Special Commission of Inquiry into Healthcare Funding

Statement of Adjunct Professor Michael Nicholl

Name:	Adjunct Professor Michael Nicholl
Professional address:	1 Reserve Road St Leonards NSW 2065
Occupation:	Chief Executive, Clinical Excellence Commission

1. This statement made by me accurately sets out the evidence that I would be prepared, if necessary, to give to the Special Commission of Inquiry into Healthcare Funding (**the Inquiry**) as a witness. The statement is true to the best of my knowledge and belief.

A. BACKGROUND

2. My name is Adjunct Professor Michael Nicholl. I am the Chief Executive of the Clinical Excellence Commission (**CEC**). My CV is Exhibit 4 NSW Health Tranche 2 Consolidated Exhibit List.

3. I joined the CEC as chief executive in August 2022 after a 40-year clinical career spanning specialist obstetric and gynaecologist roles. I was the senior clinical advisor obstetrics to NSW Health for 15 years. I focussed my professional purpose as a leader for excellence in safety and quality in healthcare with a firm focus on NSW public health services.

4. I have bachelor's degrees in Medicine and Surgery, a master's degree in Business Administration specialising in Public Sector Management, and a doctorate in Medicine, the subject of which is related to the applicability of a risk matrix to high risk pregnancy and birth. I am a retired fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, a fellow of the Royal College of Obstetricians and Gynaecologists, a fellow of the Australasian College of Health Service Managers and a fellow of the Australasian Association for Quality in Health Care.

5. I have extensive practical experience across operational and strategic issues, together with clinical academic expertise and insight into the broader quality and safety agenda in healthcare. I also have expertise in healthcare risk and measurement.

6. I was the first obstetrician in Australia to become a Fellow of the Australasian Association for Quality in Health Care, and nationally I have worked with the Australian Institute for Health and Welfare and the Australian Commission on Safety and Quality in Health Care on key patient safety issues.

7. In 2017 I was awarded the NSW government insurer (iCare – Treasury Managed Fund) NSW Public Sector Risk Leadership Award.

8. The CEC is a board-governed statutory health corporation, responsible for leading statewide safety and quality improvement in NSW Health. It was established in 2004 to reduce adverse events in public hospitals, support improvements in transparency and review of these events, and promote improved clinical care, safety and quality in health services across NSW. The Determination of Functions dated 13 July 2012 sets out the functions of the CEC pursuant to sections 12 and 53 of the *Health Services Act 1997* (Exhibit 76 NSW Health Tranche 2 Consolidated Exhibit List).

B. SCOPE OF PROCUREMENT AND SERVICE DELIVERY

9. This statement addresses the questions raised in the Inquiry's letter dated 20 December 2023 and also broadly addresses Term of Reference E. On direction from the Inquiry, this statement does not address procurement of capital or workforce.

10. In discussing delivery of services, this statement focusses on the shared services provided by HealthShare NSW (**HealthShare**) and eHealth NSW (**eHealth**).

Role of CEC

11. The CEC's role is neither one of procurement nor delivery of services. It is not a services provider to NSW Health agencies. I nevertheless outline the CEC's role below, which centres on providing subject-matter expertise in respect of clinical safety and quality to NSW Health agencies who procure goods and services, and governance expertise in managing established programs.

12. The CEC is one of the five so called "pillar" organisations (the other pillar organisations being the Bureau of Health Information, the Health Education and Training Institute, the Agency for Clinical Innovation and the Cancer Institute NSW). The role of the pillar organisation as described in the Director General's Governance Review in 2011 was to "*have a key role on their respective areas of health care design, standards, reports, educative and associated policy*".

13. Through its functions, the CEC provides system wide clinical governance and leadership to promote and support improvement in clinical quality and safety in NSW Health agencies in the provision of safer care, which is best value care, and supply chain resilience.

Procurement by the CEC

14. The CEC does not have any role in relation to procurement (other than in undertaking its own procurement as required).

Acquisition of shared services

15. Section 126G of the *Health Services Act 1997* provides that the Minister may direct that a Public Health Organisation acquire specified services from the Health Secretary:

> "**126G Directions by Minister in relation to acquisition of services**
>
> (1) The Minister may, by order in writing, from time to time—
>
> (a) require a public health organisation to acquire specified services from the Health Secretary or some other specified person if and when such services are required, and
>
> (b) give a public health organisation any necessary directions for the purposes of paragraph (a).
>
> (2) The following conduct is specifically authorised by this Act for the purposes of the *Competition and Consumer Act 2010* of the Commonwealth and the *Competition Code of New South Wales*—
>
> (a) a requirement or direction of the Minister given under subsection (1),

(b) the entering or making of a contract, agreement, arrangement or understanding as the result of such a requirement or direction,

(c) conduct authorised or required by or under the terms or conditions of any such contract, agreement, arrangement or understanding,

(d) any conduct of the Health Secretary in carrying out the Health Secretary's functions or exercising the Health Secretary's powers under this Part,

(e) any conduct of a public health organisation, its agents, a person concerned in the management of the organisation or a person who is engaged or employed by the organisation—

(i) in relation to obtaining services in accordance with this Part, or

(ii) in complying with a requirement or direction of the Minister given under subsection (1).

(3) Conduct authorised by subsection (2) is authorised only to the extent (if any) that it would otherwise contravene Part IV of the Competition and Consumer Act 2010 of the *Commonwealth and the Competition Code of New South Wales*."

16. The CEC is directed to obtain services from HealthShare and eHealth in accordance with the Direction of the Minister s. 4.1 of the *Accounts and Audit Determination for Public Health Entities in NSW 2020* (**the Determination**, Exhibit 35 NSW Health Tranche 2 Consolidated Exhibit List).

17. Relevant to the CEC and this statement, the determination provides:

"**4. 1 NSW Health Shared Services**

a. Unless otherwise approved by the Health Secretary, PHEs [public health entities] other than AHOs must use the following NSW Health shared services:

a) *HealthShare NSW*:
1. Transaction services such as accounts payable, including VMO payment processing, accounts receivable, payroll, and general ledger reconciliations, interfaces and journal postings associated with transaction services
2. Procurement services, including purchasing, warehousing and distribution
3. Hotel and support services, including food and linen
4. Disability support services through Enable NSW
5. Asset register;
6. Payment services, such as payments for accounts payable, including VMO payments, payroll and PAYG from a HealthShare NSW bank account.

b) …

c) *NSW eHealth* for Statewide information and communication technology services;

…

c) unless otherwise approved by the Secretary, PHEs receiving services from a NSW Health Shared Service must pay the Shared Service recovery charge set out in the respective Shared Service Customer Service Charters, as adjusted from time to time. The Shared Service recovery charge will be paid by the Ministry on behalf of the PHE;

d) …

e) PHEs must appropriately record in the PHE accounts all Shared Service Recovery charges paid by the Ministry to a NSW Health Shared Service on behalf of the PHE and other NSW Intra-Health payments made on behalf of the PHE by the Ministry through the Ministry of Health State Pool, as set out in the Accounting Manual for Public Health Organisations; and

f) PHEs must promptly pay for other services received from other NSW Health entities on receipt of a correctly rendered tax invoice.

Use of HealthShare NSW for payments

a) PHEs, other than AHOs, must use HealthShare NSW for all payroll and accounts payable transactions unless exempt by the Ministry and where the payment is urgently required and cannot be processed by HealthShare on the same or next Business Day; and

b) if an urgent payment directly by the PHE is required, the payment must be made by cheque or electronic funds transfer and the payment approved by two officers authorised to do so under approved delegations."

18. Accordingly, the CEC receives shared services delivered by:

a. HealthShare: financial services such as accounts payable, accounts receivable, financial accounting, procurement, and payroll services, and other human resource (**HR**) core workforce services such as operational HR advice, transactional HR services, industrial advice, role description evaluation and grading, recruitment support and performance development. Additional workforce services such as training and development, vaccination screening, annual influenza vaccination, workforce reports and wellbeing initiatives are opted occasionally and discussed at the time prior to delivery;

b. eHealth: provides foundational shared information and communication technology (**ICT**) services. This spans everything from physical servers and networks, shared virtual infrastructure like identity and access management, to key shared services and applications like ServiceNow, StaffLink and the desktop applications of the Microsoft productivity suite. In support of this they also manage shared storage, cloud and back-up. As CEC's mandated shared ICT services provider, eHealth is the business owner for NSW Health for cyber security risk, network management, software and hardware provision and assurances, help desk, Incident management and. eHealth are ISO-27001 certified as part of their assurance framework, and their maturity and approach

to fulfilment of these responsibilities has a direct bearing on the CEC's capabilities, maturity and risk controls. eHealth manage many services essential to CEC operations including the contracts behind productivity software, operating systems and anti-virus, email, the records' system, web system and incident management system (ims+).

C. ROLE AND FUNCTION OF THE CEC

19. The CEC is a board-governed statutory health corporation, responsible for leading safety and quality improvement in NSW Health. It was established in 2004 to reduce adverse events in public hospitals, support improvements in transparency and review of these events, and promote improved clinical care, safety and quality in health services across NSW.

20. The determination of functions for the CEC are:

    a. to provide system wide clinical governance leadership with local health districts and specialty networks, including supporting the implementation and ongoing development of local quality systems;

    b. to develop policy and strategy related to improvements of clinical quality and safety across the NSW public health system and promote and support improvement in clinical quality and safety in public and private health service;

    c. to identify, develop and disseminate information about clinical quality and safety in health care on a statewide basis, including (but not limited to):

        i. working with the Health Education and Training Institute to develop, provide and promote training and education programs;

        ii. identifying priorities for and promoting the conduct of research about clinical quality and safety in health care;

    d. to review adverse clinical incidents arising in the NSW public health system and develop responses to those incidents including (but not limited to)

        i. co-ordinating responses to specific incidents with system or statewide implications; and

        ii. providing advice to the Director General on urgent or emergent patient safety issues and staff safety issues in a clinical setting;

    e. to monitor clinical quality and safety processes and performance of public health organisations and to report to the Director General and Minister thereon;

    f. to provide the Bureau of Health Information with relevant data on clinical quality and safety performance of the public health system to support the Bureau's public reporting function;

    g. to consult broadly with public health organisations, health professionals and members of the community in performing its functions;

    h. to provide advice to the Director General and Minister for Health on issues arising out of its functions;

i. to develop three year Strategic Plans and an Annual Work Plan, linking these activities and priorities of the Commission to the statewide directions and priorities of NSW and work in accordance with these plans and Service Compact agreed with the Director General.

21. In its first five years, the CEC bridged the gaps between managers and clinicians through the development of clinical practice improvement projects, demonstrated its independence in reporting risks and vulnerabilities in patient care and gained the trust and respect of clinicians working in NSW Health.

22. Initial programs of work focused on blood product governance, hand hygiene, central line associated blood infections in intensive care units, establishment of surgical and anaesthetic mortality reviews, a Clinical Leadership Program and a Quality Systems Assessment process. These were followed by programs focused on publicly reported safety and quality data (prior to the creation of the Bureau of Health Information), deteriorating patients, sepsis, and clinical practice improvement training.

Supply chain

23. CEC leads responses to urgent system-level medicine, medical device, chemical and equipment shortages in the NSW Health system, to ensure clinical quality and safety.

24. Supply chain disruptions have occurred with medicines, radiopharmaceuticals, surgical products, medical devices, equipment, and consumables.

25. There has been an increase in supply chain disruptions for medicines and medical devices. During 2022-2023 the CEC risk-assessed 828 issues notified by the TGA (778) and other agencies (50). This incorporated disruptions related to medical devices (627), medicines (123) and biological agents (78), with an increase in Class I notifications. A Class I notification is the most serious safety-related recall action, when there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious, permanent or long-term adverse health consequences or death.

26. CEC responses to urgent system-level medicine and medical device issues often includes Inter-agency Management Team (**IMT**) coordination to ensure expert clinical and product advice in managing critical issues. CEC works with clinicians and procurement teams to make recommendations about suitable alternatives. The IMT provides consolidated information, advice and mandatory direction to stakeholders. This may be in the form of emails, intranet updates or Safety Alert Broadcasts. The CEC works with HealthShare to monitor the clinical impact of supply chain disruptions until the level of risk is reduced or mitigated and can be managed locally.

27. At any time, the CEC may be monitoring 60-70 medicine shortages, providing expert advice or direction if a medicine needs to be quarantined, and advising about alternatives that are safe and appropriate.

28. This monitoring also occurs for radiopharmaceuticals and medical devices including surgical products.

29. During 2022-2023, CEC managed 17 system-wide critical responses and published 47 safety alert broadcasts.

30. The Pharmaceutical Procurement Review being implemented as part of the broader NSW health procurement reforms will also result in enhanced supply chain resilience, which will improve the management of medicine shortages and reduce risk to supply.

Procurement and service delivery projects/evaluations

31. In addition to the NSW Medicines Formulary (discussed below in Section D), statewide procurement projects with CEC involvement include the Single Digital Patient Record in NSW (**SPDR**, ongoing, estimated implementation is anticipated to be six years, from 2023 to 2029) and medical device reforms (ongoing, estimated implementation in 2029).

32. The SDPR program will transform the digital systems NSW Health staff use every day to deliver care. All NSW Health care teams, no matter where they work, will securely access the same information about a patient in real time from one source. It will replace several existing systems that are widely used across NSW Health services. This includes 228 public hospitals, over 600 community health centres, 60 pathology laboratories and over 150 pathology collection centres. The highly secure system will house medical, pathology and administration records all in one place. The SDPR will be delivered collaboratively and in partnership with local health districts (**LHD**s), specialty health networks (**SHN**s) and other NSW Health organisations, facilitated by eHealth and NSW Health Pathology. Input will be sought from clinicians, consumers, patients and technical experts.

33. The purpose and outcomes identified for the medical device reforms are to enhance the safety, performance and quality of medical devices in Australia and focus on patient safety. The strategies will impact on how information about devices is provided to patients, how adverse events involving devices are reported and how devices are manufactured in NSW Health facilities. The reforms will result in improved monitoring and follow up of devices already in use. Compliance with reforms will require changes to current processes and infrastructure.

Funding

34. The NSW Health Budget, derived from both NSW and Commonwealth government funding, is fixed by reference to a 'base' level of funding, which is determined from recurrent levels of previous funding. Although there are mechanisms for new funding, via New Policy Proposals accepted by the Government during the Expenditure Review Committee process, funding for the Ministry of Health, including for the Strategic Procurement Branch, is generally a recurring expense captured in the base.

35. CEC operates on a traditional salaries and wages and goods and services-based budget build. Any escalations for wages, consistent with applicable industrial agreements, is incorporated in the recurring base funding.

36. As a new function of the pharmaceutical reform review, additional funding was received to establish and maintain the Formulary, associated governance and electronic publishing platform.

37. The current CEC Performance Agreement (Exhibit 77 NSW Health Tranche 2 Consolidated Exhibit List) sets out that the CEC's budget adjustment to HealthShare is $3,000, and its budget adjustment to eHealth is $34,000.

D. NSW MEDICINES FORMULARY

38. The NSW Medicines Formulary project was established as a result of the broader Pharmaceutical Procurement Review, with the reform aimed 'to develop a holistic framework governing the procurement and usage of pharmaceuticals to support

optimum clinical governance and better value health care leading to improved patient outcomes'.

39. The NSW Medicines Formulary (**the Formulary**) is a continuously updated list of medicines approved for initiation in inpatients in NSW public hospitals and health services. The Formulary includes the approved indication, dose formulations and prescribing restrictions for individual medicines, where applicable.

40. The overall aim of establishing the Formulary and the associated centralised governance arrangements was to achieve several benefits, including:

    a. Equity of access to medicines for all patients in NSW.

    b. Consistency of medicines use, while maintaining appropriate clinician choice.

    c. Improving patient outcomes by supporting evidence-based use of medicines.

    d. Enhancing supply chain resilience.

    e. Improving medication safety and the ability to monitor medication use and outcomes.

    f. Supporting clinical governance through streamlined formulary medicine decision making and reduced duplication of effort

    g. Supporting monitoring and feedback of data to clinicians and managers to enable the delivery of high-quality care.

41. The main aim of the CEC Formulary work was to improve medication safety, through standardisation and strengthening clinical governance as core elements of safe and high-value care.

Development

42. The pharmaceutical aspect of the Formulary reform project was initiated and led by the Office of the Chief Health Officer (**OCHO**). When the reform project entered the establishment phase, OCHO worked in partnership with the CEC to create the governance structure and formation of the Formulary. Other agencies involved as partners included eHealth (to identify a solution and preferred provider for a statewide digital formulary platform) and HealthShare (to align pharmaceutical procurement processes with clinical decisions).

43. Consultation throughout the establishment and implementation phase was undertaken with Chief Executives of LHDs, SHNs, Chairs of Drug and Therapeutic Committees (**DTC**s), Directors of Pharmacy, Clinical Expert Advisory Groups (**EAG**s), Agency of Clinical Innovation clinical networks, and LHD and SHN change lead representatives.

44. The Formulary was based on a core formulary used across six rural local health districts. A comprehensive and robust process occurred to build the Formulary to ensure the medicines meet the needs of both the rural and metropolitan clinicians and patients.

45. To determine which medicines should be considered for addition to the Formulary, multidisciplinary EAGs were established based on therapeutic areas and using the current quality use of evidenced-base medicines. The NSW Ministry of Health and CEC worked with each LHD, SHN and NSW Ambulance to seek nominees for representatives

to participate in these groups. Each of these groups included representatives from rural, regional, and metropolitan areas.

46. The EAGs provided expert clinical advice and applied quality use of medicines principles to make evidence-based recommendations regarding the inclusion of medicines on the Formulary. Other specialty groups were consulted, including paediatrics /neonatology, geriatrics, critical care, palliative care, clinical toxicology, and nurse practitioners where appropriate.

47. The CEC, NSW Ministry of Health and eHealth worked together to oversee the implementation of the electronic online platform, which is user-friendly and easy for clinicians to access from wherever they practice. The online platform provides clinicians with a single source of information relating to the state-wide formulary.

Structure and governance

48. The CEC, in partnership with the Ministry of Health, has established the NSW Medicines Formulary Committee (**the Formulary Committee**) and the NSW High-Cost Medicines Subcommittee. The CEC provides secretariat support to these committees.

49. The Formulary Committee is the peak governance committee for medicines and therapeutic agents initiated in NSW Health facilities. During the establishment phase, the Formulary Committee was responsible for approving the initial list of medicines for inclusion on the Formulary. The Formulary Committee oversees the maintenance of the Formulary to ensure appropriate evidence based, safe, and cost-effective use of medicines within NSW Health.

50. The Formulary Committee membership is multidisciplinary and includes representatives from clinicians, clinical governance, senior executives, and relevant state-wide advisory groups.

51. The ongoing responsibilities of the Formulary Committee include:

    a. Implementing systematic, fair, and transparent process for adding, amending, removing, and reviewing medicines included in the NSW Medicines Formulary.

    b. Evaluating medicines for Formulary inclusion with a considered and consistent approach, underpinned by evidence-based best practice and cost-effectiveness.

    c. Consulting with expert advisory groups and committees, and other lead clinicians and experts.

    d. Recommending the development of state-wide clinical guidance, protocols, or other educational resources to accompany formulary medicines.

    e. Ensuring effective and timely decision making and communication of formulary matters to existing LHD and SHN DTCs and other relevant medicines-related governance committees.

    f. Ensuring all clinicians involved in the submission and assessment of applications for formulary listings disclose any perceived or actual conflicts of interest.

g. Reviewing reports received for Individual Patient Use (**IPU**) approvals and nonformulary medicine use within the LHDs and SHNs to determine if a formulary evaluation is required.

h. Advising the formulary secretariat regarding the need for medicines use evaluations (**MUE**s) to inform the review of formulary medicines.

52. The High-Cost Medicines Sub-committee has also been established to make recommendations to the Formulary Committee about whether high-cost medicines should be included on the Formulary. This will improve the allocation of resources and access to these medicines for NSW patients. The responsibilities of the sub-committee are to:

a. Evaluate the clinical, ethical, and economic impact of high-cost medicines proposed for inclusion in the state-wide formulary and make recommendations to the Formulary Committee.

b. Monitor use of high-cost medicines in NSW hospitals included in the Formulary.

c. Monitor reports received for high-cost IPU approvals and non-formulary medicine use within LHDs and SHNs to determine whether a formulary evaluation or guidance is required.

53. If medicine shortages or recalls occur, the Formulary Committee has a process in place to facilitate the rapid assessment and approval of an alternative medicine.

Medicines considered and not considered for inclusion on the Formulary

54. Medicines considered for inclusion on the Formulary (for initiation of therapy) include:

a. Medicines included on the Australian Register of Therapeutic Goods (**ARTG**).

b. Plasma derived and recombinant blood products are only considered for medicines / indications that are not available via the National Blood Agreement.

c. Parental oncology medications for inpatient use.

d. Diagnostic agents with therapeutic indications.

e. IV Fluids, excluding peritoneal dialysis solutions and perfusion fluids.

f. Some parenteral and enteral nutrition products, specifically enteral products available under the Pharmaceutical Benefits Scheme (**PBS**), and standardised base products for parenteral nutrition.

g. Special Access Scheme (**SAS**) medicines. SAS medicines are considered on a case-by-case basis when a medicine is used statewide, such as medicines in NSW Health guidelines, on the NSW Life Saving Drugs Register, or as substitutes for medicines shortages.

h. Schedule 5A medicines are considered on a case-by-case basis. Schedule 5A medicines refer to Schedule 5A of the *Therapeutic Goods Regulations 1990 (Cth)*, and broadly relate to therapeutic goods exempt from operation of Parts 3-2 and 3-2A of Act subject to conditions.

55. Medicines not considered for listing on the Formulary are:

    a. Plasma derived and recombinant blood products that are available via the National Blood Agreement.

    b. Medications used in the outpatient setting.

    c. Extemporaneous products, including third party supplied compounders (such as infusors, injections, and infusions required for individual patients).

    d. Clinical trial medications.

    e. Medicines Access Program (**MAP**) medicines (for example, compassionate use, product familiarisation, and cost share programs).

    f. Medical devices containing medicines.

    g. Gene therapies.

    h. Non-core pharmacy items. For example:

        i. Diluents used in reconstitution (for example, water for injection and sodium chloride 0.9%).

        ii. Ingredients used in extemporaneous manufacturing, including core active ingredients and associated vehicles, excipients, and solvents.

        iii. Nutritional and dietary supplements (for example, Ensure).

        iv. Irrigations and flushes, antiseptics, disinfectants, soap, soap substitutes, and washes.

        v. Non-medicated creams, lotions, lip balms, emollients, barrier creams, moisturising lotions, skin cleansers, and protective agents, including sunscreen.

        vi. Dressings.

        vii. Lubricants, substitutes, and associated products (for example, saliva substitute, sodium chloride nasal sprays, and mouthwashes).

        viii. Non-medicated powders and talcs.

        ix. Other devices, including delivery aids, test agents and controls, and dyes and diagnostic agents, such as allergen extracts and Pathology department consumables.

        x. All pharmacy related consumables.

56. If a patient is admitted to hospital and already taking a medicine that is not included on the formulary, existing local processes for medication review and supply of these medicines for continuation of therapy remain. Switching to the preferred or first-line alternative medicine listed on the formulary requires individual consideration of safety implications, clinical appropriateness, and discussion with the patient (and/or their carer) and the initiating prescriber if relevant.

57. The Formulary Committee will continue to review and expand or amend the scope of the statewide formulary based on emerging the quality use of medicine evidence base.

58. The approval to prescribe medicines which are outside the scope of the Formulary will remain within the remit of LHD/SHN DTCs or equivalent, as per current processes.

59. Individual facilities will decide which medicines will be routinely stocked according to local needs. Facilities may choose not to stock certain Formulary medicines for local reasons. However, to support equity of access, these medicines should be made available in a timely manner when prescribed under the Formulary criteria and where clinically appropriate.

60. Clinicians, with endorsement of their local DTC, can request to add or amend medicines included on the Formulary.

61. The CEC, as Formulary Committee secretariat also conducts regular horizon scans to assess PBS updates, medicines shortages, discontinuations, safety notices, and therapeutic information updates. Based on the findings of these environmental scans and an evidence-based review, the secretariat may request that the Formulary Committee considers amending the Formulary accordingly.

Policies

62. Relevant existing State policies have been reviewed and updated to support the implementation of the Formulary and the associated governance arrangements. Key updated policies include:

    a. PD2022_056, Approval Process for Medicines and Their Use, published 2 December 2022. Exhibit 78 NSW Health Tranche 2 Consolidated Exhibit List.

    b. PD2022_032, Medication Handling, published 11 August 2022. Exhibit 79 NSW Health Tranche 2 Consolidated Exhibit List.

63. The normal consultation processes apply for any changes to the policy documentation.

Current status

64. The following key deliverables of NSW Formulary reform project have been completed:

    a. creating a statewide medicines formulary with associated governance arrangements and processes;

    b. strengthening policy framework to support a statewide approach;

    c. improved integration and alignment of clinical-decision making with state-based pharmaceutical procurement processes;

    d. creating a state-based formulary publishing platform (excluding IPU module).

65. Key deliverables in progress:

    a. IPU module of the publishing platform (estimated delivery November 2024);

    b. benefits realisation data collection, analysis and reporting (five-year plan from 2024 to 2029).

E. ADVANTAGES AND DISADVANTAGES OF THE CURRENT SYSTEM

66. There are advantages that flow from the CEC's provision of clinical governance and patient safety expertise and advice to support procurement activities of other NSW health agencies.

67. For example, establishing centralised clinical governance for the Formulary (in addition to contributing to safe, high-value care) supports the standardisation and reduction in unwarranted clinical variation as well as the quality use of medicines in the local health districts/specialty health networks. Similar clinical safety and quality expertise to standardise clinical practice could be used to inform future procurement.

68. For example, CEC is supporting the establishment of governance structures and a patient safety lens for the implementation of the Therapeutic Goods Administration (**TGA**) medical device reforms. Changes to procurement practices will enable tracking and traceability of medical devices.

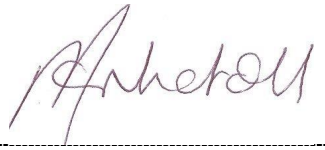
69. Similarly, although the Single Digital Patient Record is being led by eHealth, CEC is providing a key contribution to meet our roles and responsibilities as the NSW Health pillar agency for safety and quality. The role of the CEC is to ensure safety governance/assurance is applied rigorously and consistently, ensure statewide safety principles are applied and provide safety system expertise and advice.

70. A challenge for the CEC is that responding to a supply shortage requires reprioritisation of resources which impacts on business as usual functions.

71. A further challenge is that CEC received time-limited funding to implement the mandatory TGA medical device reforms. This resulted in the CEC's coordinating role for the various Pillars and Agencies that contribute to this body of work. Many of the TGA timelines for the regulations have been extended until 2029 however the current NSW funding is time limited ending June 2024. Without a further extension of funding, a number of elements of the reform will not be addressed.

F. OPPORTUNITIES

72. Prior to the commencement of the medical device reforms, the CEC's relationship with the TGA was ad hoc, and with the commencement of the medical device reforms regular meetings have been instituted with the TGA. These meetings occur as part of the medical governance steering committee, and governance process of the medical device reforms. An opportunity is to continue to develop a closer relationship with Commonwealth agencies, such as the TGA, to attempt to obtain proactive and advance notice of supply chain issues.



Adjunct Professor Michael Nicholl

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