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3 June 2022

[redacted]

Re: OIA request - Integrated Community Pharmacy Services Agreement (ICPSA)

I refer to your official information request dated 6 May 2022 seeking information from Waitematā and Auckland District Health Boards (DHBs) about the Integrated Pharmacy Services Agreement (ICPSA).

1. **Any policy document the DHB has in place addressing the risk that an Integrated Community Pharmacy Services Agreement (ICPSA) is granted to a pharmacy in which medicines are co-located (i.e. offered for sale) within the same physical premises as alcohol, cigarettes.**

Auckland and Waitematā DHBs do not have a policy in place regarding the issuing of an ICPSA to a pharmacy in which medicines are co-located (i.e. offered for sale) within the same physical premises as alcohol, cigarettes.

2. **To the extent your DHB has such a policy document, documents recording any discussion about the potential issues raised by co-location of pharmacies and alcohol and/or cigarettes during the development of the DHB's pharmacy contracting policy.**

Please refer to our response to question 1. The DHBs do not have policy documents or other documents relating to this.

3. **Any documents showing that the DHB and its personnel took into account and/or addressed the fact that alcohol and/or cigarettes are available for sale within the same premises as a pharmacy when considering the application for an ICPSA by a Countdown Pharmacy. This request is limited to ICPSA applications submitted to the DHB by a Countdown Pharmacy after 1 May 2020.**

A 'License to Operate Pharmacy' is issued by the Ministry of Health's Medicines Control regulatory team to an operator for a designated premise. This process ensures that the pharmacy has met the quality standards and regulatory expectations to operate a pharmacy. Therefore, once the license to operate is granted, the DHBs do not impose any further requirements and, as a consequence, issues the ICPSA.

4. **Any policy document the DHB has in place to monitor the operation of an ICPSA (or, if no such specific policy exists, any policy document the DHB has in place to monitor the operation of**

service agreements it has entered into pursuant to section 25 of the New Zealand Public Health and Disability Act 2000).

The ICPSA agreement provides an overall framework to enable DHBs to monitor and respond to failures by pharmacies to comply with the requirements within it. Regular quality audits are conducted by Medicines Control on behalf of the DHBs.

The standard ICPSA can be found on the TAS website by selecting the 1 October 2021 version - https://tas.health.nz/dhb-programmes-and-contracts/community-pharmacy-programme/icpsa/

5. **Any policy document the DHB has in place addressing how it should respond to a failure to comply with the terms of an ICPSA (or, if no such specific policy exists, any policy document the DHB has in place to address a failure to comply with a service agreement it has entered into pursuant to section 25 of the New Zealand Public Health and Disability Act 2000).**

Waitematā and Auckland DHBs' joint internal policy, addressing how they should respond to any failures to comply with the terms of an ICPSA, is provided below, together with a notification letter that was distributed to all community pharmacies in the DHB catchment:

Attachment 1 - **Pharmacy Quality and Inspection Audit Policy**
Attachment 2 - Notification letter

6. **Documents recording the DHBs' response to any failure by a pharmacy to comply with the terms of its ICPSA. This request is limited to failures since 1 January 2021.**

Medicines Control, on behalf of the DHBs, carries out routine audits to determine if pharmacies are compliant with the terms of the ICPSA.

It should be noted that, as at March 2022, Auckland DHB has 137 community pharmacies and Waitematā DHB has 132 community pharmacies.

Since 1 January 2021:

- two Notice of Failure letters have been sent to pharmacies in the Auckland DHB region under ICPSA Clause C.31(1)(a), with 30 days to take corrective actions
- four Notice of Failure letters have been sent to pharmacies in the Waitematā DHB region under ICPSA Clause C.31(1)(a), with 30 days to take corrective actions
- no Notice of Failure letters were issued under ICPSA Clause C.31(1)(b). These letters are only issued if the failure cannot be remedied and a 30-day notice period to terminate the ICPSA is given.

We are withholding the letters under Section 9(2)(b)(ii) of Official Information Act on the grounds that making the information available is likely to unreasonably prejudice the commercial position of the six pharmacies issued with Notice of Failure letters, particularly given that they corrected the failures identified and, as such, continue to operate.

If information about their failures were to be made publicly available without detailed contextual information about the audit process and corrective actions taken this would be highly likely to impact their commercial position.

You have the right to seek an investigation and review of this decision by the Ombudsman. Information about how to seek a review is available at www.ombudsman.parliament.nz or Freephone 0800 802 602.

However, we are able to advise that the six pharmacies referred to above were notified of anywhere between five to 13 of the following failures:

Criterion 1.02.01 The pharmacy was unable to demonstrate that all staff are suitably qualified for the pharmacy services provided from the premises.
Criterion 1.02.03 The pharmacy could not demonstrate that training and development is provided for all staff.
Criterion 2.02.01 The pharmacy could not demonstrate there is ready access at the premises to all the required pharmacy equipment.
Criterion 3.01.01 The pharmacy could not demonstrate that all standard operating procedures (SOPs) were maintained.
Criterion 3.03.02 The pharmacy could not demonstrate that appropriate corrective actions are implemented, documented and reviewed contributing to continuous quality improvement.
Criterion 4.01.01 The Pharmacy could not demonstrate that Pharmaceuticals are stored appropriately and are suitable for dispensing.
Criterion 4.01.02 The Pharmacy could not demonstrate that controlled drugs requiring storage in a safe, are securely held in an approved controlled drugs safe.
Criterion 4.01.03 The pharmacy could not demonstrate that all Pharmaceuticals requiring refrigerated storage were always stored appropriately, and that the fridge had been serviced within the last 12 months.
Criterion 4.01.04 The pharmacy could not demonstrate fridge temperatures are consistently maintained between 2-8°C, or that records are appropriately maintained.
Criterion 4.01.06 The pharmacy could not demonstrate that Pharmaceutical waste is appropriately disposed of.
Criterion 5.01.02 The pharmacy could not demonstrate prescription medicines are supplied in accordance with regulatory and professional requirements.
Criterion 5.02.01 An approved form of controlled drugs register is retained on the premises for four years. However, the pharmacy was unable to demonstrate that the controlled drugs register is appropriately and accurately maintained.
Criterion 5.02.02 The pharmacy could not demonstrate that the half yearly stock taking was performed as at the close of business on the 30 June and 31 December. A Quantity Stock Account was not always performed.
Criterion 5.02.04 The pharmacy could not demonstrate that controlled drug prescriptions were always annotated correctly and retained on the premises for four years.
Criterion 5.03.02 The pharmacy could not demonstrate that measuring equipment.
Criterion 5.04.01 The pharmacy could not demonstrate that Clozapine is dispensed appropriately and records maintained in accordance with the clozapine dispensing protocol.
(burette/syringe/Dispensette) is suitable, regularly validated and appropriately cleaned after each use.
Criterion 5.05.02 The pharmacy could not demonstrate that starting materials are of pharmaceutical grade, within expiry date and appropriately stored
Criterion 5.05.04 The pharmacy could not demonstrate compounding records for individually compounded products are appropriately maintained and stored on the premises for at least three years.
Criterion 5.07.04 The pharmacy could not demonstrate medicines requiring supply by an accredited. pharmacist are recorded and labelled in accordance with regulatory and professional requirements.
Criterion 5.08.01 The pharmacy could not demonstrate that online pharmacy services were provided in a manner that complies with regulatory and professional requirements.
Criterion 5.08.02 The pharmacy could not demonstrate that the sales of medicines or advice. provided via online contact always complied with all regulatory requirements including pharmacist involvement.
Criterion 5.10.01 The pharmacy could not demonstrate that compliance packaging services are provided in a safe and appropriate manner that produces accurately.

Criterion 5.10.03 The pharmacy could not demonstrate compliance packaging is labelled sufficiently in accordance with regulatory and professional requirements.

This information is provided to you at no charge and under the Official Information Act 1982. I trust this meets your requirements.

Auckland and Waitematā DHBs support the open disclosure of information to assist community understanding of how we are delivering publicly funded healthcare.

This includes the proactive publication of anonymised Official Information Act responses on our websites from 10 working days after they have been released.

If you consider there are good reasons why this response should not be made publicly available, we will be happy to consider your views.

Yours sincerely

Dr Debbie Holdsworth
Director Funding
Auckland and Waitematā District Health Boards

Pharmacy Quality and Inspection Audit Policy (revised)

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1. Overview

Purpose

The purpose of this policy is to document the actions Auckland and Waitematā District Health Boards (DHBs) will follow when a community pharmacy provider has failed to meet their obligations under the Integrated Community Pharmacy Services Agreement (ICPSA).

Scope

This policy is applicable to all community pharmacies that hold an ICPSA with Auckland and Waitematā DHBs.

2. Introduction

The Auckland and Waitematā DHBs monitor the delivery and performance of services provided by community pharmacies. These services must comply with the legal and regulatory requirements and the relevant codes of practice, to maintain patient safety.

Pharmacy quality and inspection audits are undertaken jointly by Medicines Control and the DHBs. The audit checks for compliance with legislative and quality requirements of the ICPSA. *Professional obligations are set out in clause B5 of the ICPSA as follows:*

The Provider must comply with the following when providing the Services:

a) the Pharmacy Services Standards;

b) the Code of Ethics; and

c) any professional requirements or regulatory standards that may be specified by the Pharmacy Council, the Ministry, or any other regulatory body, from time to time.

All audit criteria within the pharmacy quality and inspection audits reference specific aspects of the Pharmacy Services Standards, Code of Ethics or relevant legislation (eg Medicines Act 1981 and Medicines Regulation 1984). Therefore, compliance with these requirements is a material obligation under the ICPSA.

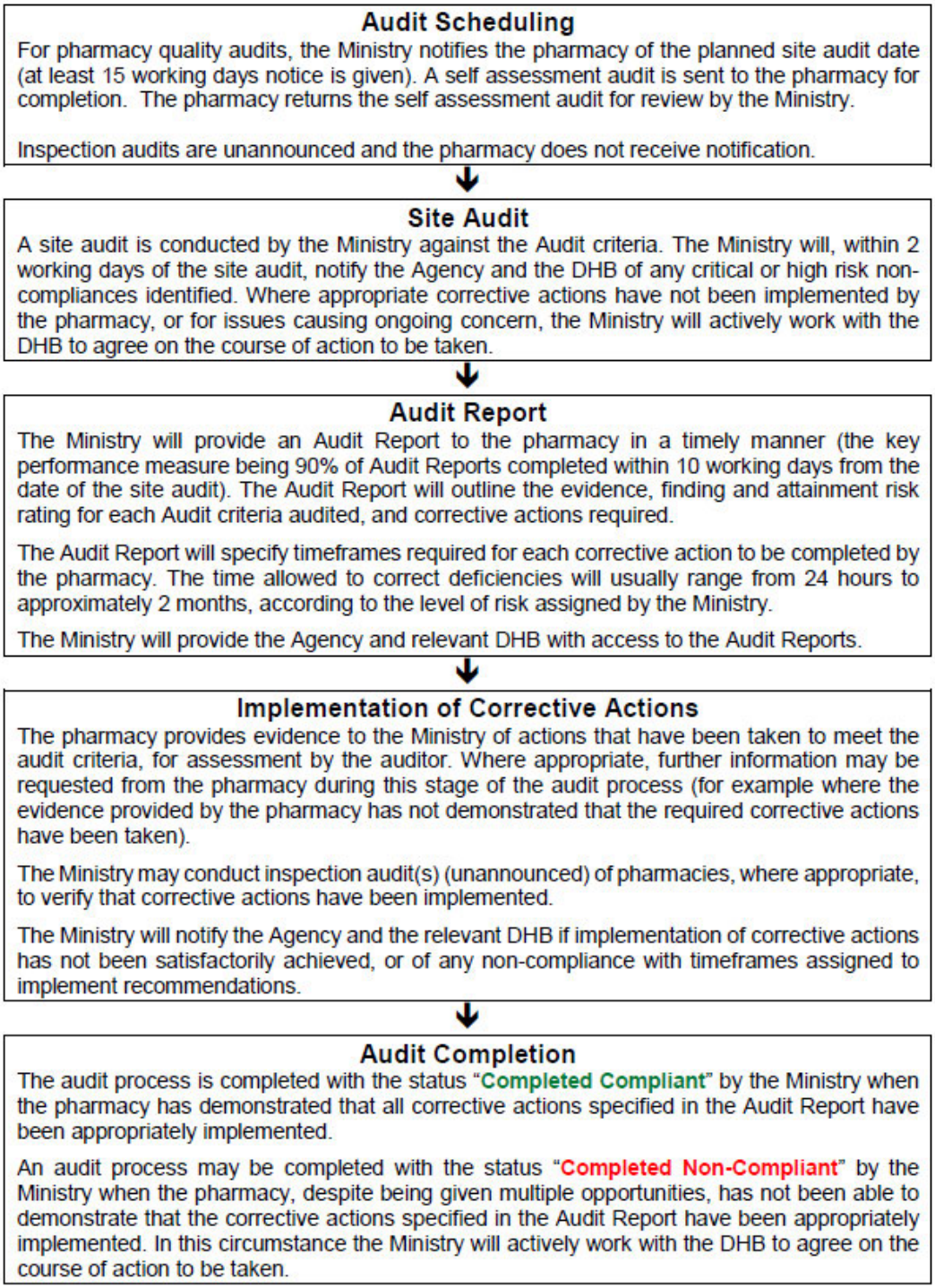
3. Definitions

Term	Definition
Pharmacy Quality Audit (PQA)	A full audit assessing all services provided from the premises (up to 67 criteria)
Inspection Audit (IA)	A risk based audit assessing some of the services provided from the premises (the 10 current risk-based criteria)
DHB	District Health Board
ICPSA	The Integrated Community Pharmacy Services Agreement
HPCA	Health Practitioners Competency Assurance Act
Medicines Control	Medicines Control is a regulatory team within the Ministry of Health. They issue licences and authorities, undertake drug abuse containment activities and monitor compliance with legislation (in particular, the Medicines Act 1981, Medicines Regulations 1984, the Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977).
Material obligation	The terms and conditions set out in the ICPSA that all providers must comply with

4. Auditing process

The two types of audits for community pharmacy are Pharmacy Quality Audits (PQA) and Inspection Audits (IA); the latter are unannounced. A PQA assesses up to 67 audit criteria applicable to pharmacy services provided at the premises. An IA assesses 10 risk-based audit criteria that are commonly identified non-compliances.

Medicines Control will carry out audits on behalf of the DHB in the following way:



5. Termination procedures

Pharmacies in the Auckland and Waitematā District Health Boards are required to meet standards that ensure that safe and optimal delivery of pharmacy services are delivered and sustained over a period of time.

In situations where pharmacies are unable to meet the required level of compliance specified in the ICPSA, the DHB will assess the audit findings and consider various actions to take.

Illustrative examples of scenarios where the DHB may initiate termination procedures:

Scenario 1: Significant failure to meet contractual obligations
Following the review of the final audit report, the DHB considers that the provider is not meeting a material obligation. This may be as a result of an individual significant failure, or as a result of several failures that are being considered collectively.

Scenario 2: Corrective actions not completed in time
Audit finding highlights partial attainment in certain audit criteria and the provider is given a timeframe by Medicines Control to complete the required corrective action(s).
The provider does not complete the corrective actions by the due date.

Scenario 3: Unable to demonstrate sustained compliance
Following the events of Scenario 1 or 2, the provider is able to remedy the failure within the required timeframe but a similar non-compliance is identified in subsequent audits (ie the provider is unable to sustain the performance).

ICPSA clause C.31 *Notice of failure:*

(1) If the DHB has reasonable grounds to believe that the Provider has not met any material obligation under this Agreement, the DHB will give the Provider written notice setting out the details of the obligation that the DHB believes has not been met; and

(a) if the failure can be remedied, give the Provider 30 days to meet the obligation and to demonstrate to the DHB's reasonable satisfaction that the obligation has been met; or
(b) if the failure cannot be remedied, terminate this Agreement on the expiry of a period of 30 days, or a shorter period as the DHB considers reasonable in the interests of the health and safety of Service Users.

ICPSA clause C.41 *The DHB's right to terminate:*

(1) The DHB may terminate any part of all of this Agreement, including any Service Schedule:

(b) if the DHB has good reason to believe that the Provider is unable to carry out all of its obligations under this Agreement, immediately on written notice, subject to the DHB consulting with the Provider first about the possibility of termination.

Note: *Refer to ICPSA for comprehensive details.*

6. Right of refusal to issue a pharmacy services agreement

Auckland and Waitematā DHBs reserve the right not to issue a pharmacy services agreement to pharmacy owners, directors and/or pharmacists affiliated to a company that was party to the ICPSA agreement terminated as a result of non-compliance against the pharmacy quality standards.

DHBs will evaluate all potential pharmacy owners, directors and pharmacists who are applying for an ICPSA. Each request for a pharmacy services agreement or variation to agreements will be assessed on an individual basis.

Furthermore, this policy will inform local commissioning decisions in the future when pharmacy providers seek variation to agreements to deliver additional pharmacy services, such as clozapine, extended methadone and aseptic dispensing services.

7. Associated Documents

Type	Document Titles
Legislation	This policy complies with the following legislative requirements: • Code of Health and Disability Services Consumers' Rights (1996) • Code of Ethics • Public Health and Disability Act 2000 • Public Records Act 2005 • Medicines Act 1981 • Medicines Regulations 1984 • Misuse of Drugs Act 1975 • Misuse of Drugs Regulations 1977 • Health Practitioners Competency Assurance Act • Health and Disability Services– Pharmacy Service Standards NZ8134.7:2010
Strategies	NZ Health Strategy 2016 Pharmacy Action Plan 2016 to 2020
Ministry of Health	Pharmacy Quality Audit (Community Pharmacy) – Audit criteria Version 5.2.1 Medicines Control

District Health Boards	Integrated Community Pharmacy Services Agreement (ICPSA)

AUCKLAND DISTRICT HEALTH BOARD
Te Toka Tumai

Waitematā District Health Board
Best Care for Everyone

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8th December 2019

Attention: Pharmacy contract-holder

Dear Pharmacist

Notification regarding Pharmacy Quality and Inspection Audits

Pharmacy Quality audits (PQA) and Inspection audits (IA) are conducted by Medicines Control at regular periods over the year. A PQA assesses up to 67 audit criteria applicable to pharmacy services provided at the premises. An IA assesses 10 risk-based audit criteria that are commonly identified non-compliances. The audits ensure that pharmacy services are complying with the legal and regulatory standards required to provide safe and optimal delivery of pharmaceutical services.

An overview of results from audits carried out in Auckland (62) and Waitematā (54) District Health Boards (DHBs), during July 2018 to June 2019 is provided below in Table 1. This demonstrates that a number of pharmacies in the Auckland and Waitematā districts are not meeting the standards required and that the overall level of non-compliance amongst audited pharmacies continues to be higher than expected. This includes a number of critical and high risk instances of non-compliance that have implications for patient safety. It is also noted that many pharmacies are unable to sustain a level of compliance over a period of time.

Table 1: Audits results for Auckland and Waitematā July 2018 – June 2019

	Auckland DHB	Waitematā DHB
Total number of pharmacy quality audits	5	3
Total number of Inspection audits	57	51
Pharmacies with >50% Fully Attained	34	30
Pharmacies who achieved full attainment	5	12

Auckland and Waitematā DHBs wish to inform you that they will work in conjunction with Medicines Control and will be implementing a systematic response when a community pharmacy provider has failed to meet their obligations under the Integrated Community Pharmacy Services Agreement (ICPSA).

This will involve follow up actions to ensure that the quality of pharmacy services across the region is improved and sustained. Providers are required to implement quality improvements, and achieve all corrective actions during a specified timeframe.

Suspension or termination for material failure to perform

In situations where pharmacies have not met their material obligations under the terms of the ICPSA (for example, by failing to undertake corrective actions within the specified timeframe following an audit) the DHB may issue a 'Notice of Failure' in accordance with the **ICPSA.**

If a provider has been issued with a 'Notice of Failure' and is not able to demonstrate that the failure has been remedied within the required timeframe, the consequence may be the termination of the service agreement. This will provide the DHBs and the public with certainty that poor performing providers will no longer be providing services within the DHBs.

Auckland and Waitematā DHBs wish to notify all pharmacies operating within their catchments that the DHBs intend to apply the contractual framework set out in the ICPSA for audits, failure to perform, and suspension or termination.

Illustrative examples of scenarios where the DHB may initiate termination procedures

Scenario 1: Significant failure to meet contractual obligations
Following the review of the final audit report, the DHB considers that the provider is not meeting a material obligation. This may be as a result of an individual significant failure, or as a result of several failures that are being considered collectively.

Scenario 2: Corrective actions not completed in time
Audit finding highlights partial attainment in certain audit criteria and the provider is given a timeframe by Medicines Control to complete the required corrective action(s).
The provider does not complete the corrective actions by the due date.

Scenario 3: Unable to demonstrate sustained compliance
Following the events of Scenario 1 or 2, the provider is able to remedy the failure within the required timeframe but a similar non-compliance is identified in subsequent audits (ie the provider is unable to sustain the performance).

Please note these are illustrative examples of the actions that may be taken by the DHB to enforce the terms of the ICPSA and the DHBs reserve the right to exercise their powers under the ICPSA.

Please refer to ICPSA for comprehensive details.

If you have any questions, please contact Liz Fagan, Programme Manager – Community Pharmacy, Auckland and Waitematā DHBs – Elizabeth.Fagan@waitematadhb.govt.nz.

Yours sincerely,

Vicki Scott
Funding and Development Manager, Primary Care
AUCKLAND DISTRICT HEALTH BOARD and
WAITEMATĀ DISTRICT HEALTH BOARD