

## **Consultation response: Duty of Candour and Being Open**

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Mr Gerard Greene, Chief Executive, Community Pharmacy NI,  
5 Annadale Avenue, Belfast, BT7 3JA [REDACTED]

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CPNI welcomes the opportunity to comment on this consultation on draft policy proposals in respect of Duty of Candour and Being Open and, as an organisation, we are committed to working with the Department of Health and others to implement appropriate outworkings of the recommendations of the Hyponatremia-Related Deaths Report as it relates to duty of candour.

### **Background**

Community Pharmacy NI (CPNI) represents community pharmacy contractors in Northern Ireland in negotiations with the Health and Social Care Board and the Department of Health (NI) on services, the pharmacy contract, and remuneration and reimbursement.

In Northern Ireland, community pharmacy makes up one of the four pillars of primary care, alongside general practice medicine, ophthalmic services, and dental services, and provides a wide range of professional services commissioned by the HSCB including ordinary and multiple dispensing, as well as the minor ailments programme.

The sector's proximity to the population which it serves, coupled with the walk-in nature of most of its services, means it is easily accessible to most of the population for the provision of medicines and of advice on their safe and effective use. Some 42 million prescriptions are dispensed every year in Northern Ireland and community pharmacies are used by 123,000 people every day.

In developing a response to this consultation, CPNI has brought the matter to the attention of pharmacy contractors who have been encouraged to provide individual consultation feedback where possible. However, given the current sustained and increased pressure faced by the community pharmacy sector, CPNI is conscious that many contractors may not have had the capacity to divert time from essential pandemic related services towards review of these proposals.

Community pharmacy has a unique position within primary healthcare structures and, due to this and the very specific concerns that we raise, this response is made with the expectation that further consultation and opportunities to engage will be afforded, and that the timelines will allow for the excessive workload of the professionals concerned as they continue to work towards pandemic recovery and the rebuilding of healthcare services.

### **General overview**

CPNI recognises that there is a critical necessity for an open and learning culture within the health service which can contribute to improving patient safety and promoting public

confidence in the healthcare system. Patients and their families have the right to an apology and an honest explanation when things go wrong.

CPNI echoes the grave concern expressed by a wide range of individuals and organisations in respect of any actions and behaviours that fell short of the standards expected of those working in the health service as revealed by the Hyponatraemia Inquiry.

This policy document contains a wide range of proposals which go towards securing Justice O’Hara’s objectives in respect of candour and which CPNI supports. CPNI’s detailed comments are underpinned by the unique position that community pharmacy has within the healthcare sector.

## **SECTION A: Statutory Organisational Duty of Candour**

### **Statutory Organisational Duty of Candour - General Comments**

CPNI is of a view that a statutory organisational duty of candour for relevant healthcare organisations would, in principle, be likely to help ensure that registered providers of health and social care are more open and transparent when things go wrong.

CPNI agrees with the proposals that such a duty should include the following mandatory legal requirements for those organisations which are determined to be within scope:

- An obligation to act in an open and honest way towards patients and service users.
- An obligation to support staff to give full and honest answers to any question reasonably asked by a patient about their treatment.
- Additional and specific obligations in circumstances where unintended or unexpected harms occur.
- An obligation to ensure that any statements given to their Regulator or the public are honest, candid and without omission.
- An obligation to provide annual reporting on compliance with the duty.
- Criminal sanctions including a fine for organisations who fail to comply with the duty in a serious or repeated manner.
- Criminal sanctions in respect of obstruction of an individual in complying with the duty of candour, by an organisation.

However, CPNI has concerns and reservations with the following aspects of the proposals:

- CPNI’s principal reservation is that “organisation” is not defined in the consultation and, in the context of what is proposed, the term “organisation” is not appropriate to describe community pharmacies because of their size and typical business structure, compared to hospitals and trusts. CPNI’s support for the introduction of a statutory duty of candour for organisations does not extend to the imposition of such a duty on community pharmacy businesses (see further comment below).
- CPNI is cautious of the general requirement for organisations to be “proactively open”. While we agree that information should be shared candidly with patients, we suggest this should always be in a balanced, sensitive and patient-centred way which respects immediate and long-term health and wellbeing.

- CPNI disagrees with setting out a single mandatory procedure to be followed by all organisations in circumstances “when care goes wrong”. A single procedure for all healthcare organisations would not take account of the many nuanced, specific and highly specialised areas of healthcare provision. Quite simply, one procedure will not fit all and will not best serve all patient populations in all contexts.
- CPNI would caution that the proposed threshold definition for harms which will trigger notifiable incidents is overly broad. Use of terminology such as “may have caused harm” or “potential harm” are vague, subjective and open to interpretation.
- CPNI have concerns about the inclusion of future potential harms (as described in paragraph 3.14) as this too will be open to interpretation and subjectivity. For example, it might be argued that almost all healthcare interventions and treatments have the potential to cause future harm.
- CPNI is of the view that requiring organisations to undergo notifiable incident procedures for a broad range of incidents will lead to a tick-box type of approach and will greatly diminish the meaningful value of the procedure in situations where it is most needed, and where the opportunity for true reflection and learning is most abundant.
- While CPNI fully agree that patients and their carers deserve a sincere apology when care goes wrong, we are unconvinced of the value or appropriateness of imposing a statutory legal requirement on organisations to provide an apology, particularly in a prescriptive fashion and within a set timeframe. CPNI shares the concerns of others that an apology of this sort may lack sincerity and could risk becoming standardised or generic. Such an outcome would not be in the best interests of patients and may make a sincere apology more difficult to obtain.
- CPNI have further concerns that notifiable incident reports (including apologies) have a real and/or perceived potential to be used in evidence against an organisation. While we note from paragraph 3.26 that apologies given under the procedure will not be taken as an admission of guilt, we are unconvinced of the legal value of this reassurance. Such a requirement, and the fear it may induce in organisations, has the potential to challenge overall compliance with the duty.

### **Statutory Organisational Duty of Candour - The Pharmacy Perspective**

While CPNI agrees in principle that a statutory organisational duty of candour should apply to relevant healthcare organisations, we consider this most applicable to large scale healthcare organisations such as hospitals and Trusts.

However, it is evident that community pharmacies are distinct from the other organisations included in the suggested scope set out in Section 3, and, as such, require separate and specific consideration. CPNI **does not** agree with the inclusion of community pharmacies as “organisations” within the scope of these proposals.

#### **1. It is not practical or proportionate to include community pharmacies in the scope for organisational statutory duty of candour given the scale and structure of the majority of community pharmacies in Northern Ireland.**

There are 528 community pharmacies in Northern Ireland which are operated by some 200 pharmacy contractors ranging from sole traders, limited companies (in many cases de-facto sole traders), small to medium enterprises, up to large chains of national and international multiples.

The level of corporate sophistication, governance structure, administrative support and human resourcing capabilities varies greatly across the sector, as does the range of services offered and the number of patients served. A community pharmacy is not comparable to other healthcare organisations included in the suggested scope such as the health and social care Trusts or the Department of Health.

CPNI considers it would be inappropriate, disproportionate and unworkable to impose an organisational statutory duty of candour across the breadth of community pharmacies, particularly those at the smaller end of the scale.

**2. It is not in keeping with the overarching aims of the Hyponatraemia (IHRD) report recommendations to include community pharmacies in the scope for a statutory organisational duty of candour.**

CPNI's understanding and interpretation of the IHRD report is that the recommendations are in the main intended towards larger scale organisations such as Trusts and hospitals. We note recommendations 3 and 4 of the report specifically refer to Trusts. The recommendations do not refer to pharmacies or pharmacists and the wider report does not appear to find specific issues or failings within the community pharmacy sector. CPNI has not found any compelling evidence in the research conducted by the candour and openness workstream to support the inclusion of community pharmacies in the scope for organisational statutory duty of candour.

**3. The inclusion of pharmacies in the scope for organisational duty of candour is unnecessary given the existing professional and regulatory duties which apply to the profession.**

As the duty of candour workstream will be aware, the pharmacy regulator (The Pharmaceutical Society of Northern Ireland (PSNI)) has outlined the robust existing professional duty of candour for pharmacists and pharmacy owners. Following public consultation, the PSNI published "The Code, Professional Standards of Conduct, Ethics and Performance for Pharmacists in Northern Ireland" in March 2016. The standards which relate to the duty of candour include:

**Standard 1.2.3:** Respond quickly and appropriately to any complaint about the care or service you provide and take all necessary and appropriate measures.

**Standard 1.2.4:** When something goes wrong with a pharmacy service, explain fully to the patient or service user what has happened, and where appropriate:

- offer an apology
- offer an appropriate and effective remedy
- explain the short and long term effects
- provide support and assist to put matters right.

**Standard 1.2.5:** Be open and honest with patients, service users, colleagues, and employers when something goes wrong.

**Standard 1.2.6:** If you employ, manage or lead staff, make sure that there is an effective procedure in place that allows staff to raise concerns openly and safely without fear of reprisals.

Standard 1.2.6 is particularly relevant to pharmacy organisations in that it places clear responsibility for candour on those in management roles. Additionally, the PSNI published guidance on “Raising Concerns” (June 2019) which reinforces the professional duty for pharmacists to raise concerns about colleagues or practices within their organisation which have or may lead to harm.

Robust sanctions exist for non-compliance with the duty of candour set out in these standards in that such a failure may lead to findings of professional misconduct (where applicable) and suspension or removal from the register. Sanctions are also likely to have significant secondary consequences for pharmacy owners in respect of reputational damage, financial impacts and knock on effects on other directorships or professional registrations.

**4. The inclusion of pharmacies in the scope for organisational duty of candour is inappropriate due to the unique position of pharmacists and pharmacy owners under Section 64 of the Medicines Act 1968.**

It is also critical to understand that pharmacists and pharmacy owners are uniquely exposed to criminal sanction by virtue of Section 64 of the Medicines Act 1968 in that they are the only healthcare professionals who can be prosecuted for making a mistake when supplying medicines. Section 67C of the same Act establishes a defense against prosecution for pharmacists in these circumstances on conditions, one of which is acting with candour.

CPNI accepts that there may be barriers to pharmacists and pharmacy staff members raising concerns within a pharmacy organisation, however these are mitigated largely by the legal protections afforded by the Public Interest Disclosure (Northern Ireland) Order 1998, the Employment Rights (Northern Ireland) Order 1996 and the Employment Act (Northern Ireland) 2016.

**5. The procedural aspects of the statutory duty of candour are incompatible with the Pharmacy profession.**

a) The proposed procedure for notifiable incidents and the associated notifiable incident report described in paragraphs 3.19 to 3.23 would have a potential to be prejudicial and self-incriminating in the pharmacy context given the strict liability offences which apply to the profession under Section 64 of the Medicines Act 1968.

Similarly, the proposed mandatory inclusion of an apology poses particular difficulties for pharmacists and pharmacies. If this proposed procedure were applied to pharmacies, it would likely conflict with natural justice principles and the right to avoid self-incrimination. While we note paragraph 3.26 indicates such reports and apologies would not be taken as admission of guilt, we are unconvinced of the value of this reassurance in the highly specific pharmacy context.

b) The suggested legal requirement for relevant organisations to produce an end of year report on their duty of candour is, in CPNI’s view, further supportive of our position that the duty is more appropriate and applicable to large scale healthcare organisations such as a hospital or Trust. It would not be workable or valuable for the 528 community pharmacies in Northern Ireland to submit such a report.

c) The proposal that RQIA will be the authorised body in respect of overseeing compliance with the organisational statutory duty of candour is further supportive of our view that pharmacies do not belong in this group. This may be appropriate for organisations such as hospitals and Trusts where RQIA already have a level of experience, expertise and oversight, however it would not be appropriate or workable for RQIA to have this role in respect of pharmacies where it has no understanding or current involvement.

d) We note that the maximum fine suggested in the proposal is of a level which would have an overly burdensome impact on a community pharmacy business. Such a fine is, in our view more appropriate for larger scale healthcare organisations.

e) Finally, we note that paragraph 3.40 indicates that the individuals behind organisations may face criminal sanction on behalf of an organisation in certain circumstances. Given that many pharmacies differ from large scale healthcare organisations in that they are operated by small, limited companies and/or sole traders, this provision may constitute a form of double jeopardy in their case, and further underpins how it is not a workable fit for pharmacy.

### **Statutory Organisational Duty of Candour - Conclusion**

In conclusion, CPNI supports the recommendations of the IHRD report in increasing the overall openness and candour within healthcare organisations but on the basis of points 1-5 above we would argue that the proposed organisational statutory of candour would not be appropriate, necessary or helpful in the pharmacy context.

CPNI remains committed to supporting the improvement of openness and candour in pharmacy but suggests that this can be better achieved through further awareness raising of the existing professional requirements for candour within the code of conduct, the guidelines on whistleblowing and the legal protection for pharmacist disclosures. Much of this could be brought about through engagement between the pharmacy regulator and the profession, without necessity for any legislative changes or new statutory requirements.

## **SECTION B: Statutory Individual Duty of Candour**

### **Statutory Individual Duty of Candour – General Comments**

While CPNI fully supports the desired outcome of ensuring that staff will be open and honest regarding their errors, we agree with a number of submissions made by other professional representative bodies and regulators that the correct balance between assuring accountability and openness may not be achieved by introducing a statutory individual duty of candour backed by criminal sanctions.

### **Statutory Individual Duty of Candour – The Pharmacy Perspective**

In considering this proposal, CPNI notes that:

- A statutory duty of candour of this kind with associated criminal sanction, does not apply to pharmacies or pharmacists in any of the other jurisdictions looked at by the workstream group nor is it proposed for any of the other devolved administrations of the UK.

- The pharmacy regulator (The Pharmaceutical Society of Northern Ireland (PSNI)) in their evidence submissions of March and April 2019, has provided the workstream group with an overview of the well-established and robust professional regulatory duty of candour which forms part of the professional code to which pharmacists are bound (see above). This code applies to individual pharmacists and those in management and leadership positions and therefore works on both an individual and organisation level. PSNI has previously indicated that their position is contrary to the introduction of a statutory duty of candour for pharmacists.
- At present, members of the public, other healthcare practitioners, the pharmacy inspectorate, the Registrar, or any other concerned parties can raise a concern or make a complaint against a pharmacy or pharmacist to the PSNI as the pharmacy regulator. Grounds for concern or complaint may include (amongst other things) a failure to uphold the duty of candour.
- The Public Interest Disclosure (Northern Ireland) Order 1998, the Employment Rights (Northern Ireland) Order 1996 and the Employment Act (Northern Ireland) 2016, provide protection for pharmacists where they raise a concern about a pharmacy organisation. The PSNI have provided information on these protections to the profession in their guidance on raising concerns and “whistleblowing”.
- The PSNI’s guide to sanctions in fitness to practise recommends that breaches of the code (including failure to uphold the duty of candour) can warrant suspension or striking off from the register. Therefore, failure to uphold the professional duty of candour is of the utmost seriousness and has potential to end a pharmacist’s career and affect their livelihood and reputation. CPNI is not aware of any weakness or failing in the operation of the current regulatory and professional candour requirements for pharmacies or pharmacists. CPNI argues that the current sanctions for breach of the code are an effective deterrent, but fully accepts that if improvements are needed, then steps should be taken to review and improve the existing mechanisms rather than introducing a statutory duty of candour put forward in this proposal.
- In addition to professional sanctions, pharmacists are also open to criminal and civil proceedings that can be used in connection with other inappropriate behaviour associated with their professional role.
- There is additional unique position in respect of criminal sanctions and candour which warrants particular consideration from a pharmacy perspective. Exceptionally, except in a gross negligence manslaughter case, pharmacy owners and pharmacists are the only healthcare professionals who can be prosecuted for making a mistake (under section 64 of the Medicines Act 1968 concerning an error when supplying a medicine), and recent Northern Ireland case law illustrates this. Indeed, since that case, a statutory defence has been introduced into section 67C of the Medicines Act. To be able to rely on this statutory defence, the defendant must have satisfied conditions that include acting with candour.

The purpose of the introduction of these defences and the rebalancing of the legislation in this regard, is aimed at reducing the possibility of inappropriate prosecution of pharmacists under the Medicines Act and to ensure increased reporting of errors (and subsequent learning). Indeed, the Government’s rationale when introducing the rebalancing programme included the observation that *“Despite the relative rarity of prosecutions, the evidence demonstrates that the “fear factor” persists. The fundamental premise on which this draft Order and the related*

*Registered Pharmacies Order is based is that reduction in the risk of prosecution will increase the number of reported errors...”*

CPNI has great concerns that the introduction of the individual duty of candour risks contradicting this reasoning in that it appears to propose the introduction of criminal sanctions in an attempt to increase openness.

- Community pharmacy in Northern Ireland is experiencing a very difficult and intense period of workforce crisis. The introduction of the proposed criminal sanctions into the professional arena here, and thus placing the pharmacists in what could be viewed as a much harsher working environment than colleagues within the rest of the United Kingdom, could have a detrimental impact on the morale of the workforce here and may make it more difficult to recruit and retain pharmacists. Such sanctions may also have a negative impact on university recruitment. Ultimately patients will be disadvantaged by such outcomes.

### **Statutory Individual Duty of Candour – Conclusion**

CPNI shares the view that it is critical that appropriate systems are in place to protect patients and ensure openness and learning in all areas of health care provision.

CPNI sees no evidence to support the proposition that an imposition of a statutory individual duty of candour with criminal sanctions upon the community pharmacy sector is an appropriate vehicle to attain and maintain an open and learning culture.

## **SECTION C: Being Open**

### **Being Open Framework – Policy Proposals for Being Open Guidance**

CPNI is of the view that the proposals in respect of the openness framework are challenging to consider at this juncture while the statutory provisions are yet to be agreed and confirmed. Given the co-dependence of the framework and the statutory duty (including the scope and procedures which sit within it), CPNI feels it would be premature to give detailed views on the wider framework to support the culture of openness in healthcare settings at this time.

In general terms, CPNI support efforts to provide explicit guidance to each of the relevant parties as to what is expected of them, and equally, what they can expect of others. However, we would encourage a simplified approach be taken to this framework to ensure ease of use and clarity for all involved. The presentation put forward in the proposals at present risks overengineering concepts which might be better formatted for quick reference. Rather than setting out the detailed position of each relevant party at each level, it may be helpful to set out the general principles and then discuss what is unique to each party and each level. CPNI would welcome further opportunity to revisit the finer details of these proposals once the fundamental building blocks of candour and openness have been agreed upon.