

# THE CARE STANDARDS ACT 2000 — IMPLICATIONS FOR COMMUNITY PHARMACISTS

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*In this article the author looks at the Care Standards Act 2000 and the implications of the Act for community pharmacists using the existing arrangements in Cornwall as an example. He also makes recommendations on how funding could be secured in order to provide the additional services necessary as a result of the Act*

The Care Standards Act (CSA)<sup>1</sup> became law in July 2000 with its key provisions effective from April 2002. The main purpose of the Act is to reform the regulatory system for care services in England and Wales. Care services range from residential and nursing homes, children's homes, domiciliary care agencies, fostering agencies and voluntary adoption agencies through to private and voluntary health care services, including private hospitals, clinics and private primary care services. The Act is in nine parts of which the following two parts are relevant to community pharmacy:

- Part I provides for the establishment of the National Care Standards Commission (NCSC) in England and establishes the National Assembly for Wales as the equivalent registration authority in Wales. Part I also contains definitions for the purposes of the Act
- Part II makes provision for the regulatory procedures to be followed by the NCSC in England and the National Assembly for Wales. The Secretary of State and the National Assembly for Wales are given powers to make regulations in relation to the care services regulated under this part of the Act and to issue national minimum standards applicable to all the services to which the registration authorities and providers must have regard

The CSA for the first time places the responsibility for regulation of residential care, nursing homes, adult placement and domiciliary support in England under a single, non-departmental national agency — the NCSC. Through the regulatory functions of registration, inspection, complaint investigation and enforcement (RICE), the NCSC has the role of supporting consumers and advising ministers. It has its headquarters in Newcastle, nine regional offices and 71 area offices relating to "continuing care" establishments, and a division for private and voluntary healthcare (PVH), which is responsible for the regulation of acute independent hospitals, clinics, hospices and mental health establishments that accept patients sectioned under the Mental Health Act 1983. The NCSC acquired its registra-

tion and inspection functions from health (nursing homes) and local (residential homes) authorities in April 2002. At this time, the Registered Homes Act 1984 (under which care homes were previously regulated) was repealed.

## NATIONAL MINIMUM STANDARDS

A statement of national minimum standards (NMS) was published by the Secretary of State for Health under section 23(1) of the Care Standards Act in March 2001.<sup>2</sup> The Department of Health has now provided specific NMS for differing services and the NCSC uses the standards as the basis for registration and inspection. The NMS cannot be enforced but are used to assess to what extent service providers meet, or fail to meet, the regulations that are published by the Secretary of State. The inspections are conducted by generic inspectors who are based at one of the NCSC area or regional offices. The standards and regulations no longer distinguish between large homes and small homes. Adult placements are designated for a maximum of two people sharing a family household. For the first time local authorities are required to meet the same standards as independent sector providers.

The functions of the NCSC cover a wide range of private health care provision for adults and children, from care homes and private hospitals to cosmetic laser clinics. The terms residential and nursing homes, formerly defined within the Registered Homes Act 1984, are no longer recognised, the terms now in use include "care home" and "care home with nursing".

The service specific NMS are extensive and each NMS includes a separate section on medication. The specific standards that interest community pharmacists are 9.4 and 9.9 in standards for care homes for older people, which are identical to 20.6 and 20.12 in standards for care homes for adults (18–65 years). Standard 19 in standards for adult placements is also of interest to pharmacists — see below. The NMS for all regu-

lated services can be accessed via the internet at [www.carestandards.org.uk](http://www.carestandards.org.uk).

**Standard 9.4** Medicines in the custody of the home are handled according to the requirements of the Medicines Act 1968, guidelines from the Royal Pharmaceutical Society, the requirements of the Misuse of Drugs Act 1971 and nursing staff abide by the UKCC standards for the administration of medicines.

**Standard 9.7** In residential care homes, all medicines, including Controlled Drugs (except those for self-administration), are administered by designated and appropriately trained staff. The administration of CDs is witnessed by another designated appropriately trained member of staff. The training of care staff must be accredited and must include:

- Basic knowledge of how medicines are used and how to recognise and deal with problems in use
- The principles behind all aspects of the home's policy on medicines handling and records

**Standard 9.9** The registered manager seeks information and advice from a pharmacist regarding medicines policies within the home and medicines dispensed for individuals in the home.

**Standard 9.10** Staff monitor the condition of the service user on medication and call in the general practitioner if staff are concerned about change in the condition that may be a result of medication, and prompt the review of medication on a regular basis.

**Standard 19.4** The registered person seeks information and advice, if needed with the consent of the service user, from a pharmacist regarding medicines dispensed for service users.

## CONTROLLED DRUGS

It is notable that the DoH included in the NMS for older people and adults additional requirements for the handling of Controlled Drugs irrespective of whether the care home offers nursing care. All care homes

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are expected to meet the safe custody requirements as described in the Misuse of Drugs (Safe Custody) Regulations 1973 for those CDs that are handled by care staff, ie, that the resident is not self-administering. This change of storage requirement in the former "residential" home will have implications for community pharmacists who have routinely packaged CDs within monitored dosage systems. Also the care home is to record the receipt, administration and disposal of CDs in a bound register in addition to the medicine administration records. This will have implications for the following:

**Temazepam** The full CD safe custody regulations are legally required in nursing homes and, for good practice, are also required in all other care homes. There may be circumstances when a care home is required to maintain full CD records of the procurement, administration and disposal of temazepam although it is accepted that this is not legally required. This is to avoid confusion for care home staff about different treatment of CDs and to emphasise the need for additional care with this drug.

**Oramorph** NCSC inspectors are not empowered to require a care home to treat Oramorph 10mg in 5ml as a full CD. However, they may recommend that, although it is in Schedule 5, it is treated as a CD to avoid confusion for care staff about the handling of morphine.

#### SAFE DISPOSAL OF MEDICINES

The regulations that cover all care homes (including children's homes) require a system of medicines management which can be audited, ie, the receipt, use and return of medicines can be verified. It is helpful if pharmacists can confirm the receipt of any medicines returned for disposal.

#### TRAINING OF CARE HOME STAFF

It should be noted that standard 9.7 not only sets out the requirement for appropriate training of care staff but goes even further with a need for accreditation. This is already proving to be a problem area for NCSC inspectors, care homes and community pharmacists who for many years have made an excellent contribution in this area. Until the NCSC has recognised a means to accredit pharmacist training, generic inspectors have been advised to establish whether or not training has been accessed, whether the training is geared to the written policy for medication within the care home, and whether there is an element of "in house" assessment of the competence of care staff to administer medicines safely to residents.

Until such time as accreditation is available to pharmacist trainers, the courses offered should be tailored to the needs of the individual care home. The National Pharmaceutical Association's comprehensive course "Helping residents with their

## Arrangements in Cornwall

The arrangements in Cornwall are included here as an example of the practical implications of the CSA.

A review of the advice arrangements incorporating the requirements of the CSA will have far-reaching consequences for PCTs and community pharmacists. The existing arrangements are:

- 31 pharmacies are providing pharmaceutical advice to 156 residential care homes
- 20 pharmacies are providing pharmaceutical advice to 34 nursing homes
- Thus 51 pharmacies are providing pharmaceutical advice to 190 care homes for older people

Using service lists made available by the area office of the NCSC, a summary of the number of care homes for older people, by places, for each PCT, is set out in Table 1.

Thus 168 care homes do not have a formal contact with a pharmacist which will enable them to meet the NMS published by the DoH and regulated by the NCSC. The vast majority of the 105 smaller homes with five or fewer places cater for client groups with learning disabilities, 41 of these homes have two or fewer places.

In providing services for residential or nursing homes, pharmacy contractors are required to fulfil requirements set out under the Royal Pharmaceutical Society code of ethics and standards. A clinical governance assessment baseline survey conducted in Cornwall with a response rate of 98.95 per cent of Cornish pharmacy contractors was published in May 2002. The survey results show that some community pharmacists are not fulfilling the "service specifications" set out under the code of ethics and standards. On the other hand, the validity of some procedures, such as the extensive use of MDS, may be open to question. Few contracts however, between both PCTs and community pharmacies, and community pharmacies and care homes, prescribe specific details of all the procedures to be completed. Most imply that "guidelines" should be followed. Guidelines were originally published by registration and inspection units of health and local authorities and these no longer exist, having been superseded by the NMS. Specific contractual obligations to ensure NCSC standards are fully implemented at care homes through formal audit by community pharmacists may need to be established. It is worthy of mention that the vast majority of care home residents are NHS patients. Setting up a formal agreement between the PCT and a community pharmacist should also relieve the anxieties of the NCSC with regard to medicines management in care homes.

TABLE 1: NUMBER OF CARE HOMES FOR OLDER PEOPLE IN CORNWALL

	West of Cornwall PCT	Central Cornwall PCT	North and East Cornwall PCT
Care homes	103	96	99
Care homes with nursing	17	17	26
Totals	120	113	125

medicines, a training course for residential care staff", is one template for use in conjunction with the agreed medicines policy of each individual care home. Other pharmacy providers have similar courses.

#### PHARMACEUTICAL ADVICE

Included in the NMS for older people (9.9) and adults (20.12) is the standard that "the registered person seeks the advice of a pharmacist". The standard does not specify the nature of contact between care home and pharmacist. However, NCSC inspectors will be seeking evidence that the care home has met this standard. A formal contract for pharmaceutical advice together with written records and reports made by the pharmacist concerned is a prime means of evidencing the standard. These standards also provide a link into the National Service Framework for Older People,<sup>4</sup> since community pharmacists have the expertise to participate, and thus alleviate the burden on hard-pressed GPs.

#### BASIS FOR THE TERMS AND CONDITIONS TO BE AGREED LOCALLY

The arrangements for "advice to care homes" are set out in Part XIVA of the Drug Tariff. Contracted pharmacists are obliged to provide advice regarding:

- The proper and effective ordering of medicines and appliances in the home
- The proper and effective administration and use of medicines and appliances in the home
- The safe and appropriate storage of medicines and appliances
- In addition the pharmacist must keep a record of the services provided in such a manner as may be specified by the PCT and make the record available on request

It is essential that community pharmacists have a full understanding of their obligations through the completion of the Centre for Pharmacy Postgraduate Education dis-

## Actions required

1. When the original arrangements were agreed and recognised by the Pharmaceutical Services Negotiating Committee, in accordance with directions from the Secretary of State, the terms and conditions, including remuneration for residential and nursing homes were to be determined by health authorities. About £10m was made over to primary care trusts/primary care groups to cover costs in 1999. Since that date it would appear there has been no monitoring of Department of Health annual payments to establish the budgets available to PCTs to cover the cost of pharmacy contractors providing additional pharmacy services. It is recommended that such national monitoring should occur to ensure LPCs can carry out meaningful negotiations, ie, negotiations are not a charade because there is no money available and neither can PCTs claim that no money has been made available by the DoH.
2. The implementation of national minimum standards for care homes and their monitoring by the NCSC will ensure that implementation of these minimum standards is mandatory for care home managers and will place a significant additional burden on community pharmacists. The implications of the introduction of these standards must be made known, with some urgency, at a national level to ensure the DoH makes funding adjustments so that next year's PCT budgets are not compromised.
3. The significance of this legislation to the Government is evident when it is noted that the Act was introduced after the publication of two White Papers in November 1998 and March 1999 — "Fit for the future" and "Lost in care". It is recommended that national pressure be brought to bear on the DoH to recognise the additional burden and contractual responsibilities of the implementation of the Act upon community pharmacies.
4. Included in the argument for additional funding should be the recognition that the pharmacist will be required to complete specialist training and will be in a position to review patient's medication regimens and thus reduce the workload of GPs, in line with the National Service Framework for Older People "that patients prescribed four items should be reviewed twice a year". Funding would therefore be legitimately available via PCTs from two sources: devolved pharmacy budget payments for care homes and medicine management programmes. Creating a validation of eligibility for the locally negotiated fee may best be approached via a competence scrutiny related to clinical governance. This mechanism would additionally have the merit of decreasing management time commitment.
5. Negotiations with regard to locally devolved budgets and contractors' remuneration could be based on the various NCSC categories for care homes, number of beds, level of medication management service and training obligations.
6. Performance review and monitoring of advice to care homes is now the subject of detailed scrutiny by the NHS counter fraud service. In November 2002, its policy unit issued a survey to PCTs that included four sections and 15 questions about advisory visits to care homes by community pharmacists.

tance learning course for pharmacists, "The home away from home". Evidence of completion of the course may be a prerequisite of the signing of a contract between a PCT and a community pharmacist.

The NCSC categorises care homes for inspection as either care home only, care home with nursing, care home providing adult placement or care homes not providing medicines or medical treatment.

The terms of remuneration could be based on the above NCSC categories, the number of beds, an agreed level of medica-

tion management protocol and training commitments. The protocol could also be designed using subsidiary client group categories, eg, dementia, mental disorder, physical disabilities, terminal illness, learning disabilities and old age.

### PHARMACIST INSPECTORS IN NCSC

The NCSC has already employed and is continuing to recruit pharmacist inspectors who have a specialist role to support the team of generic inspectors. At implementa-

tion of the CSA, the DoH identified a total of 66 WTE pharmacist inspectors for England. Additionally, there are two senior professional adviser pharmacists to the NCSC.

Pharmacists are employed by the NCSC as inspectors within the PVH division or the continuing care element of NCSC. The latter group do not have a defined case load of homes to inspect. Their principal roles include:

- Training generic inspectors in aspects of safe handling of medicines
- Undertaking pharmaceutical inspections on the basis of risk assessment
- Inspecting new registrations
- Involvement in complaint investigation concerning medicines
- Involvement in legal enforcement concerning medicines

Pharmacist inspectors are authorised in law to enter and inspect regulated premises and may be called on to give expert evidence in court. The DoH allocation for pharmacists has provided for a three-year rolling inspection programme of care homes. It is therefore reasonable to postulate that local advice on a day-to-day basis via a community pharmacist is the pragmatic solution to ensure that specific national standards are maintained in local care homes. These roles of inspection and implementation must be fully understood by all who are employed in this domain, so that conflict does not arise between different agencies, such as social services and health care professionals.

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### REFERENCES

1. Care Standards Act 2000. Chapter 14. London: The Stationery Office; 2001.
2. Department of Health. Care homes for older people, national minimum standards. Care homes regulations. London: The Stationery Office; 2001.
3. Royal Pharmaceutical Society of Great Britain. Medicines, ethics and practice: a guide for pharmacists. Number 26. London: The Society; 2002.
4. Department of Health. National Service Framework for Older People. London: The Department; 2001.