.

Wellbeing information
DACs also provide literature on diet, travel, lifestyle, relationships, and other related topics to their patients to enhance their patients' quality of life. DACs also signpost patients to other Patient associations for additional and on-going support information.

The various patient organisations and the NHS, where the patient either is a member of such an organisation or is in touch with their specialist nurses, can also provide this information but DACs are an easy way to access the lifestyle information if the patient has no other contact information.



Product supply
DACs have provided an effective and reliable service to the NHS and patients for over 40 years. They provide home delivery of appliances to 99.9% of their patients, on average 500,000 prescriptions are dispensed each month as well as other bespoke services are provided such as stoma product customisation.

At the height of the Covid pandemic in 2020, the DAC organisations, across the UK, maintained their consistently high-quality customer service to all their patients and maintained high levels of deliveries, on time and in full, to patients at home. This resulted in patients, many of whom were shielding, not having to risk being exposed to the virus by leaving their homes to collect their prescriptions.

3. A specialist nurse is a company or NHS nurse who is registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(f) (establishment and maintenance of register).

The details of the Code of Ethical Business Practice

Principles	Clarification points

1. BHTA, SIACA and UTA Members

All BHTA, SIACA and UTA Members will adhere to NHS Pharmaceutical Regulations 2013. In particular all clinical governance elements will be enforced including reporting fitness to practice documentation, having a robust complaints process in place, and ensuring any dispensing errors are investigated through a Corrective Action Preventative Action (CAPA) process.

2. Appliance Use Reviews

An AUR can be a valuable service by which inappropriate usage can be managed. AURs should therefore only be performed where they are in the patient's best interest.

All AURs will be carried out in accordance with the regulations (see appendix):

- At either the pharmacy, the DACs registered premises, at a place the patient calls home or by telephone or video link.
- By a DAC specialist nurse registered with the NHS to provide AURs or a pharmacist
- All required organisations will be informed of the AUR taking place, and advising them of the outcome is considered to be good practice

AURs will be provided for the benefit of the patient to improve their quality of life and with the patients consent. DACs should ensure that the way they offer and perform AURs cannot be characterised as for commercial gain.

A dispensing contractor will offer AURs when they have evidence that the patient's use of appliances is not consistent with the recommendations of PrescQIPP or the PIP's Forum guidelines. These inconsistencies should be documented on the patients care record.

Question 1: Are AURs intended to be used as a means to change a patient's product or service choice?
Answer 1: No, they are to be used only to establish the four key points and the other important directions should be adhered to.

Question 2: Should the dispensing contractor be informed if the patient is on another contractor's service?
Answer 2: Yes, as is the specialist nurse of the patient if known.

Question 3: If a patient presents with a clinical issue i.e., granulomas or a urinary tract infection (UTI), can I perform an AUR?
Answer 3: No, the patient should receive a clinical review, as appropriate to the local pathway. This does not prevent an AUR being carried out after the clinical review, if appropriate.

Question 4: Is an AUR a clinical review?
Answer 4: No, an AUR should only include the elements detailed in the regulations.

Principles	Clarification points
The reasons for, and outcomes of, an AUR will be recorded and provided to any NHS body that wishes to assess the effectiveness of the activity in line with the Enhanced and Advanced NHS Regulations. This outcome data can be used to demonstrate the support DAC's deliver over and above the base terms of service. Where proactive reviews of patient usage are required, by an NHS organisation, a clinical review pathway should be agreed with that body. This will not be exclusive and should not exclude the ability of other dispensers to perform AURs if felt necessary. No incentives should be offered to clinical staff to conduct AUR's or to customer service staff for arranging patients to agree to an AUR.	**Question 5: If I am requested by an NHS body to carry out annual reviews on their patients, can this activity take place?** Answer 5: Yes, you can offer a clinical review, and you should make the appropriate contractual arrangements. Contractors should be mindful of the appropriateness of then offering an AUR. In addition, as per the Advanced and Enhanced services regulations patient consent must be obtained before any type of review takes place.
3. Sampling to patients As NHS dispensers, DACs recognise that appliances are medical devices, prescribed and dispensed on behalf of the NHS, and DACs will ensure that any samples provided to patients reflect this. There may be benefits to some patients in changing the appliance used. In these circumstances, patient sample requests should be referred to a specialist clinician, or the patient's prescriber, for review against the patients' medical history and needs, with the patients' consent. The clinician's or prescriber's approval should be obtained before a sample is sent. DACs must not allow their dispensing databases to be used for proactive product sampling. The patient details should only be used for dispensing the appliance unless the patient has given their consent for any other activity. As previously stated, members should ensure all conflicts of interest are mitigated no matter what the DAC business structure is, to ensure all sampling activities are in the best interest of the patient.	**Question 1: Should samples be sent to patients that have not been requested by the specialist nurse or the patient?** Answer 1: No, samples should not be proactively distributed. **Question 2: If the patient or the DAC does not know a specialist nurse, or the patient does not want the nurse to be contacted, should a sample be sent?** Answer 2: No, the patient's prescriber should be contacted for approval. **Question 3: A manufacturer has approached me to send out samples of their new product, is this activity allowed?** Answer 3: No, the purpose of this code is to ensure that all dispensing is in the best interests of the patient. It is not appropriate for an NHS dispenser to be involved in product sales and marketing activities. **Question 4: If the patient is in critical need of their supplies what should I do?** Answer 4: If there is an emergency requirement, you should utilise the urgent supply arrangements or you can send a small supply of the current products used by the patient while waiting for the prescription.

Principles	Clarification points
	Question 5: I have a patient who is using an incorrect length of leg bag. Can I sample a more appropriate variant of that product? Answer 5: Yes, samples, such as a longer leg pack or smaller pouch, can be supplied if requested by the patient, as long as they are the same brand that the patient is currently using.
4. Product Change To ensure patient outcomes are optimised, DACs will actively monitor their dispensing and highlight to a specialist clinician or the patient's prescriber when a patient in their care raises a concern or highlights a change in their health. The code recognises that there may be times when a patient's health or needs have changed from when they were last reviewed by a specialist clinician. If a patient needs a product change, they will (with the patient's consent) be referred to a specialist clinician or prescriber so that their medical history and needs can be assessed. Patients entrust access to their clinical records to their DAC and access to this record needs to be managed appropriately. This is important for data protection reasons and to respect the clinical nature of the DAC/patient relationship. The Code recommends separate databases should be in place for manufacturer marketing and dispensing activities. Where this is not the case, explicit consent and strict adherence to data protection regulations should be followed. DAC customer service staff should not be incentivised in any way to influence the patient on the type of product they use. If a prescription is received, by the DAC, that is different to the patient's normal request, the DAC should check with the patient that this is what is required, before dispensing the product(s) detailed on the prescription. As previously stated, members should ensure all conflicts of interest are mitigated no matter what the DAC business structure is to ensure all potential product changes, or urgent supply, are in the best interest of the patient.	**Question 1: Where patients are self-caring, what are their options if they want access to a product that better suits their need?** Answer 1: They should go to their specialist nurse if known, or to their prescriber to have this discussion. **Question 2: Should a patient's product be requested to be changed without contacting in the first instance their specialist nurse, if known, or their prescriber?** Answer 2: No. the DAC or the patient must contact the nurse, if known or the prescriber (when the patient does not give consent for the DAC to contact their nurse) if the patient wants to change their product choice. **Question 3: Is removing items from a prescription acceptable?** Answer 3: Yes, as part of the DAC terms of service, the patient should be asked if they require all the items on their last prescription, and if not, they should not be dispensed. **Question 4: If a product has been marked to be discontinued in the Drug Tariff, what should I do?** Answer 4: You should contact the specialist nurse or prescriber and enquire what actions they would like to take to identify a suitable alternative.

Principles	Clarification points
	Question 5: If a product is out of stock what should I do? Answer 5: The patient should be asked when they require their appliances and if stock is available for the requested date the order can be held. In other circumstances the DAC should signpost the patient to at least two other contractors. **Question 6: If a product is marked in the Drug Tariff as not available, what should I do?** Answer 6: You should contact the specialist nurse or the prescriber to discuss an alternative.
5. New Product development Where product testing or development is taking place, this must take place in an ethical controlled way and in a manner reflecting the needs of a product trial, assessment, or feedback survey.	Question 1: Should DACs support manufacturers by informing them of patients who would want to be part of a new product trial, assessment, or feedback survey? **Answer 1: Yes, but only when the patient has given consent to be contacted for this purpose and they should be given the option to opt out at any point of the trial, assessment, or feedback survey.**

Administering the code

Members should engage with their relevant trade association or their NHSEI local team if they need support or guidance.

The secretariats of the BHTA, SIACA and UTA will investigate and adjudicate on all complaints from member companies and external stakeholders. Sanctions, as set out in Schedule 1, below, may be imposed which will be proportionate to the code infringement and will be published in accordance with Schedule 1, below.

It is a duty of all members to report any breaches you suspect of the Code of Ethical Business Practice to the BHTA, SIACA and UTA. All reports will be treated as strictly confidential. The trade associations will actively monitor for breaches to the Code In the spirit of supporting DAC members, driving continuous improvements, and demonstrating best practice to all our stakeholders and patients.

Complaints process

When the association receives notification in writing of a complaint against a Code member, it will consider whether the company:

- has infringed the complainant's legal rights
- has not complied with this Code of Practice

The associations cannot deal with a complaint if:

- the complaint is against a company that is not a Code member
- the complainant has not gone through the relevant company's complaints process and reached stalemate
- the complaint is being, or has been dealt with by a court, an alternative dispute resolution provider, or similar body
- the complaint relates to a point in time prior to the company becoming a Code member

The associations will:

- Request to see all the complainant's documentation to back up their alleged complaint
- Ask the company to report within 7 working days, giving as much evidence as possible

- Look for evidence of any breaches of this Code
- Attempt to settle the dispute by agreement between the two parties within 90 days

If agreement cannot be reached, the complainant has two options:

- To take up their own independent action
- Referral by the associations to the Independent Arbitrator (it should be noted that the Arbitrator's decision, to all intents and purposes, is binding)

Where referral to the Independent Arbitrator is chosen, the associations will pass all the evidence gathered, including copies of all correspondence between the parties and the associations, to the Independent Arbitrator within five working days. At this juncture, either party may make direct representation of further evidence to the Arbitrator.

Independent Arbitrator

The objective of the Arbitrator is to arrive at a conclusion that is fair and reasonable in the circumstances, looking at all the evidence presented by both parties. The Arbitrator is an individual with the technical expertise to investigate the complaint in full. The Arbitrator's initial reaction will be notified to the parties concerned within 21 working days.

The Arbitrator's findings (which may, for example, be that the company is not at fault or that the complainant has a valid complaint) will be issued in writing and will give a summary of the facts, the conclusions, and reasons for reaching them. The Arbitrator's decision is binding on both parties.

Where an identified breach of the Code is minor, the arbitrator will issue a warning and suggest action, if appropriate, to prevent repetition

- take all reasonable steps, including any specified actions, to prevent a recurrence of the breach

Sanctions / Disciplinary Action

All serious, or repeated, breaches of the Code will result in the Code Administrator calling upon the Code member concerned to appear before a Disciplinary Committee which will consist of a panel of 3 people, 1 drawn from the relevant industry sector and 2 from appropriate external organisations.

The nature of the breach will be identified to the Code member in writing, and they will be given the opportunity to offer any evidence in writing in advance of the hearing, which will be on a date arranged/ agreed with the Code member.

The Committee's decision may include one or more of the following:

- no further action be taken
- the Code member be required to undertake a specified course of remedial action (such as re-training of a particular employee)
- the Code member be issued with a formal warning
- suspension, for a stated period, of the Code member from the register of companies signed up to the Code (and hence from the associations)
- expulsion of the Code member from the register of companies signed up to the Code (and hence from the associations)
- Where expulsion occurs, a minimum period of twelve months must pass before any application to re-join the register of companies signed up to the Code, and to re-join the associations, will be considered. If any complaints against the company have been made to the associations during that time, such application may be rejected for a further period of time.

From establishing that a serious breach has occurred through to final decision of the Disciplinary Committee and instigation of any action should take no more than 90 days.

Decision publication

A summary of the decision will be published on the Associations website and NHSE will be informed of the complaint and action taken.

Appendix

1. NHS Pharmaceutical Regulations

Full details can be found here on page 15:
https://www.gov.uk/government/publications/pharmaceutical-services-advanced-and-enhanced-services-england-directions-2013

British Healthcare Trades Association
Office 404 · Tower Bridge Business Centre · 46-48 East Smithfield
London · E1W 1AW
Telephone: 020 7702 2141
Email: bhta@bhta.com
Twitter: @wwwbhta
www.bhta.com

SIACA
Z15 Westpark · Chelston · Wellington · England · TA21 9AD
www.siaca.co.uk

UTA
32 Blackfriars Road · London · SE1 9PB
Telephone: 020 3855 5760
www.urologytradeassociation.com
uta@whitehousecomms.com

APRIL 2023

Dispensing Appliance Contractors
– DAC Code of Ethical Business Practice