

HSA Outpatient Pharmacy Services





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EXECUTIVE SUMMARY

The delivery of efficient and effective pharmacy services is important to ensure that the population has access to essential medicines for both curing diseases and keeping the population healthy. Favourable health outcomes require the public to have access to safe and high-quality medicines.

One of the Cayman Islands Government's strategic broad outcomes (SBOs) for 2020-21 is "Access to quality, affordable healthcare".¹ This includes a specific outcome that seeks to use new procurement practices to reduce the cost of medicines and equipment. The Cayman Islands Health Services Authority (HSA) is the principal provider of healthcare and public health services for residents of the Cayman Islands and spends around \$9 million a year on medicines for use in inpatient and outpatient care (around eight per cent of HSA's total annual expenditure).

The Office of the Auditor General (OAG)'s 2017 performance audit report *Ensuring Quality Health Care and a Healthy Population* highlighted several issues that affect the HSA's ability to deliver efficient and effective pharmacy services. These include the need to update the *Pharmacy Act (1979)* as well as concerns about shortages of physical space and staffing levels to provide pharmacy services to an increasing population. We therefore decided to carry out a specific performance audit on HSA's pharmacy services.

The overall objective of the audit was to evaluate the efficiency and effectiveness of the HSA's outpatient pharmacy services. We examined and assessed the framework, processes and structures that have been established to support and deliver these services. Specifically, we aimed to answer the following audit questions:

- Are the legal framework and oversight arrangements sufficient for efficient and effective pharmacy services?
- How effective is HSA Pharmacy at ensuring the availability, safety and quality of medicines while delivering value for money?
- How efficiently is HSA Pharmacy delivering dispensary services?

KEY MESSAGES

Legal framework

The legal framework for pharmacy contains some key provisions to safeguard the public but is outdated. An integral piece of the legal framework, the *Pharmacy Act*, has not been revised since 1979 despite

¹ 2020-2021 Strategic Policy Statement, Cayman Islands Government, April 2019.

numerous advancements in medicines and the accompanying public health and safety considerations. The Act has no overarching provision to control the quality and safety of medicines or other substances administered for medicinal purposes.

We found that the legal framework is lagging behind other jurisdictions such as Bermuda and the UK. Those legal frameworks include provisions that govern the use of herbal medicines and the labelling of medicinal products and provide protection for pharmacy enforcement authorities.

The Pharmacy Council promotes high standards of practice through its registration of pharmacists and code of ethics. However, the legislation needs to be fully enforced to limit loopholes, as there is currently no registration of or code of standards for other pharmacy staff, such as pharmacy technicians.

Strategic direction and governance

The Government's National Health Policy and Strategic Plan expired at the end of 2017 and has not been updated. The 2012-17 strategic plan had an objective to establish a policy framework to ensure access to and rational use of quality, safe and efficacious medicines and other health technologies. However, this was never put in place.

The HSA has a five-year strategic plan (2018-23), but this does not specifically set out a strategy for pharmacy services. Although HSA's five strategic objectives can be applied to pharmacy services, it is not clear how pharmacy is intended to contribute to each of these. We also found that there is no clear link between HSA's strategic plan and the Government's SBO for healthcare.

There is no strategic or business plan for pharmacy services and no formal performance management framework in place to manage and monitor performance. We found that the HSA board of directors had made some strategic decisions about pharmacy services, including the expansion and relocation to Smith Road Centre, which aims to improve service quality and capacity.

Availability, safety and quality of medicines

Despite the gaps in the legal framework, the HSA has established standards for the selection of medicines, which are aligned with international standards, to ensure the quality and safety of medicines. The HSA has a Drug and Therapeutics Committee (D&TC) that is responsible for maintaining a formulary that sets out what medicines can be used and distributed by HSA practitioners. The D&TC is effective in ensuring that medicines are sourced from jurisdictions with high quality standards.

Improvements have been made to the pharmacy inventory system, which means that the number of stock-outs and the volume of expired medicines have fallen significantly over the past five years. Storage space has increased in the main pharmacy, but shortage of space remains a problem in some district pharmacies.

Pharmacy procurement

The HSA carried out a procurement exercise in 2017 that resulted in nine contracts for the supply of medicines being awarded for the period July 2017 to December 2019. There were some challenges with that procurement exercise, and it is not clear if lessons were learned.

We found that there were a number of deficiencies in the contract provisions, which did not ensure fixed prices or best value for money. For example, the HSA's contract templates did not include standard clauses outlining consequences for late delivery or non-delivery of orders. The contracts state that the prices offered in the tender process must be fixed for the first year, and thereafter proposals for price changes should be submitted in writing; it is not clear if these provisions were enforced.

A new procurement exercise was started in December 2019. However, this made it impossible for new contracts to be awarded in a timely manner, as contracts for the supply of medicines were due to expire. The HSA prepared a business case for the pharmacy procurement that was structured in line with good practice, but the quality of options evaluated was not sufficient. We found that two of the options did not comply with the *Procurement Act* and one option was not adequately explored. The business case set out milestones, but these were not adhered to, and the procurement process suffered lengthy delays. We were told that the emergence of the COVID-19 pandemic in early 2020 further contributed to the delays in completing the procurement process. As a result, the existing contracts were extended numerous times.

The HSA cancelled the 2019 procurement exercise in early 2021 at the vendor evaluation stage, and existing contracts were further extended to March 2022. A new tender was launched in September 2021 and is expected to be completed in January 2022. Lessons learned from the 2019 and previous procurement exercises need to be applied in the current procurement exercise.

Performance management

There is no formal performance management framework for pharmacy services. HSA senior management has identified a range of key performance indicators (KPIs) that include customer satisfaction, financial performance, waiting times, staffing and quality. However, these KPIs are not adequately documented and communicated or effectively monitored.

Pharmacy services are intended to operate as a profit-generating department, but no profit target has been set and profit is not adequately measured. The only KPI reported is revenue, and the current reporting process does not present revenue and costs by location. It is therefore unclear how much profit each pharmacy location generates.

In the absence of robust performance measurement and reporting practices, it is not clear if complete and relevant information is being used to make key decisions.

Dispensary services

Since 2014, a number of improvements have been made to dispensary services at George Town and other district pharmacies. As part of our audit, we carried out a limited survey of patients at each location. The results showed that customers and patients are generally satisfied with the level of service, but there is scope to do more.

Patients are able to order their prescriptions in a number of ways (in person, by phone, online or by using a physical drop box or WhatsApp) for pick-up at pharmacy locations or delivery by the Government Administration Building (GAB) delivery service. The main pharmacy operates a 24/7 service and is open to the public 13 hours a day while other locations operate on varying schedules. However, pharmacy opening hours are not based on data such as busiest times or customer feedback; there is scope to revisit operating hours to ensure that pharmacy staff are deployed more efficiently to better suit the needs of customers.

The pharmacy waiting rooms and patient areas need significant improvement. Many are small, leading to congestion and compromising patients' privacy. Only the main pharmacy in George Town has a dedicated consultation room for confidential conversations. Plans are in place to improve facilities in George Town with the extension and permanent relocation of the main pharmacy to the Smith Road Centre later in 2021, but more needs to be done in district pharmacies to improve waiting room and confidential areas for customers and working areas for staff.

The number of outpatient pharmacists has remained relatively constant over the past five years, despite increasing demand and expansion. We have been told that the service has struggled to achieve and maintain optimal staffing at the pharmacist level as a result of high employee turnover. In response, more pharmacy technicians were recruited to assist with dispensing, almost doubling the number since 2018. This has improved efficiency to some extent, but the overall impact is limited, as all prescriptions still need to be verified by a pharmacist before medicines can be dispensed to patients.

GLOSSARY OF TERMS AND ABBREVIATIONS

Bonfire	A competitive bidding platform used by the Cayman Islands Government (and public sector) to manages the procurement process electronically end to end. Its purpose is to help public sector entities reach broader audiences through accessibility and to consolidate/streamline the various steps in the procurement process.
Central Procurement Office (CPO)	The department within the Government that oversees and provides guidance on the procurement exercised of government entities and departments.
Dispensary	A place where medicines are prepared and distributed.
Drug and Therapeutics Committee (D&TC)	The decision-making body within the HSA that determines the list of medicines to be used for inpatient care and outpatient care. The committee has no authority to make such a determination for other agencies or entities outside the HSA.
Efficacy	The effectiveness of a medicine to produce the result as determined in its development.
Entity Procurement Committee (EPC)	The committee within each government entity established to undertake the procurement process. The EPC, comprising a chairman and at least two persons appointed by the Chief Executive Officer, is responsible for reviewing the business case for purchases, evaluating purchase options and making recommendations for award.
Essential medicines	Medicines that meet the most important healthcare needs of the population and to which people should have access at all times in sufficient amounts.
Formulary	An official list of medicines that may be prescribed by healthcare providers. Medicine formularies are developed based on effectiveness, safety and cost.
Generic medicine	A medicine in the same dosage form and with the same level of safety, strength, quality, effectiveness and intended use as a medicine already marketed under a brand name. A generic medicine works in the same

way and provides the same clinical benefit as a brand-name medicine and is generally a medicine that is no longer patented.

Governance

The way in which an organisation is structured and the processes and procedures it follows to fulfil its mission or purpose and achieve desired outcomes. Effective governance in the public sector can encourage the efficient use of resources, strengthen accountability for the stewardship of those resources, improve management and service delivery, and thereby contribute to improving people’s lives.

Management

The planning, implementation and monitoring of processes, structures and arrangements to transform the available physical, human and financial resources to achieve desired outcomes.

Medicine

A substance used as a medication or in the preparation of medication; a substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.

Pharmacist

A healthcare professional who prepares and dispenses prescriptions, ensures that medicines and doses are correct, prevents harmful medicine interactions and counsels patients on the safe and appropriate use of their medications. Pharmacists are required to keep abreast of developments in pharmacy practice and sciences, professional standards and advances in the use of medicines.

Pharmacy technician

A healthcare professional who works closely with a pharmacist. Pharmacy technicians locate, dispense, pack and label prescribed medicines. Their work is then reviewed for accuracy by a pharmacist before the medicines are dispensed to the patient.

Regulation

A rule or directive made and maintained by an authority or government

Terms of reference (TOR)

A document that sets out the purpose, membership and scope of the responsibilities of a committee (such as the Drug and Therapeutics Committee).

Value for money

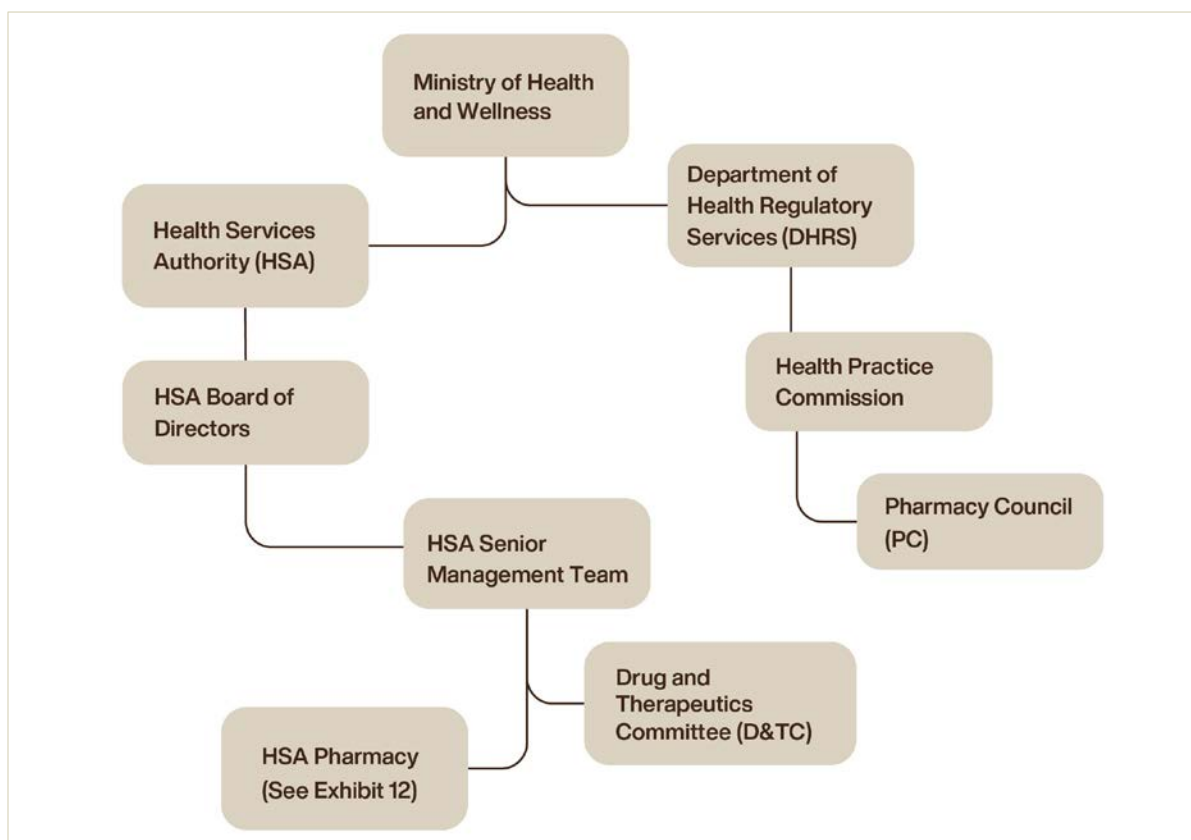
A measure of value that weighs the cost of a good or service against its quality and the benefits it brings, taking into account factors such as fitness for purpose. Maximising value for money ensures that public resources are used most efficiently and effectively.

INTRODUCTION

PHARMACY SERVICES IN THE CAYMAN ISLANDS

1. Pharmacy services in the Cayman Islands are delivered through a mix of 17 private and public sector pharmacies (some are hospital based) that are supplied by a number of local distributors. In general, pharmacies have qualified registered pharmacists on hand to review medicines for safety and efficacy and to dispense medicines to customers. Pharmacies also have good accessibility; some are open seven days a week and several pharmacies have multiple branches in different locations across the islands.
2. A number of bodies oversee healthcare, including pharmacy services, in the Cayman Islands. Exhibit 1 provides a summary of the overall governance structure for pharmacy services.

Exhibit 1 – Governance structure for pharmacy services



Note: The Ministry of Health, Environment, Culture and Housing was changed to the Ministry of Health and Wellness on 1 July 2021.

Source: OAG.

3. The Ministry of Health and Wellness (Ministry of Health) is responsible for developing and setting national strategy and policies for health.² Within the Ministry, the Department of Health Regulatory Services regulates healthcare professionals and entities through a number of professional councils, including the Pharmacy Council, that are overseen by the Health Practice Commission. The Pharmacy Council regulates all pharmacy services; its chairperson and members are appointed by the Cabinet.
4. The HSA is the primary provider of healthcare and public health services for residents of the Cayman Islands. It is a statutory authority that is wholly owned by the Cayman Islands Government and operates under the oversight of the Ministry of Health. The HSA’s mission is to “provide the highest quality healthcare and improve the well-being of the people in the Cayman Islands through accessible, sustainable, patient-focused services by highly-skilled, empowered and caring staff”. The HSA is governed by a board of directors (the board). The board comprises a Chair and members appointed by the Cabinet, as well as ex-officio public servants, including the Chief Officer of the Ministry of Health or his or her delegate. The HSA senior management is made up of the Chief Executive Officer (CEO), who is appointed by the board and is responsible for the operations of the HSA, the Deputy Chief Executive Officer, the Chief Nursing Officer, the Chief Human Resources Officer, the Director of Primary Health Care, the Director of Sister Islands Health Services, the Director of Corporate Services, the Director of Support Services, the Chief Financial Officer, the Chief Information Officer and the Medical Director, who has overall oversight of pharmacy services, together with all medical specialties, and is assisted by the Deputy Medical Director.
5. The HSA’s D&TC determines the types and quality of medicines that are prescribed by HSA clinical and medical practitioners and dispensed by HSA Pharmacy. We discuss the D&TC’s role in more detail in the Chapter on Availability, Safety and Quality of Medicines.

HSA IS A PRINCIPAL PROVIDER OF PHARMACY SERVICES IN THE CAYMAN ISLANDS

6. The HSA has the biggest pharmacy service in the Cayman Islands, operating eight outpatient pharmacies. The largest of these is the main pharmacy in the lobby of the Cayman Islands Hospital (a new location is currently being fitted out at the Smith Road Centre). The hospital campus also has an outpatient pharmacy at the General Practice Clinic (GP Pharmacy). The HSA has five satellite dispensaries that are located at the district health centres throughout Grand Cayman (in West Bay, Bodden Town, East End and North Side) and at the Smith Road Centre. Faith Hospital in Cayman

² The Ministry of Health and Wellness came into existence on 1 July 2021, as a result of the restructure of government after the April 2021 election. Prior to this, the core government entity responsible for healthcare was the Ministry of Health, Environment, Culture and Housing.

Brac also has its own pharmacy. In addition to outpatient services, the HSA also operates clinical pharmacies (dialysis, wards and oncology) within the hospital, mostly for inpatients.

- Over the four-year period 2016 to 2019, the HSA’s pharmacies dispensed over 400,000 prescriptions a year; in 2020 that number increased to over 600,000. Exhibit 2 provides a summary of annual dispensing statistics and also shows that the majority of prescriptions (between 59 and 87 per cent) was dispensed from three pharmacies in George Town (the main pharmacy, the GP pharmacy and Smith Road Centre pharmacy).

Exhibit 2 – HSA Pharmacy outpatient prescriptions dispensed over five years (2016-20)

	2016	2017	2018	2019	2020
District Clinics	76,510	77,861	79,018	72,454	17,690
George Town Pharmacies	245,207	275,451	283,685	285,202	560,034
Faith Hospital	43,315	45,257	48,144	46,723	35,612
Total	365,032	398,569	410,847	404,379	613,336

Source: HSA Pharmacy Monthly Reports.

THE COVID-19 PANDEMIC AFFECTED THE OPERATION OF PHARMACY SERVICES

- The COVID-19 pandemic has had an impact on the HSA’s pharmacy services. Some effects have been positive. For example, the safety and social distancing protocols imposed as a result of the pandemic placed restrictions on how the HSA was able to deliver pharmacy services to the public. With limited space to operate, the HSA had to quickly set up another satellite dispensary at the Smith Road Centre. This was relatively easy to arrange, as the Smith Road Centre had already been identified as the pharmacy’s new permanent location in HSA’s Master Facility Plan (2018), which sets out planned infrastructure developments over 30 years. The opening of the Smith Road Centre dispensary allowed HSA to alleviate pre-existing capacity pressures and comply with new COVID-19 safety and social distancing protocols. The pharmacy service also introduced an option for customers to order prescription refills using WhatsApp. This new service has proven popular with customers and continues to be used.
- However, the pandemic also had an adverse impact on the HSA’s ability to source medicines and contain costs. The pandemic severely disrupted supply chains, resulting in reduced availability of medicines and increased costs, including rates for shipping costs. Some suppliers were unable to honour agreements, and the HSA faced challenges because, operating in a small jurisdiction, it had limited bargaining power to negotiate the capping of prices under existing contracts. Across the world, the cost of transportation has also increased significantly since the pandemic. As the price of

medicines continues to trend upwards internationally, local suppliers have been forced to pass on costs to the HSA to maintain profitability. As a result, the overall cost of medicines (including freight) increased by approximately \$2 million in 2020 (revenue from pharmacy services over the same period increased by \$780,000).

THE HSA’S PHARMACY SERVICES HAVE IMPROVED IN RECENT YEARS BUT MORE CAN BE DONE

10. In 2014, the HSA’s Medical Director commissioned an expert pharmacist from the UK to review pharmacy operations and identify areas for improvement. The consultant prepared a report (the “2014 consultant’s report”) that made a total of 53 recommendations. Of these, 39 related to outpatient pharmacy services, covering a wide range of issues including the pricing policy, patient services, management leadership structure, technology, inventory management, clinical and formulary guidelines, and customer experience. Exhibit 3 provides a summary of progress with the recommendations. An update on the implementation of all recommendations is presented at Appendix 3 of this report.

Exhibit 3 – The HSA’s progress in implementing the consultant’s recommendations from 2014 for pharmacy services

Areas of Consultant’s Review	Total recommendations	Status of recommendations*		
		Fully Implemented	Partly Implemented	Not Implemented
Pricing policy	2	2	-	-
Pharmacy patient services	12	5	1	6
Management leadership	5	3	1	1
Technology	6	-	-	N/A
Inventory management	10	5	5	-
Clinical and formulary	3	2	1	-
Customer experience	1	-	1	-
Total	39	17	9	7

Source: OAG analysis of the 2014 consultant’s report and the HSA’s assessment of progress.

11. The HSA pharmacy service has achieved reasonable progress in implementing the consultant’s recommendations. Overall, we found that, as at the end of 2020, the HSA had fully implemented 17 recommendations and partly implemented a further nine. We discuss the progress on implementing

some of these recommendations and their impact throughout this report. However, it is worth noting that a total of seven recommendations have not been, and will not be, implemented and six recommendations are no longer relevant.

12. Of the seven recommendations not accepted, six related to improving patient services. For example, one recommendation was that prescription refills for each patient be combined so that patients need make only a single trip to the pharmacy each month, which would reduce footfall in the pharmacy and waiting time. Another was to increase the quantity of medicines dispensed on repeat prescriptions to two to three months' supply rather than one month's. At the time of the review, the West Bay pharmacy had successfully introduced both of these approaches and patients had responded well to these developments. However, the HSA later determined that the process could not be implemented at its other locations because of supply constraints that limited the quantity of medicines in stock, and it had concerns about wastage and misuse of medicines by patients. These practices have since been stopped at West Bay pharmacy. We discuss the other recommendations related to improving patient services later in this report.
13. Six recommendations related to the IT system. The Suvarna system that was in place at the time of the review has now been replaced by the Cerner pharmacy system and, as a result, the recommendations are no longer relevant.

ABOUT THE AUDIT

14. The objective of the audit was to evaluate the efficiency and effectiveness of the HSA's outpatient pharmacy services. The audit sought to answer the following questions:
 - Are the legal framework and oversight arrangements sufficient for efficient and effective pharmacy services?
 - How effective is HSA Pharmacy at ensuring the availability, safety and quality of medicines while delivering value for money?
 - How efficiently is HSA Pharmacy delivering dispensary services?
15. The audit focused on the HSA outpatient pharmacy operations over the five-year period 2016 to 2020, and covered the pharmacy stores (warehouse) and the following eight outpatient pharmacy locations:³
 - Cayman Islands Hospital main pharmacy

³ The audit used financial information from five financial periods: 2015-16 (from 1 January to 30 June 2016); 2016-17 covered the 18-month period from 1 July 2016 to 31 December 2017; and the financial year 2018 to 2020 covered the calendar year from 1 January to 31 December.

- Cayman Island Hospital GP pharmacy
- Smith Road Centre pharmacy
- West Bay Health Centre pharmacy
- Bodden Town Health Centre pharmacy
- East End Health Centre pharmacy
- North Side Health Centre pharmacy
- Faith Hospital pharmacy.

16. The audit did not cover the HSA's clinical (i.e. inpatient) pharmacies, although their informatics and quality functions support dispensary and were therefore touched upon. The audit reviewed the national health policy and strategy, which covers the private sector, and the regulation of the pharmacy sector, which includes private sector pharmacies. The audit did not cover the operations of private sector pharmacies in the Cayman Islands.

17. The report is structured into three chapters:

- Strategic Direction and Governance
- Availability, Safety and Quality of Medicines
- Performance of Outpatient Pharmacy Services.

18. More information about the audit, including the audit criteria, approach and methodology, can be found in Appendix 1 of this report.

STRATEGIC DIRECTION AND GOVERNANCE

19. Having access to safe and good-quality medicines is essential for the healthcare of the whole population. It is therefore important that governments establish a comprehensive legal framework to control and regulate substances that can enter the country and ensure the quality, safety and effectiveness of medicines that can be used in hospitals and pharmacies, and are traded by authorised distributors. The legal framework should also cover the licensing and conduct of pharmacy practitioners and standards of patient care.

THE EXISTING LEGAL FRAMEWORK IS OUTDATED AND HAS SIGNIFICANT GAPS

20. The legal framework covering pharmacy and the trading of medication in the Cayman Islands comprises several laws, including the *Pharmacy Act (1979)* and the *Health Practice Act (2021 Revision)*. In addition, the HSA is governed by the *Health Services Authority Act (2018 Revision)*. Exhibit 4 summarises the relevant acts and regulations governing pharmacy.

Exhibit 4 – Legal framework for pharmacy services

Act	Date Initially passed by Parliament	Date initially brought into force	Purpose and Main Provisions
Pharmacy Act 1979	6 Sep 1979	2 Oct 1979	Specifically enacted to control dealings in poisonous substances and pharmaceutical products. Establishes restrictions for dealing with poisons, importing and dispensing restricted pharmaceuticals, record keeping requirements and penalties for violating the Act. Includes a discretionary provision that allows for the development of regulations prescribing pharmaceuticals, poisons and restricted pharmaceuticals, procedures for importation, fees to be charges and anything by Act required to be prescribed.
Pharmacy Regulations (2017 Revision)	22 May 2017	31 May 2017	The Regulations lay out, under two Schedules, substances classified as poisons and restricted pharmaceuticals under the <i>Pharmacy Act, 1979</i>
Health Practice Act (2021 Revision)	22 May 2017	31 May 2017	Establishes the Pharmacy Council as the public oversight authority for pharmaceutical professional practice in the Cayman Islands. Establishes registration requirements for pharmacy practitioners, professional education and development requirements and codes of standards of professional practice.
Health Services Authority Act (2018 Revision)	13 March 2018	21 March 2018	Gives HSA the responsibility of managing the public health care facilities: <ul style="list-style-type: none"> • providing health care services and facilities in the Islands in accordance with the National Strategic Plan for Health; • administering the health care facilities in an efficient manner to maintain and promote the health and wellness; • making recommendations to the Minister on the development of the health care facilities and services in the Islands; • adhering to directives given by the Minister or the Cabinet under this Act; and • providing health care for employees of the Government, indigent persons and other such persons.

Note: the Health Services Authority Act (2018 Revision) applies only to HSA pharmacy services; it does not apply to private sector pharmacies.

Source: OAG analysis of legislation.

THE PHARMACY ACT DOES NOT COMPLY WITH INTERNATIONAL GOOD PRACTICE AND NEEDS TO BE UPDATED

21. The World Health Organization (WHO) *Guidelines on Good Pharmacy Practice (GGPP)* set out three necessary requirements of a legal framework for pharmacy: it should define who can practise pharmacy; it should establish the scope of pharmacy practice; and it should ensure the integrity of

the supply chain and the safety and quality of medicines.⁴ Exhibit 5 summarises the three key elements and some of the requirements of the GGPP.

Exhibit 5 – Good practice key elements of a legal framework for pharmacy



Source: World Health Organization Guidelines on Good Pharmacy Practice.

22. As part of our audit we assessed the legal framework against the GGPP and identified a number of deficiencies. Most significantly, the *Pharmacy Act*, which dates back to 1979, does not clearly outline standards for the safety, efficacy and quality of medicines that are imported or dispensed in the Cayman Islands. The GGPP recommends that minimum national standards for medicines should be established to ensure that procurement is supported by strong quality assurance principles to ensure that substandard, adulterated, unlicensed and counterfeit medicines are not procured or allowed into the system. Without these provisions the Cayman Islands is vulnerable to the risk of unsafe medicines being imported, sold and used in the healthcare system. In addition, because there are no quality criteria, the legal framework does not ensure that quality standards are consistently applied across all pharmacies. The HSA has put systems in place to assure the quality and safety of the medicines that it uses, which is discussed later in this report. The *Pharmacy Act* needs to be significantly updated to address a number of issues including narcotics control and the abuse of medication, and to set out a national list of approved medicines.

23. In addition to the WHO guidelines, other countries' legal frameworks for pharmacy could provide a good benchmark for the Cayman Islands. For example, the WHO identifies the UK and Singapore as two of leading healthcare system performers in the world. We compared the local legal framework with legal frameworks in those two countries and in Bermuda (a Caribbean jurisdiction of similar size to the Cayman Islands), and with the WHO GGPP, and identified a number of gaps. Exhibit 6

⁴ *Guidelines on Good Pharmacy Practice*, World Health Organization (WHO) Technical Report Series no. 961, 2011.

summarises the provisions that are absent from the local framework or which could be strengthened.

Exhibit 6 – Comparison of the Cayman Islands’ legal framework for pharmacy with the legal frameworks of Bermuda, the UK and Singapore and the WHO GGPP

Key Provisions	Cayman ⁵	Bermuda ⁶	UK ⁷	Singapore ⁸
Administration and Licenses Relating to Medicinal Products				
Applications for, and grant and renewal of, licenses	⊕	✓	✓	✓
Exemptions for health practitioners in respect of herbal remedies	✗	✗	✓	✓
Clinical trials and medicinal tests	⊕	✓	✓	✓
Further Provisions Relating to Dealings with Medicinal Products				
Importation and exportation of medicines	⊕	✓	✓	✓
General sale lists or formulary	✗	✓	✓	✓
Prohibition or restriction of sale, supply, or importation, of medicinal products of specified description	⊕	✓	✓	✓
Substances to be available at pharmacies only	✗	✓	✓	✓
Pharmacies and Identification of Medicinal Products				
Use of titles, descriptions and emblems	✗	✗	✓	✓
Promotion of Sales of Medicinal Products				
False or misleading advertisements and representations	✗	✗	✓	✓
Supplementary Provisions				
Power to take samples and seize goods and documents	✗	✓	✓	✓
Protection for officers of enforcement authorities	✗	✓	✓	✓

Key: ✓ meets GGPP; ⊕ partly meets GGPP; ✗ does not meet GGPP.

Source: OAG gap analysis of the pharmacy legal framework in the Cayman Islands, the WHO GGPP and relevant laws in the UK, Singapore and Bermuda.

24. Advancements in medicine and pharmacy have prompted some jurisdictions around the world to update their legal framework to maintain the effectiveness of government’s oversight of its national pharmaceutical industries; this is also good practice under the GGPP. However, the local legal framework does not adequately cover several areas, including substances used for medicinal

⁵ Pharmacy Law 1979.

⁶ Pharmacy and Poisons Act 1979 (Amended 2020).

⁷ Medicines Act 1968 (Amended 2019).

⁸ Medicines Act.

purposes (outside the legal definition of medicine), basic standards for licensed premises, equipment used and the arrangements made for storing medicinal products securely.

25. We found that the Cayman Islands' legal framework lags behind in the following areas: national formulary, restrictions for selling medicines in pharmacies only, enforcement-related powers, the promotion of medicines, rules involving titles, descriptions and emblems, and exemptions for health practitioners in respect of herbal remedies.
26. We found that other jurisdictions have more restrictive provisions in relation to the sale, and supply or importation, of medicines, and prescribe that certain medicines should meet established standards, offering greater protection to the public. The Cayman Islands does not have a national formulary, which is an approved list of medicines that can be prescribed and have been evaluated based on national quality and safety standards. Other jurisdictions also have stronger provisions for pharmacy inspections. The local framework establishes powers to inspect dispensing facilities, but their scope is not as extensive as in other jurisdictions, where the framework provides for the protection of officers of enforcement authorities and permits them to take samples and seize goods and documents.
27. In 1991, a revised *Pharmacy Act* was prepared, but this was not approved by the (then) Legislative Assembly. The revised Act would have, among other things, expanded the powers of pharmacy inspectors, enabling them to carry out tasks that are currently the responsibility of the Chief Medical Officer. However, inspections are only carried out once a year, with the risk that poor practices may not be detected and corrected. We understand that, during 2020, the Ministry of Health drafted revisions to the *Pharmacy Act* and these are in the early stages of review.

THERE ARE SOME CONFLICTING PROVISIONS IN THE LEGAL FRAMEWORK

28. Our review of the legal framework found that there are some conflicting provisions that need to be addressed. For example, we found that two different bodies have been established in law to regulate the pharmacy profession. The *Pharmacy Act* created a Pharmacy Board to regulate the industry, and in 2017 the *Health Practice Act* also created the Pharmacy Council, which was intended to work in conjunction with the Health Practice Council to regulate the industry. The scope of responsibilities of the Pharmacy Council and Pharmacy Board differ under the two pieces of legislation, but this means that responsibility for some important areas, such as the importation of poisons, is not clearly defined in law. We understand that, in practice, a Pharmacy Board has not been in place since the Pharmacy Council was created, but the legal framework needs to be updated to remove the requirement for the Pharmacy Board.

Recommendation 1: The Government should ensure that a revised *Pharmacy Act*, one that reflects international good practice, including national standards for medicines, is finalised, enacted and brought into force as soon as possible.

THE PHARMACY COUNCIL REGULATES THE PHARMACY PROFESSION BUT THERE IS SCOPE TO IMPROVE THIS

29. The Pharmacy Council was created under the *Health Practice Act* and is responsible for the regulation of professional pharmacy practice.

THE PHARMACY COUNCIL REGULATES PHARMACISTS AND ENSURES PROFESSIONAL COMPLIANCE

30. The Pharmacy Council grants registration for pharmacists to operate and maintains a register of pharmacists in good standing. In the process of validating pharmacists, the Council ensures that pharmacists comply with continuing professional education requirements. If the education requirements are not met, pharmacists lose their registration status and cannot legally provide pharmacy services. The Council publishes the register of pharmacists in good standing on the Department of Health Regulatory Services website and in the *Cayman Gazette*.

31. In May 2011, the Pharmacy Council developed and adopted a Code of Standards of Professional Practice (CSPP) for Pharmacists. The CSPP is based on the National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards of Practice for Canadian pharmacists, and compares well with good practice and standards for pharmacists in other jurisdictions.⁹ The CSPP outlines the professional duties and level of professional care required from all registered pharmacists and incorporates the code of ethics for pharmacists, in line with the requirements of the *Health Practice Act*. The CSPP is divided into 11 codes of professional practice, including, for example, the requirement for pharmacists to continuously improve their professional competence and to establish and maintain patient relationships based on an ethical covenant. The CSPP incorporates the concepts of ethics, self-directed learning and professional identity, and sets out specific professional competencies that require pharmacists to have a broad, integrated knowledge of the core pharmacy information and effective communication skills and to exhibit professional conduct, demonstrate altruism, accountability, excellence, duty, integrity and respect for others.

32. The Pharmacy Council does not have the powers to regulate the carrying on of pharmacy businesses, or to restrict business activity. This means that the Pharmacy Council must collaborate with other agencies, such as the Department of Health Regulatory Services or the Royal Cayman Islands Police Service, to investigate instances of reported malpractice or illegal operations. However, we have been told that this approach is not always effective.

⁹ NAPRA is an alliance of pharmacy regulatory agencies established to protect and serve the public interest.

THE PHARMACY COUNCIL HAS NOT IMPLEMENTED A REGULATORY FRAMEWORK FOR PHARMACY TECHNICIANS

33. The *Health Practice Act* also gave the Pharmacy Council powers to regulate the professional practice of pharmacy technicians. However, the Council has not yet implemented any aspects of regulation for pharmacy technicians. This creates a risk that pharmacies may not be operating to the highest standards. At the time of our audit, the Pharmacy Council had drafted standards of practice for pharmacy technicians and we were told that these were being reviewed, but the target date for finalisation was not clear. In the absence of approved standards of practice, the HSA sets its own standards for its pharmacy technicians, who must sit a (US) State Board certification course.

Recommendation 2: The Pharmacy Council should ensure that standards of practice for pharmacy technicians are finalised, published and brought into force as soon as possible.

THERE IS NO CLEAR STRATEGIC DIRECTION FOR PHARMACY SERVICES

34. To ensure that policies, practices and organisations achieve the intended outcomes, there needs to be clear leadership and strategic direction. These are generally provided through strategic plans that set out the overall vision, strategic objectives, goals, actions planned to achieve goals, and how success will be measured. Governments across the world have medium- to long-term strategies for significant policy areas, such as healthcare, and most organisations (public and private sector) also have strategic plans.

THERE IS NO NATIONAL HEALTH STRATEGY

35. We reported in 2017 that the Ministry had developed a national health policy and strategic plan (the strategic plan) for the five years 2012-17, but action plans were not in place to support the execution of the strategy.¹⁰ The 2012-17 strategic plan included nine strategic directions based on the then current and forecasted health situation, but it had no specific broad objective for pharmacy. The strategic plan covered areas such as workforce, collaboration for prevention, service delivery and health information, all of which have implications for pharmacy services. One of the objectives in the strategic plan was to establish an action plan to ensure access to and rational use of high-quality, safe and efficacious medicines and other health technologies, but this was never put in place. The strategic plan expired at the end of 2017 and a new strategy has not been developed.

36. However, since then all of the Government's Strategic Policy Statements (SPSs) have included an SBO on healthcare. The 2020-21 SPS has an SBO of "Access to quality, affordable healthcare", which

¹⁰ *Ensuring Quality Health Care and a Healthy Population*, Office of the Auditor General, January 2017.

included a specific outcome that seeks to use new procurement practices to reduce the cost of medicines and equipment. This has clear implications for pharmacy and the HSA, but it is not clear how it was intended to be achieved. The recently published SPS for 2022-24 includes the SBO “Ensure an equitable, sustainable and successful healthcare system”.¹¹ This includes a number of specific outcomes that may have implications for pharmacy services, for example, improving facilities in district clinics and reducing waiting times.

Recommendation 3: The Ministry of Health and Wellness should prioritise the development of a new national strategy for health, one that provides overarching direction for pharmacy services and the use of medicines, and publish this as soon as possible.

THE HSA HAS A STRATEGIC PLAN BUT IT IS NOT CLEAR HOW PHARMACY SERVICES ARE EXPECTED TO CONTRIBUTE TO THIS

37. The HSA’s strategic plan 2018-23 includes the following objectives:

- to implement a financial management framework to sustain operations by 2023;
- to have at least 90 per cent of the population rate the HSA as satisfactory or better for high-quality healthcare by 2020;
- to maintain and provide facilities that meet recognised international standards and support service delivery by 2023;
- to strengthen services for the improvement of women’s health by 2020;
- to continuously decrease the incidence and adverse effects of chronic non-communicable diseases (e.g. obesity, diabetes, cancer, hypertension, etc.).

38. Our review of the HSA strategy found that it does not reference the Government’s SBO for healthcare. As reported previously, the 2020-21 SPS included a specific outcome that sought to use new procurement practices to reduce the cost of medicines and equipment. Although the HSA’s strategic objectives fit with the Government’s SBO, it is not clear how the HSA’s strategic actions and plans are intended to contribute to the achievement of the SBO or the specific outcome, as they are not mentioned in the HSA’s strategic plan. As outlined above, the Government has recently published the SPS for 2022-24, which includes a revised SBO for healthcare. It is important that the HSA, as the main healthcare provider in the Cayman Islands, has a strategic plan that clearly aligns with the Government’s vision and strategic priorities for healthcare and demonstrates how the HSA will support the delivery of that vision.

¹¹ 2022-2024 Strategic Policy Statement, Cayman Islands Government, July 2021.

39. Our review also found that, although the HSA’s five strategic objectives have implications for pharmacy services, it is not entirely clear how the pharmacy service is intended to contribute to each of these. For example, one goal in the strategic plan is to strengthen primary healthcare at the HSA by enhancing patient services, health promotion and disease prevention activities. However, there are no clear targets for departments, including pharmacy services, to contribute to the achievement of this goal. The HSA’s third strategic objective is to provide, by 2023, facilities that meet recognised international standards and support service delivery. To enable the delivery of this objective, the HSA developed a master facility plan in 2018; approved by its board of directors and later by the Cabinet. The plan included the expansion of a satellite pharmacy at Smith Road Centre and the expansion and renovation of pharmacy stores. Renovations to the pharmacy stores warehouse were completed in the first quarter of 2021. The planned retrofitting of the Smith Road Centre, the future site of HSA’s main pharmacy, started in February 2021 and was expected to be completed in the third quarter of 2021.

Recommendation 4: The Health Services Authority should ensure that its strategic plan clearly aligns with the Government’s priorities and Strategic Broad Outcomes for healthcare, and provides clarity on how departments, including pharmacy services, are expected to contribute to the Government’s strategic objectives.

THERE IS NO CLEAR PLAN FOR PHARMACY SERVICES

40. The Royal Pharmaceutical Society of Great Britain’s *Guide for Chief Pharmacists or Equivalent* states that pharmacy leaders are required to have the skills to negotiate at board level, to provide the vision necessary to strategically consolidate the position of pharmacy to play a key role in the future and to manage change in a dynamic environment.¹²

41. Our review of the job descriptions of the two pharmacy managers, that is, the Chief Pharmacist and Pharmacy Stores Manager, revealed that they included the following strategic planning objectives:

- develop a clear vision for the pharmacy service and a business plan that takes account of, and reflects, the demand for services from government and local and national trends and developments and which adhere to the HSA’s strategic plan;
- develop strategies to implement national pharmacy initiatives to improve efficiency, reduce risk and enhance the patient experience;
- develop and implement information services in line with new technology;

¹² *Guide for Chief Pharmacists or Equivalent*, Royal Pharmaceutical Society of Great Britain, June 2020.

- manage the supply chain to ensure timely availability of all pharmaceutical products and adequate stock levels; and
- manage the pharmacy purchasing budget.

42. Although the Chief Pharmacist and Pharmacy Stores Manager deliver against some of these objectives, we would expect them to provide more strategic direction. For example, there is no business plan for pharmacy services, and it appears that much of the strategic direction for pharmacy is provided at a higher level by the Medical Director and Deputy Medical Director rather than by the Chief Pharmacist.

Recommendation 5: HSA Pharmacy should develop a business plan that sets out how pharmacy services will be delivered efficiently and effectively to meet current and future needs, sets success measures that allow performance to be monitored, and demonstrates how pharmacy services will contribute to the HSA’s strategic objectives.

GOVERNANCE OF PHARMACY SERVICES COULD BE IMPROVED THROUGH BETTER REPORTING

43. As reported earlier, the HSA’s senior management has responsibility for pharmacy services (Exhibit 1). In practice, the Medical Director has overall responsibility and oversight for pharmacy services and the pharmacy stores, and reports to the HSA board as appropriate.

THE HSA BOARD OF DIRECTORS PROVIDES OVERSIGHT

44. The HSA board of directors is responsible for providing proper scrutiny and oversight to ensure that the HSA is achieving its strategic objectives. The board is supported by a number of subcommittees, including the Risk Subcommittee, which oversees quality control and other related risks. There is another Risk Management Committee at the management level, and these two bodies work together closely to identify, monitor and address healthcare risks. However, there is no performance management or reporting system in place at the HSA that would allow the board to effectively and comprehensively track the progress of its strategic objectives that would need to be delivered through HSA operations, including pharmacy services.

45. We understand that the board (and senior management) operates a system of exception reporting, that is, rather than receiving updates on every corporate and clinical area, it is updated on issues that are deemed important or significant enough to be brought to its attention, and is consulted when a decision or approval is required. The board receives regular updates from senior management and its subcommittees. For example, the CEO provides a regular monthly update on matters relating to risk management, key projects and overall financial performance. The Medical Director attends board meetings, and important matters related to pharmacy are communicated as part of the CEO’s report or as a separate agenda item.

46. We reviewed the minutes of HSA board meetings between January 2015 and December 2020 and found some discussions and actions in relation to pharmacy services. Matters discussed included a shortfall in the pharmacy budget, the recruitment of a Business Coordinator to oversee revenue collection, procurement challenges and delays in the tender process, and procurement possibilities (partnering with other Caribbean countries). The board also approved certain plans for pharmacy, as part of the HSA's budget process, including the decision to relocate pharmacy services to the Smith Road Centre. We noted that the minutes did not record any updates to the board on the progress of relocation plans.
47. As reported earlier, the Chief Officer of the Ministry of Health (or delegate) is an ex-officio member of the HSA board of directors, but we found that the current Chief Officer has not regularly attended board meetings. We also noted that there were no directives from the Ministry of Health to the HSA generally or related to pharmacy services during the period of examination, for example the strategic outcome of pharmacy procurement.

REPORTING ON PHARMACY NEEDS TO IMPROVE

48. The pharmacy service prepares monthly reports for its Grand Cayman dispensaries, but these are not structured in a way that supports strategic oversight by HSA senior management. We would expect reports on pharmacy performance from the Chief Pharmacist to the Medical Director and Deputy Medical Director, to include information that would inform:
- workforce planning, such as dispensing volumes and trends per location;
 - procurement, such as dispensing volumes by medicine type;
 - service delivery, such as average waiting time per patient and delivery mode statistics (drop-off, WhatsApp, online refill applications); and
 - quality assurance, such as errors and near-misses.
49. We would also expect to see a report on financial performance that captures all pharmacy cost centre revenue and costs by location, which would allow management to monitor the profitability of the main pharmacy and all dispensaries.
50. We found that reports contain information about day-to-day operations such as staffing levels and updates on the progress of projects such as the relocation to Smith Road Centre and how related issues were resolved. However, the reports are inconsistent and provide limited information to assist in decision-making. The pharmacy stores produces quarterly operating reports that provide information on personnel, purchases, medicine stocks and stock movement. However, the district clinic pharmacies do not prepare monthly reports. We found that the district pharmacies function relatively autonomously and have varied dispensing logistics and policies across locations. Oversight by management is limited to resource allocation managed by pharmacy team leaders and matters raised by district pharmacists with the Chief Pharmacist during ad hoc discussions or calls.

51. There is a need for better strategic reporting throughout the entire pharmacy service that incorporates reporting against agreed performance outcomes to support effective decision-making. The final chapter of this report focuses on pharmacy performance and provides examples of some of the performance metrics that could be regularly reported to management to better inform decision-making.

Recommendation 6: HSA Pharmacy should improve its reporting on pharmacy, by including performance information and ensuring that the information included is consistent and covers all locations to better inform decision-making at the senior management and board levels.

AVAILABILITY, SAFETY AND QUALITY OF MEDICINES

52. The World Health Organization states that, because medicines are critical to the effectiveness of any healthcare system, healthcare providers need to ensure that safe, good-quality medicines are accessible at the right time to the people who need them.¹³ To achieve this, governments and healthcare systems need to collaborate with stakeholders, and to have strong and effective processes in place to manage medicine selection, procurement and distribution.

53. As reported earlier, the Cayman Islands legal framework does not have adequate provisions to ensure the availability, safety and quality of medicines. However, the HSA has put measures in place to ensure the availability, safety and quality of medicines through three main vehicles, which we will discuss in this chapter of the report:

- the Drug and Therapeutic Committee (D&TC);
- the procurement of medicines; and
- the internal supply chain.

54. A number of HSA departments and committees play important roles, and act as checks and balances to ensure that effective controls are in place for the availability, safety and quality of medicines (Exhibit 7).

Exhibit 7 – HSA departments and committees’ roles in ensuring the availability, safety and quality of medicines



Source: OAG interviews with HSA senior management

¹³ *Effective Drug Regulation: what can countries do?*, World Health Organization, 2002.

55. The Pharmacy Department, including all of the dispensaries, and the Pharmacy Stores Department are the key departments involved in ensuring the availability, safety and quality of medicines. The Pharmacy Stores Department monitors inventory levels and ensures that medicines are stored safely and efficiently distributed to dispensaries. The D&TC manages the HSA formulary through its decisions on what medicines should be removed or added, and therefore controls the quality of medicines that can be prescribed by HSA medical practitioners and dispensed by HSA pharmacists. The Procurement Department and HSA Entity Procurement Committee (EPC) provide key supporting roles by overseeing and managing procurement of medicines for the pharmacy. The Risk Management Department and Risk Management Committee provide further support to the pharmacy, although indirectly, through data collection and by reporting on quality-related matters.

THE HSA ADOPTS HIGHER STANDARDS THAN LAWS REQUIRE TO ENSURE THE SAFETY AND QUALITY OF MEDICINES

56. As reported earlier, the legal framework does not set national safety standards for medicines. However, in 2008 the HSA established the D&TC to set up and maintain a formulary of all medicines that can be prescribed, and which is used by HSA medical practitioners when selecting the most appropriate medicine to prescribe to patients.
57. The formulary is a list of approximately 1,200 medicines that are authorised for use within the HSA. Since 2008, the DT&C has added 191 new medicines to, and removed 53 medicines from, the formulary.¹⁴ Medicines were removed for various reasons, such as obsolescence due to advancements in medicine. The formulary streamlines procurement, improves medicine availability, improves the ease of dispensing due to familiarity, and allows better recognition of adverse medicine reactions.
58. We found that the lack of a formulary and clearly defined safety standards at the national level may be adversely affecting the HSA pharmacies' competitiveness. For example, HSA charges more for some medicines than its competitors, but this may be a direct result of the higher standards that HSA has put in place to ensure the quality and safety of medicines that it stocks and dispenses to customers. The HSA's competitors may be able to procure medicines at lower prices, but this may be because they are sourced from jurisdictions or suppliers that the HSA has determined do not meet its safety and quality standards. The HSA's pricing policy allows for price matching when such instances are brought to the attention of pharmacy management, and any subsequent reduction in price to match competitors is approved by senior management.

¹⁴ The HSA formulary is published on the HSA website.

THE PURPOSE AND GOALS OF THE D&TC ALIGN WITH GOOD PRACTICE BUT SOME ARE NOT YET IMPLEMENTED

59. The DT&C’s terms of reference set out its purpose and goals. It is responsible for developing, managing and updating the hospital formulary, evaluating non-formulary medicines, maintaining the essential medicines list, developing and implementing standard medicine treatment guidelines, and providing education and objective medicine information for prescribers. Our assessment found that the D&TC’s terms of reference are in line with international good practice.¹⁵
60. However, we found that the D&TC does not yet comply with some of its terms of reference. Exhibit 8 assesses the D&TC’s terms of reference against good practice and assesses whether the terms are being implemented.

Exhibit 8 – Terms of Reference of the D&TC compared with good practice

Goals of the D&TC	Aligned with Good Practice?	Implemented by D&TC?
Develop and implement policies and guidelines on the use of medicines within HSA.	✓	✓
Evaluate non-formulary medicines, recommend for approval and review uses accordingly.	✓	✓
Monitor trends in medicine expenditure and consider financial outcomes.	✓	✓
Commission, organise and approve clinical audit of medicines prescribed in the hospital	✓	✗
Evaluate, promote and disseminate information on medicines to all health care professionals within HSA as requested.	✓	✓
Develop, manage and update a hospital formulary and essential medicines list	✓	✓
Develop and implement standard medicine treatment guidelines	✓	✓
Conduct medicine utilization reviews in the hospital	✓	✗
Provide prescribers with objective medicine information	✓	✓
Conduct educational and other activities aimed at improving prescribing and dispensing practices.	✓	✓
Monitor and report adverse medicine reactions trends	✓	✓
Monitor medication errors and act to prevent their recurrence.	✓	✗
Regulate operations of the pharmaceutical industry in the hospital.	✓	✓

Source: OAG’s assessment of D&TC’s Terms of Reference against WHO guidelines

¹⁵ The World Health Organization (WHO) Department of Essential Medicines and Medicines Policy, in collaboration with the Rational Pharmaceutical Management Plus Program of Management Sciences for Health, has published a manual, *Drug and Therapeutics Committees: a practical guide*, which provides guidance on the functions and structure of drug and therapeutics committees, the medicines formulary process and how to assess new medicines in hospitals.

61. We found that the D&TC does not ensure that clinical audits of medicines prescribed in hospital are conducted or monitor medication errors (although we understand that a policy for this is currently being developed). We also noted that medicine evaluation procedures and criteria for medicine selection are not published. It is important, for transparency and to prevent any future misinterpretation of the underlying rationale, to document these procedures. One of the goals of the D&TC is to monitor trends in medicine expenditure and consider financial outcomes, which it achieves through the addition of mostly generic medicines to the formulary.
62. We were told that although the D&TC does not carry out these activities, the HSA has processes in place to mitigate these deficiencies. The Chief Pharmacist oversees the clinical audit of medicines dispensed throughout HSA, and the Quality Assurance and Risk department captures and reports on some of the medication errors. We discuss error reporting later in the report.

Recommendation 7: The Drug & Therapeutics Committee should ensure that it carries out all of the functions specified in its terms of reference.

THE D&TC MANAGES THE FORMULARY EFFECTIVELY TO ENSURE SAFETY AND QUALITY

63. The D&TC has been effective in ensuring that medicines included in the formulary are of high quality based on international standards. The D&TC bases its decisions on information from the Food & Drug Administration (FDA) in the USA and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The FDA and MHRA approve medicines based on an assessment of data on the medicines' effects to determine if the medicine's benefits outweigh the known and potential risks for the intended population.¹⁶ This does not mean that medicines without FDA or MHRA approval are ineffective or unsafe, but approval provides assurance that medicines administered to the public meet objective quality standards and are unlikely to cause harm.
64. The D&TC holds regular and special committee meetings at which it decides, based on clinical requirements, which medicines should be added to or removed from the HSA formulary. Individual physicians or committee members can propose the addition of new medicines based on needs as well as developments in the international community, for example, new developments in cancer treatments. Proposals may suggest the addition of medicines for general use or for specific patients. The D&TC researches and discusses the medicine from a clinical perspective to determine whether the medicine is suitable for inclusion in the HSA's formulary and the quantity to be kept in stock. The D&TC requires generic medicines to be included in the formulary where available, which provides the flexibility to balance high-quality, efficacy standards and cost-effectiveness.

¹⁶ MHRA UK–FDA Confidentiality Commitment, Food and Drug Administration, January 2018.

THE HSA'S PROCUREMENT OF MEDICINES NEEDS TO SIGNIFICANTLY IMPROVE

65. The HSA spends around \$9 million a year on medicines. It therefore needs to have an effective procurement process in place to ensure that it obtains best value for money.
66. The *Procurement Act (2016)* and the *Procurement Regulations (2018)* came into force on 1 May 2018, and set out the legal framework for procurement of goods and services by the Cayman Islands public sector. The *HSA Procurement Policy and Procedures Manual* outlines the minimum requirements for purchases of goods and services and helps ensure that procurement practices follow legal guidelines. The current policy manual became effective on 1 January 2020 but does not differ significantly from the previous version of the manual. Exhibit 9 provides a high-level summary of HSA's procurement process.

Exhibit 9 – The HSA procurement process



Source: *HSA Procurement Policy and Procedures Manual*.

67. The HSA procurement process requires that a business case is prepared that identifies a range of options and selects the most appropriate one. An invitation to tender is then published on the Government's central procurement website, and potential suppliers submit bids to supply products. The suppliers and bids are scored based on predetermined criteria and the highest-scoring suppliers are recommended for approval. Once the necessary approvals are granted, contracts are awarded to suppliers and unsuccessful bidders are notified. Owing to the high value of the contracts, pharmacy procurement also involves open tendering and independent approval of contracts by the Public Procurement Committee.
68. The CEO has overall responsibility for procurement and appoints the members of the HSA EPC. The HSA EPC is chaired by the Chief Operations Officer and includes four senior management team members, as well as two other middle managers and a nominee of the Chief Officer of the Ministry of Health. The HSA EPC supports the CEO in ensuring compliance with the legal framework and policy, and is responsible for reviewing business cases, tenders from bidders and contracts before they are signed, and for recommending courses of action to the CEO, including recommending which companies should be awarded contracts.

THE HSA DID NOT LEARN LESSONS FROM THE PREVIOUS PROCUREMENT EXERCISE

69. An essential element of effective procurement is being an intelligent customer, to ensure that informed decisions are made throughout the procurement process. An integral part of being an

intelligent customer is improving the process based on previous experience, particularly if it proved difficult or resulted in poor value for money.

70. In September 2017, the HSA conducted a procurement exercise for pharmacy, which resulted in nine contracts being awarded for the supply of medicines from July 2017 to December 2019. We found that the HSA did not carry out a lessons learned exercise from that procurement process. However, from our review of the process and documentation for the 2017 procurement exercise we identified the following lessons that should have been learned:

- Starting the tender process earlier and setting milestones for completion of the tender evaluation avoids prolonged delays.
- Exploring enhanced procurement options would improve alignment with the Government's SBO for healthcare.
- Issuing contracts with stricter adherence provisions provides better control of prices and ensures value for money.
- Removing the reverse auction element from the procurement process as this did not generate the benefits intended.¹⁷

71. The HSA started another procurement exercise in December 2019 to replace contracts that expired at the end of December 2019. However, we found that few of the lessons that we have identified were taken into account. The most recent procurement exercise used a similar procurement route to the 2017-19 procurement exercise, with the exception that it did not include a reverse auction. It was decided that a reverse auction is not well suited for pharmacy procurement because price is not the main determinant.

THE BUSINESS CASE FOR THE 2020-21 PHARMACY PROCUREMENT WAS LATE AND THE QUALITY OF OPTIONS CONSIDERED WAS POOR

72. The *Procurement Act* requires that a business case is prepared, which should be reviewed by the EPC and approved by the CEO. The business case should identify a range of procurement options and select the most appropriate one.

73. The HSA prepared a business case but it was not completed until February 2020, and was not approved until May 2020. This meant that the procurement exercise did not start early enough to have new contracts in place for the supply of medicines before the contracts expired at the end of December 2019. We also noted that the request for proposals (RFP) was issued prior to the business

¹⁷ In a reverse auction, sellers bid the prices they are willing to be paid for their goods and services.

case being approved. The business case set out key milestones for the 2020-21 procurement. Exhibit 10 sets out key milestones identified in the business case and revised dates.

Exhibit 10 – HSA Pharmacy tender timeline

Milestones	Dates established in Business Case	Revised dates (due to delays in the process)	Revised dates met or not met?
RFP Issue date	February 28, 2020		
Initial ranking of proponents	April 24, 2020	June 3, 2020	Not Met
Final ranking of proponents	May 1, 2020	June 12, 2020	Not Met
Execution of Agreements	July 1, 2020	None	Not Met

Source: Central Procurement Office website, Bonfire.

74. The 2020-21 procurement process was also subject to significant delays, and none of the revised dates were achieved. We were told that the tender evaluation stage was prolonged initially because of COVID-19, as all resources were focused on response initiatives, but it was also the case that the procurement process was not prioritised.
75. Delays in the procurement exercise mean that potential suppliers may not be able to honour the prices that they submitted in their bids in June 2020. We found that this was also the case in the 2017 procurement exercise when, as a result of the protracted process, many suppliers did not uphold the prices in their bid submissions when it came time to award the contracts, months later.
76. To ensure value for money it is essential that all procurement options are explored. However, we noted that alternative options such as framework agreements or longer-term contracts were not considered in the business case. A framework agreement is a type of contract that establishes a long-term relationship with multiple suppliers to ensure that the goods are always available, and is allowable under the *Procurement Act*.¹⁸ We have previously reported that awarding two-year contracts may not achieve best value for money for the buyer or the supplier because of the considerable effort involved in the procurement process. Longer-term contracts may also encourage suppliers to offer lower prices, as they have the certainty of income for a longer period of time.¹⁹ Longer-term contracts have the benefit, for both HSA and suppliers, of reducing the administration associated with the procurement process, as it is carried out less frequently. In the case of

¹⁸ *Everything you need to know about a framework agreement*, Thornton and Lowe, July 2020.

¹⁹ *Government's use of outsourced services*, Office of the Auditor General, June 2019.

framework contracts, the HSA could benefit from greater bargaining power over price because of competition among suppliers in the framework.

77. Our review of the HSA’s business case for the 2020-21 pharmacy procurement found that it included some good practice.²⁰ For example, it outlined and discussed five options for the procurement process, each of which was evaluated against criteria such as the benefits delivered, strategic fit, costs and risks. However, the options appraised were not sufficiently wide. For example, one option that was not included was dividing the product offering into smaller bundles, which might have made bidding and evaluation less time-consuming. For example, medicines could have been subdivided into smaller bundles such as specialist medicines or high-cost/low-volume medicines. In addition, considering longer-term contracts may have resulted in reduced prices and lowered the administrative cost of procurement. We also found that the five options identified and appraised were poor. Exhibit 11 summarises each of the five options and our assessment of these.

Exhibit 11 – The OAG’s assessment of the five business case options

Option	OAG assessment
1 Status Quo i.e. let existing contracts expire and do not re-tender	Although do nothing is an option that most business cases include, letting existing contracts expire without re-tendering is not really an option for HSA as it would not be able to function effectively without medicines.
2 One year supply contract	As outlined carrying out a procurement exercise to award a one-year contract is unlikely to deliver value for money as the costs would be significant and may outweigh the benefits.
3 Two year supply via HSA Tender	This could be deemed reasonable, but for a six month tender evaluation process, setting contracts for two years may not be the most efficient strategy.
4 Extend existing contracts for further period – extending contracts based on the 2017 procurement	This option does not comply with the <i>Procurement Act</i> .
5 Group buy with another entity in joint procurement to leverage increased buying power	The business case prematurely discounted this option. It stated that it was non-compliant with the law but HSA did not seek advice from the CPO was not obtained in making this determination. The <i>Procurement Act</i> does not preclude group buying.

Source: OAG Assessment of the Business Case – Pharmacy Tender 2019/2020.

²⁰ Based on *Better Business Case Five Case Model Templates and Guidance*, HM Treasury.

78. The business case recommended option 3, the option to repeat the procurement method from the 2018-19 cycle, as this option was considered to deliver the most benefits, was second cheapest and carried the lowest level of risk.

CURRENT CONTRACTS FOR MEDICINES HAVE EXPIRED AND DO NOT ENSURE VALUE FOR MONEY

79. As a result of the 2017 procurement exercise, the HSA awarded nine contracts to suppliers of medicines. In 2014, the consultant recommended that contracts with pharmacy suppliers include penalties for supplier failure to honour contract terms and conditions and prices. However, we found that, although the contracts were prepared using HSA contract templates, some standard clauses, including consequences for late delivery or non-delivery and insurance requirements, were not included. We also found that the contracts required prices to be held constant by suppliers for at least one year, but it was not clear if this clause was actually honoured by suppliers or enforced by the HSA.

80. The nine contracts expired at the end of 2019. The contracts have been extended a number of times since then as a result of delays in the 2020-21 pharmacy procurement exercise; each contract extension was awarded for three and six months at a time. *The Procurement Act* requires that any contract extensions are approved by the Public Procurement Committee. This did not happen. At the time of our audit, contracts had been extended to 31 March 2022.

81. As reported earlier, since the contracts expired, the COVID-19 pandemic has arisen, and has had, and continues to have, an adverse impact on the supply and cost of medicines. As a result, the price and availability of medicines are subject to broader market forces, purchasers have limited bargaining power and current contract terms and prices cannot be enforced.

THE PROCUREMENT APPROACH USED WAS RESOURCE INTENSIVE AND LACKED TRANSPARENCY

82. The HSA published its Request for Proposals (RFP) on 28 February 2020 both in the print media and on the Government's procurement website (Bonfire).²¹ Letters were also sent to various industry contacts to ensure that a wide audience was informed of the opportunity. The RFP was based on the business case and communicated essential information to potential bidders about the tendering process to ensure that it was fair and effective. However, as noted earlier, the RFP was issued prior to the business case being approved.

²¹ Bonfire is a software vendor that has developed a strategic sourcing platform used by public agencies to run and evaluate bids for goods and services.

83. We found that the procurement approach selected resulted in a resource intensive tender process. For example:

- The tender process required potential bidders to input detailed bids for more than 1,200 items. Prior to the submission date for bids, the HSA responded to many questions from potential suppliers about the information that was to be included.
- The Evaluation Committee carried out a two-step evaluation. In the first step, bids for items that did not meet the quality standards expected were identified and eliminated. This required up to 1,200 items to be assessed for each bidder. All remaining items were then subject to a second evaluation, to identify the bidder offering the lowest cost for each item.

84. We also found that the RFP included a scoring mechanism for several factors but this scoring mechanism was not used in the process. This creates a risk that potential bidders could challenge the evaluation process.

THE PHARMACY TENDER WAS CANCELLED IN 2021

85. In early 2021, HSA senior management reviewed the status of the tender evaluation and made a decision to discontinue the current process and to relaunch the procurement exercise later in 2021. We were told the following in relation to the delays and subsequent cancellation of the procurement exercise:

- Not only was the initial launch of the tender delayed, but the evaluation was delayed several times as a result of the impact of the pandemic and reduced availability of personnel. Pricing received from vendors was also inconsistent, and some vendors were unable to commit to prices.
- A number of procurement options have since been explored in the context of the procurement regulatory framework and the ongoing need for supplies in a COVID-19-influenced operating environment.
- The Procurement Manager has led a review of the abandoned 2020-21 procurement exercise to learn lessons.
- A new business case incorporating the interim and future procurement plans has been finalised and approved by the Entity Procurement Committee. A member of staff from the CPO provided guidance on the revised business case to ensure that it complied with legal requirements. The business case was submitted for public tender on 16 September 2021.
- In the interim, current vendors have been asked to provide revised price lists, and these have been used as the basis for awarding contracts for a period of one year to 31 March 2022, to allow time for the HSA to redo the procurement exercise. The CPO has also been notified of this.

- Vendor reluctance to provide firm pricing (given current global market issues) remains an ongoing risk. The contract template will contain provisions which we anticipate should sufficiently protect the HSA.
- The HSA's next steps include:
 - Receive tender bids by midday, 12 November 2021.
 - Completing evaluation of bids by 3 December 2021.
 - Submitting contract awards for consideration to PPC for its January 2022 meeting.
- The target date to issue new awards is largely impacted by the availability of clinical teams currently stretched due to recent community outbreaks of COVID-19.
- The HSA intends to provide additional resources to the Procurement Unit to enable it to give more assistance to the various cost centres, all of which procure through this Unit.

Recommendation 8: The Health Services Authority should ensure that pharmacy procurement is planned and overseen effectively to ensure that the process is completed in a timely manner.

Recommendation 9: The Health Services Authority should explore alternative contract options that would allow for better control of price increases from suppliers.

THE INTERNAL SUPPLY CHAIN HAS IMPROVED AND IS EFFECTIVELY MANAGED

86. In 2014, the external consultant made 10 recommendations aimed at improving pharmacy stores and the internal supply chain. As at December 2020, five of these recommendations had been fully implemented and five were partly implemented. For example, recommendations implemented included the recruitment of a dedicated Pharmacy Stores Manager and establishment of the Pharmacy Stores Department, and improvements to stock control.

87. The Pharmacy Stores Department is responsible for ensuring that there is an effective internal supply chain for medicines, that is, medicines are available, safe and of sufficiently high quality to be dispensed to patients. This involves a number of factors including the following:

- having controls in place to ensure that the right items arrive at the HSA and are stored safely while awaiting dispensing;
- clear decisions about which items to stock and how many, which should be based on the volume of consumption and the turnaround time of suppliers; and
- ensuring that there is sufficient storage space and facilities to keep items safe and that medicines are stored as required, for example refrigerated, and ensuring adequate stock rotation so that medicines do not expire.

PHARMACY STORES HAVE BEEN EXPANDED AND STAFF FOLLOW INTERNATIONAL GOOD PRACTICE

88. The WHO has developed good practice guidance on the storage of medicines in community and hospital pharmacies.²² Pharmacy Stores manages its operations using standard operating procedures that align with the WHO's good practice.
89. We found that all Pharmacy Stores staff have appropriate guidelines to follow in relation to ordering, receiving stocks, storage of medicines and managing expiration dates. As an added quality assurance measure, the Chief Pharmacist also arranges for a sample of medicines to be tested by the Caribbean Public Health Agency Drug Testing Laboratory in Jamaica.
90. In early 2021, the Pharmacy Stores warehouse underwent renovation, which involved replacing shelving, fixtures and equipment, resulting in increased storage capacity. It is not clear by how much the storage and working areas were increased, but we found the new facilities to be sufficient in size to manage the current inventory volume.

STOCK MANAGEMENT HAS IMPROVED AT PHARMACY STORES

91. Historically, stock-outs and stock shortages at HSA Pharmacy have been a significant problem. The term 'stock-out' means that one or more medicines are unavailable because supplies are completely used up before new orders are received or can no longer be sourced. In 2014, the consultant made a number of recommendations aimed at improving pharmacy stores and the internal supply chain. Since then, stock-outs have become relatively uncommon.
92. The Pharmacy Stores Manager monitors inventory levels on an ongoing basis, with mass reorders implemented every two to three months. In January 2021, the department implemented the Pharmacy suite of Cerner, which provides real-time stock information and includes a feature that generates a summary of medicine reorder quantities using historical data including average daily usage over 30 days. This, we are told, has made inventory management easier and more efficient. To prevent stock-outs, orders are placed early to ensure that new supplies arrive before the stock on hand is used up. We report on the availability and management of pharmacy stock at the dispensaries in the following chapter.

²² *Guide to good storage practices for pharmaceuticals*, World Health Organization, 2003.

PERFORMANCE OF OUTPATIENT PHARMACY SERVICES

93. Pharmacy services are an integral element of healthcare services, and it is essential that they are delivered efficiently and effectively. It is also important that the performance of the pharmacy service is measured and reported, to demonstrate value for money and areas for improvement. The performance of pharmacy can be measured through a number of areas including the following:

- Resources – facilities, staffing, financial performance, for example profitability, use of technology.
- Patient services – transaction volumes, for example, number of items dispensed, number of scripts processed, number of uncollected prescriptions, and availability, quality and safety of medicines.
- Customer experience – waiting times, facilities, accessibility, customer satisfaction and/or complaints.

94. We discussed in the previous chapter how the pharmacy service ensures that it has safe and high-quality medicines available for customers. Various stages in the process can be developed into performance measures or key performance indicators (KPIs) to monitor the performance of the service. The quality of patient care and services also depends on how well the pharmacy service dispenses medicines to its customers. The quality of patient services may be dependent on a number of inputs, such as staffing, the facilities or working environment, the technology available and finances. Pharmacy services should be built around the customers and should therefore follow good customer service practices to ensure that each customer encounter results in a positive outcome. A number of factors may affect the customer experience, including accessibility, i.e. how easy it is to order and pick up prescriptions, waiting times, facilities and customer service.

THE 2014 CONSULTANT'S REPORT MADE A NUMBER OF RECOMMENDATIONS AIMED AT IMPROVING THE PERFORMANCE OF PHARMACY SERVICES

95. We reported earlier that the HSA commissioned a consultant to review pharmacy services in 2014. The consultant's report made a number of recommendations that aimed to improve the performance of the pharmacy service, for example, changing the organisational structure and improving training and development of staff, and developing a set of KPIs for pharmacy stores.

96. However, we found that, of the 12 recommendations directly related to patient services and customer satisfaction, only five were fully implemented and one was partly implemented. Of the six remaining, management decided that four could not be implemented. As reported earlier, the consultant recommended reducing dispensing frequency and increasing volumes dispensed to improve waiting times and reduce the number of times customers needed to visit pharmacies as

well as reduce administration. We were told that management did not accept this recommendation because it may result in problems with stock control. However, the feasibility of the required changes was not evaluated and customers and staff were not consulted. As reported elsewhere, the inventory management system has subsequently improved resulting in improvements in stock levels at pharmacy stores and across HSA dispensaries. There is therefore scope for management to revisit this recommendation and assess whether this would now be feasible.

Recommendation 10: In light of improvements made to the management of pharmacy stocks, the Pharmacy Service should reconsider whether recommendations made by the consultant in 2014 to improve patient services, through increasing the volume of medicines dispensed and reducing the number of times that customers need to visit the pharmacy, are now able to be implemented.

PERFORMANCE IS DIFFICULT TO ASSESS BECAUSE OF UNCLEAR TARGETS AND WEAK MONITORING

97. As reported previously, there are no specific performance measures for the HSA, but the Medical Director and Deputy Medical Director developed a set of KPIs for pharmacy services, as a result of a staff retreat to set strategic goals aimed at improving service delivery. The pharmacy KPIs include profitability and financial return; customer satisfaction; waiting times; staffing, including vacancies, staff cover and overtime; and quality assurance, including error prevention. However, we found that these KPIs have not been communicated to pharmacy management or staff and that they are not routinely monitored or reported upon. These KPIs are a good start and should be further developed into a formal performance management framework for pharmacy services with regular monitoring and reporting.

98. We found that there is some reporting of pharmacy performance, but data are limited, performance is not tracked or reported against targets or benchmarks, and it is not clear if the performance information being communicated or reported is complete. This raises concerns about the reliability of data and reporting. Monthly operation reports for the main pharmacies (George Town Hospital and Smith Road Centre) are prepared and discuss staffing levels, developments in the department and issues for the attention of senior management but the discussion is limited and reports are inconsistent.

Recommendation 11: The pharmacy service should formally adopt a performance management framework and continue to improve this, ensuring that performance is regularly monitored and reported against its key performance indicators.

STAFFING LEVELS HAVE INCREASED AND PROFESSIONAL DEVELOPMENT OPPORTUNITIES ARE PROVIDED

99. It is important that the pharmacy service has the right people with the right skills in the right place at the right time. This is an essential element of workforce planning.

100. The number of professional pharmacists in the Cayman Islands is relatively small, and pharmacists are routinely recruited from overseas. The local legal framework allows pharmacists to be recruited locally or from only seven countries in the world. Strategic workforce planning is therefore especially critical given the need to develop a pool of local talent and the lag created by overseas recruitment. Effective resource planning and scheduling are needed to ensure that there are sufficient staff on duty at all times to meet the peaks and troughs of patient volume. The continuing professional development of pharmacy staff is essential, as are good customer service skills. Providing staff with the right tools and resources to be able to do their job effectively is also necessary.

101. The pharmacy service manages its workforce at the strategic level, that is, all pharmacy locations (outpatient, inpatient and clinical) and pharmacy stores are combined. The staff at Faith Hospital pharmacy are managed separately by the Faith Hospital Medical Director.

THE TOTAL NUMBER OF STAFF IN THE PHARMACY SERVICES INCREASED FROM 46 TO 50 BETWEEN 2016 AND 2020

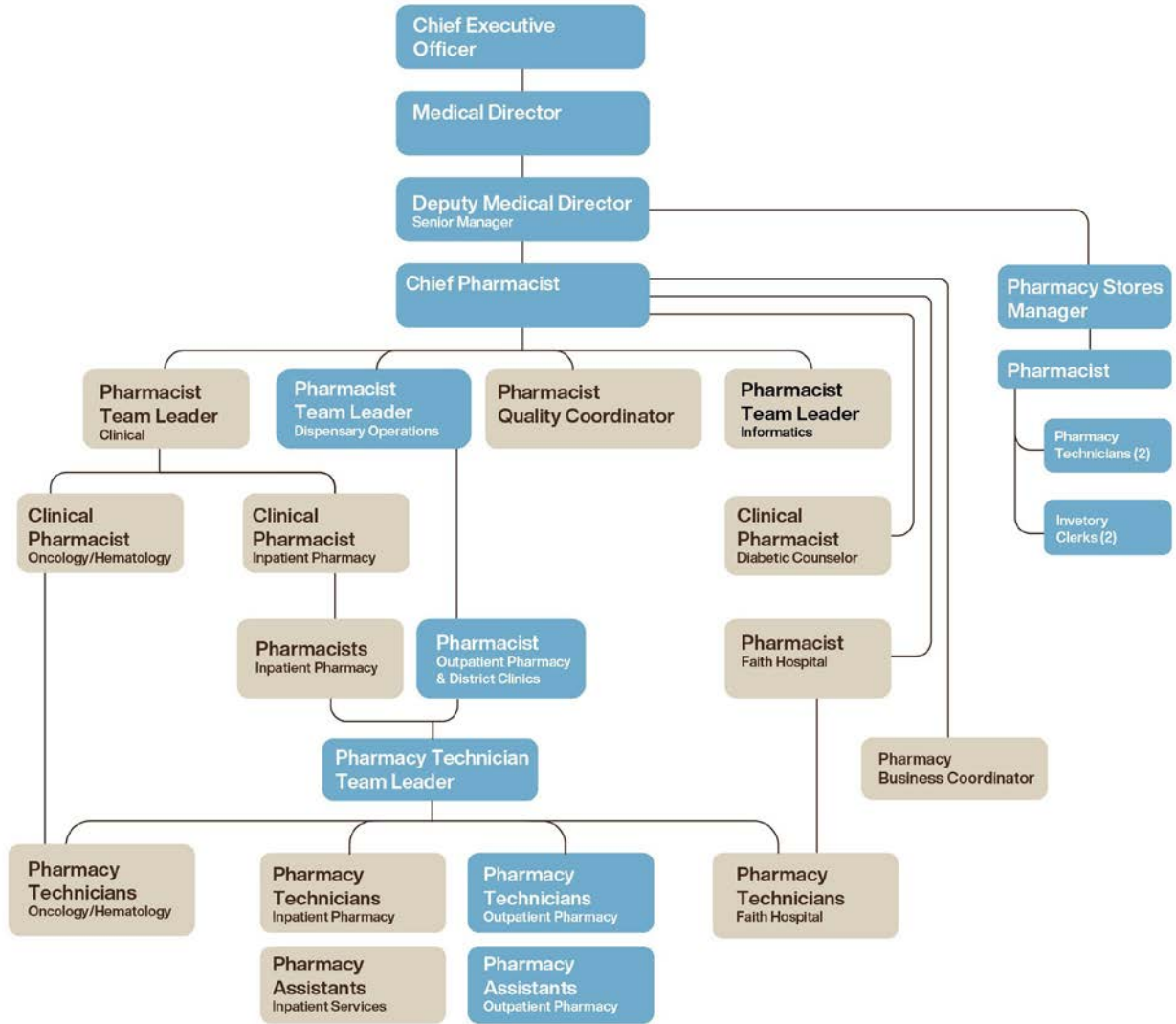
102. In 2014, the consultant recommended that the pharmacy management structure and staffing levels be reviewed. As a result of this, pharmacy services prepared a workforce plan for 2014-16 and put a new management structure in place in 2015. The workforce plan, which was approved by senior management, included a description of the operations, but it did not identify transaction volumes or peaks and troughs, which would have helped quantify the required workforce and how many staff were needed at each grade and post. Since then, a new staffing summary describing the minimum staffing levels required by post has been drafted, but this does not provide any correlation to service demand and has yet to be approved.

103. Exhibit 12 sets out the current organisational structure of HSA's pharmacy services, including pharmacy stores. It shows that, over the five years from 2016 to 2020, the number of staff employed by pharmacy services (including in clinical pharmacies, outpatient pharmacies and pharmacy stores) increased from 46 to 50.²³ The total number of Pharmacy Stores staff remained constant, at 6, while dispensary staff increased from 30 to 34. Two pharmacy team leaders are responsible for outpatient dispensary operations and oversee a team of pharmacy technicians and pharmacy assistants. Over the same period, the staffing profile has changed. We found that the number of pharmacists decreased slightly from 15 to 14, the number of pharmacy technicians almost doubled, from 8 to 15, and the number of pharmacy assistants fell from 7 to 5. The increase

²³ The audit scope included outpatient pharmacy dispensaries, but excluded inpatient and other clinical pharmacy operations. However, the analysis of the workforce takes a wider view of all these components of pharmacy services because the workforce is budgeted at the strategic level, and resources are shared as needed.

in pharmacy technicians is in line with the pharmacy services' approach to succession planning to develop a pool of local talent.

Exhibit 12 – HSA Pharmacy organisation chart



Source: HSA

104. At the end of 2020, the actual headcount in outpatient pharmacy services was in line with the budget, but there were some vacancies, including two clinical pharmacists, one pharmacist and one pharmacy assistant. We found that in some years up to three pharmacist posts were vacant for several months during the year although they were filled by year-end. We were told that even one pharmacist vacancy can severely impact productivity levels in the pharmacy.

Recommendation 12: HSA Pharmacy Services should develop a workforce plan to ensure that it can meet current and future demands and deliver effective services to its customers.

PROFESSIONAL DEVELOPMENT IS ADEQUATELY SUPPORTED AND STAFF ARE GENERALLY EQUIPPED WITH THE RIGHT TOOLS BUT CUSTOMER SERVICE TRAINING SHOULD BE REFRESHED

105. In 2014, the consultant recommended that the pharmacy services improve its training and development of staff, including accreditation for pharmacy technicians. The HSA supports staff development by providing time off to obtain higher professional designations, including further studies in clinical pharmacy, business administration (health management) and aseptic preparation and dispensing of medicines. The HSA also organises mandatory internal training sessions for all its healthcare professionals. However, we were told that some pharmacists are unable to take up some development opportunities because of their workload.

106. The HSA encourages junior staff to develop their careers by becoming pharmacy technicians. By the end of 2020, one former pharmacy assistant had been promoted to pharmacy technician. The HSA has designated a further five pharmacy technician posts for existing pharmacy assistants who complete their training and qualifications. As for training in other allied health professions, pharmacy technician accreditation is not offered locally; most staff sit online US State Board Certification courses for pharmacy and the HSA provides the required training component.

107. HSA Pharmacy has also provided staff with subscriptions to online reference sources, such as Lexicomp from the USA. In 2016, pharmacy staff were provided with hospital-wide customer service training but no refresher courses have been provided for existing staff since then. New employees also receive the customer service training at joiners' orientation.

Recommendation 13: The Health Services Authority should provide regular customer service training for all frontline staff members.

THE QUALITY OF FACILITIES NEEDS TO IMPROVE

108. Pharmacy services' facilities need to be sufficient to accommodate the needs of patients, to provide a good working environment for staff and to ensure that there is sufficient space for medicines to be stored, prepared and packaged while maintaining their quality and safety.

109. As reported earlier, pharmacy services are delivered across a range of HSA locations, which means that a dispensary may be a dedicated space or a shared space within a district clinic. The facilities for pharmacy services have not been improved or expanded for a number of years, except for some minor modifications such as the addition of a small space for confidential consultations in the main pharmacy. As part of our audit, we visited a number of pharmacy locations and found that some are satisfactory but others need to be improved. We assessed the quality of facilities at five pharmacy locations (Smith Road Centre, Bodden Town, North Side, East End and West Bay) against five criteria (availability of a customer waiting area with adequate space, availability of a private consultation area, adequate staff working space, adequate storage space and availability of a secure storage space). We found that the Smith Road Centre was the only pharmacy that was fit for purpose and

met all of the criteria. Bodden Town Health Centre’s pharmacy was deemed unsatisfactory on all five of the criteria. Exhibit 13 summarises our findings.

Exhibit 13 – OAG assessment of the quality of facilities at five pharmacy locations²⁴

Audit Inspection Criteria	SR	BT	NS	EE	WB
Customer waiting area available with adequate space	S	U	S	S	U
Consultation room or private area available	S	U	U	U	U
Adequate working area/space for processing/dispensing of prescriptions	S	U	S	S	U
Adequate storage and shelf space (for dispensary inventory)	S	U	S	S	U
Additional storage space outside of dispensary is locked and controlled by Pharmacist	S	U	S	S	S

Notes: SR = Smith Road Centre; BT = Bodden Town; NS = North Side; EE = East End; WB = West Bay; S = satisfactory; U = unsatisfactory.

Source: OAG site inspection of selected district pharmacy locations.

110. HSA pharmacy services assume that patients are willing to wait while their medicines are being prepared, checked and dispensed. This is a reasonable assumption provided that the waiting area is adequate and comfortable. As part of our audit, we carried out a limited survey of patients at each location.²⁵ We found that customers at the main pharmacy were generally satisfied with the waiting area. During COVID-19 restrictions the number of customers allowed in the main pharmacy at the same time was as low as three. The HSA plans to expand the waiting area in the main pharmacy when it moves to the Smith Road Centre; the maximum number of customers able to be accommodated will increase from 16 to 26. However, at all district health centres, the waiting area is shared with the rest of that location, which may mean that there are an insufficient number of seats at peak periods. We found that customers at Bodden Town and West Bay were unsatisfied with pharmacy waiting areas.

²⁴ At the time of our audit the Smith Road Centre was set up as an emergency location due to COVID 19 restrictions. It was operating as an extension of the main pharmacy for the pick-up of medication where no payments were involved, such as CINICO (Cayman Islands National Insurance Company) patients. CINICO patients are public sector employees who do not have to make payments. The Smith Road Centre is currently being renovated and the main pharmacy will relocate there once renovations are complete.

²⁵ OAG carried out a customer satisfaction survey. A total of 63 customers were surveyed across all locations between 27 January and 1 February 2021. Surveys were conducted in person or by email or phone. Further details on the survey methodology can be found at Appendix 1 of this report.

111. It is important, to ensure patient confidentiality, that pharmacies have a separate space where pharmacists, or others, can have private discussions with patients. These may involve discussion of medicines or other personal information, such as ability to make payments. With the exception of the main pharmacy, we found that private space for confidential conversation was not provided. At the time of our review, the Smith Road Centre was specifically set up to help enforce COVID-19 restrictions and provided privacy because only one patient a time was allowed in to the dispensary area. The sharing of common areas in district clinics limits the ability to have confidential conversations, as they may be overheard by others. We also found that patient confidentiality is at risk in district clinics, as patients drop off prescriptions, but these are not secure. For example, we saw that prescriptions had been left on counters and on top of drop boxes rather than being placed into the sealed box provided. We also found that as a result of the additional measures put in place for COVID-19, Faith Hospital pharmacy asked patients to retrieve their medication from an outdoor window, which also creates risks for patient confidentiality.

112. In relation to providing a good working environment for pharmacy staff, we found that the pharmacy facilities at Bodden Town and West Bay generally had insufficient space, but East End and North Side were sufficient. We were told that the transfer of the main pharmacy to the Smith Road Centre will significantly improve the working environment; the work area is being designed to accommodate 23 staff.

113. We also found that there was insufficient storage space for stocks of medicines at some district health centres. This meant that some pharmacy stocks were exposed, which makes it difficult to effectively control and ensure the safety of medicines. For example, West Bay has space for bulk stock but there is none in Bodden Town.

PHARMACY SERVICES ARE EXPECTED TO MAKE A PROFIT BUT THIS IS NOT ADEQUATELY MONITORED

114. The HSA pharmacy service is expected to operate as a profit centre. However, there is no set profit target, and a complete profit and loss statement for pharmacy services is not available.

115. Information on the financial performance of the pharmacy service overall and by each location is essential management information. The financial performance of each location and any reasons for certain locations operating at a loss need to be known and clearly understood. However, the way financial information is collected and reported within the HSA does not allow the pharmacy service to report whether it is making a profit. HSA staff produce monthly reports from Cerner (the health information management system), but these are limited in the following ways:

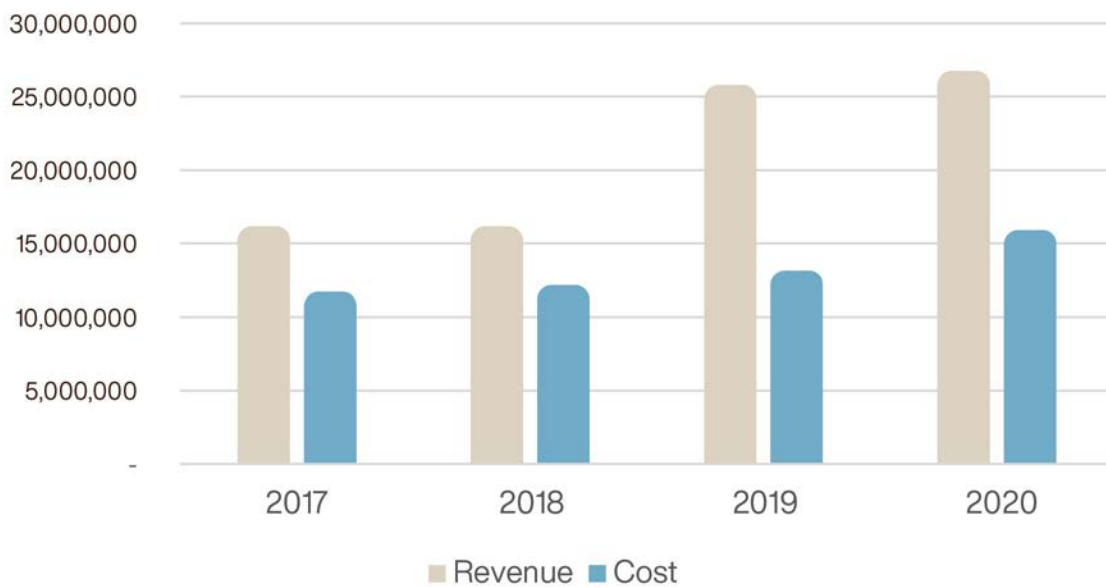
- Financial results are reported each month, but these are largely based on the revenues generated, not profit. Senior management has set a budget for pharmacy revenue of \$12 million a year. We also found that pharmacy revenues generally meet or exceed the

budget because the HSA, in response to the 2014 consultant’s report, adopted a “cost plus” pricing strategy.

- The Cerner system does not produce pharmacy-specific profit and loss reports that would allow management to monitor financial performance for all dispensary locations. The HSA’s Finance Department circulates a pharmacy monthly operating report, which presents revenue against cost by location, and the average purchase price of the medicines sold plus an allocation of estimated freight charges. However, other pharmacy costs (such as salaries and utilities) that would help assess profitability are not included.
- The financial results for pharmacies located at district clinics are included within those cost centres, which means that financial information is aggregated at district level and not across pharmacy services. It is therefore not clear if the pharmacy service overall, or each pharmacy location is generating a profit.

116. In the absence of robust information on profit, we analysed financial information for the four years 2017 to 2020 (Exhibit 14). The financial information includes all pharmacy service revenues and costs, including salaries, freight, utilities and other direct costs. Our analysis shows that pharmacy service profits ranged from 25 to 49 per cent of revenue for the four years 2017 to 2020.

Exhibit 14 – HSA Pharmacy financial performance



Note: The information included is for all pharmacy dispensaries.

Source: OAG analysis of HSA financial information for pharmacy services.

117. Pharmacy management monitors compliance with the pharmacy’s pricing policy to ensure that prices offered to patients are reasonable and accurate. Each quarter, the Pharmacy Stores Manager or the Chief Pharmacist (or designate) carries out a competitors’ pricing survey and analysis to

ensure that prices are aligned with the market. As reported previously, in exceptional circumstances, prices may be adjusted to match those of HSA's competitors. Any recommended pricing adjustments are submitted to the Medical Director and formal agreement is obtained from the Medical Director, Deputy Medical Director, CEO and CFO.

118. In addition to profitability, other financial performance KPIs could be added to the performance management framework for pharmacy. These could include average or unit costs by transaction and/or item dispensed.

Recommendation 14: The Health Services Authority should ensure that it has sufficient financial information to monitor and report the profitability of the entire pharmacy service, including individual district clinic dispensaries.

THE PHARMACY SERVICE DOES NOT ADEQUATELY MONITOR CUSTOMER SATISFACTION LEVELS

119. Customer satisfaction with the pharmacy service may be affected by a number of factors, such as accessibility, for example the ease of ordering and picking up medicines, waiting times, availability of medicines and having the right medicines dispensed.

120. In January 2021, the HSA introduced a universal survey to obtain customers' views on every service they use, including the pharmacy service. Prior to this, the HSA had a customer satisfaction monitoring service, but this did not survey all customers and it was not possible to extract information for pharmacy services, as customer satisfaction feedback was grouped together with feedback on other departments. We were told that customer feedback is received by senior managers in the HSA, and any significant pharmacy issues reported are communicated to pharmacy services management for remediation. However, we found that customer feedback on pharmacy services is not centrally stored and it is not clear how it has been used to inform effective decision-making.

121. As reported earlier, we surveyed a small sample of customers as part of the audit and found that customer satisfaction levels varied by location and age.

A RANGE OF OPTIONS ARE AVAILABLE TO CUSTOMERS FOR ORDERING AND PICKING UP MEDICINES

122. Over the last decade, the pharmacy service has improved the way it delivers its services, for example by introducing various options for ordering repeat prescriptions, including an online service, a phone service and a WhatsApp service.

123. In March 2013, the HSA introduced the online service for ordering prescriptions, but its functionality is limited. The service provides only the ability to order repeat prescriptions online. It

does not provide customers with the ability to track their order and it does not provide confirmation of the order or alert customers when their order is ready for pick-up.

124. HSA Pharmacy holds a daily, 30-minute dispensary service for civil servants at the Government Administration Building (GAB). The HSA is the main healthcare provider for all civil servants. The service is limited to refills, and all orders are prearranged by phone or using WhatsApp or the online form. Providing this service involves staff from the main pharmacy going to GAB during this time. However, it is not clear if pharmacy services monitors the use of this service, for example the volume of transactions or which days are busy, to ensure that it is making best use of its resources.

125. As a direct result of the COVID-19 pandemic, the pharmacy service also introduced the following services to minimise the impact of the pandemic and to allow the pharmacy service to carry on business in a manner as close to normal as possible:

- The pharmacy service introduced the WhatsApp service for ordering repeat prescriptions. This service provides an automated response that confirms receipt of the order and says when the prescription will be available for pick-up. If the item is not in stock, customers are sent a message to alert them to this. This service has proven extremely popular with customers, and the HSA has decided to continue the WhatsApp service.
- Pharmacy services opened a satellite dispensary at the Smith Road Centre. This provided additional flexibility, while ensuring adequate social distancing requirements. The HSA planned to open this dispensary on a temporary basis and close it in August 2020 after some of the COVID-19 restrictions were relaxed. As a result of customer feedback it remained open until January 2021, when it closed for the planned refurbishment of the Smith Road Centre. However, it is not clear what impact this service had on staffing and resource planning.
- A home delivery service was introduced that was geared towards vulnerable people, such as older people and people with certain conditions, although it was operated on an ad-hoc basis. At the peak of COVID-19 restrictions this was an essential service for vulnerable people. Clear working arrangements were not put in place for this service, and it was often delivered by senior staff, putting a strain on resources. We are told that the pharmacy service has recently started tracking medication deliveries to create a more systematic delivery service across the island.

126. It is also not clear if pharmacy opening hours are based on data such as actual dispensing statistics and customer feedback; there may be scope to revisit opening hours to ensure that dispensaries are accessible to all customers.

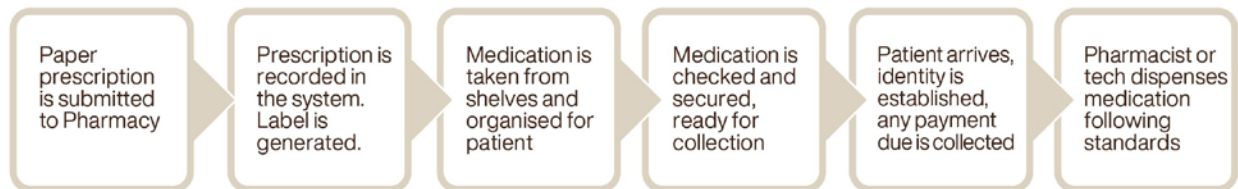
Recommendation 15: Pharmacy management should review and assess the resourcing implications of new and existing services and ensure that these are taken into account when developing the workforce plan.

WAITING TIMES ARE NOT MONITORED EFFECTIVELY AND TARGETS FOR THEM ARE NOT CLEAR

127. Customer satisfaction with pharmacy services may be affected by waiting time, and satisfaction is increased by a clear expectation of when medications will be available for pick-up, so that customers can plan and manage their time. Senior management has identified waiting time as one of the KPIs that it wants to measure, but no specific targets have been set and there is no clear definition of what waiting time means.

128. We found that accurate data that would enable customers' waiting time to be monitored are not currently captured. In setting a waiting time target, management needs to balance what is considered a reasonable time for customers to wait against the time needed to ensure that quality of medicines dispensed. Different waiting time targets should also be set depending on whether a customer is waiting for their medication to be dispensed or has used one of the alternative options for ordering and are picking up their medicines only. Useful KPIs may also measure actual waiting times (range) and average waiting times. Exhibit 15 shows a typical patient journey for pharmacy services.

Exhibit 15 – Process for dispensing a first-time prescription at the HSA's main pharmacy



Source: OAG analysis of HSA procedures on medication dispensing.

129. The dispensing process has different points of entry, and data need to be captured at each of these points to allow waiting times to be measured accurately. For example, the acceptable waiting time will be different for a patient with a new prescription to be filled and one who decides to come back later to get the medicines after dropping off the prescription, and different again for someone who has ordered their repeat prescription using one of the available methods.

130. We found that there is no universal waiting time. We were told that staff in the main pharmacy normally tell customers that the wait is 40 minutes. Although the system allows for the timing of dispensing steps to be tracked, the pharmacy does not capture information that allows it to measure actual waiting times. A typical transaction should be considered to start when the patient drops off the prescription and confirms they are willing to wait. Although staff enter into the computer system information on other stages in the process, including the time of logging the

prescription, the transaction start time is not recorded and, therefore, it is not possible to calculate the entire elapsed time that a patient has to wait.

131. Patients arriving to pick up medication, whether a prescription refill or following earlier prescription drop-off, should also have their expectations about waiting time set, but again this does not happen at present. We found that patients waiting in the main pharmacy stand in line, but information on the time when patients started waiting and the time when their medicines were dispensed is not captured.

132. Most pharmacies, including the main pharmacy, do not have a lot of flexibility to manage peak times of the day (normally during office breaks or at the end of working day) because there is no additional physical space to enable new window positions to be opened up to expand overall throughput of patients at peak times. The new pharmacy at the Smith Road Centre will increase the number of service counter windows from three (currently) to six; this should provide more flexibility but throughput will also depend on staff availability.

Recommendation 16: Pharmacy management should ensure that systems in place are used to measure, monitor and report on waiting times.

THE ACCURACY OF MEDICINES DISPENSED IS NOT CONSISTENTLY MONITORED OR REPORTED

133. Pharmacy services need to have controls in place to ensure that customers are receiving the right medicines, and are provided with clear instructions on how to take their medicines. Customers told us that they were willing to wait for the pharmacy to prepare and check their medications, as they want to be assured that they are being given the right medicines.

134. The pharmacy service has a dispensing policy and procedure that outlines the independent checks required and how to record and report near-misses.²⁶ The policy also requires a clean and safe work environment for pharmacy staff, as well as the use of appropriate equipment and supplies in accordance with the existing laws and professional practice standards. In the main pharmacy, a supervisor for each shift is responsible for overseeing compliance with these standards. However, in the satellite locations, there is no supervisory role and pharmacy staff are expected to maintain these standards.

135. The pharmacy service has processes in place to prevent dispensing errors, such as dispensing medications to the incorrect patient, to ensure correct medicine dosage and to check for possible medicine interactions. Before dispensing to a patient, a pharmacist performs both a clinical and an accuracy check. The accuracy check verifies the original prescription against the medicines

²⁶ A near-miss is an error in the dispensing process that is picked up internally before a prescription is released to a patient.

dispensed, and the clinical check involves assessment of the appropriateness of the dosage, a review of the patient's medical history and checking for prescribing errors and medicine interactions.

136. However, we found that these independent checks are not being done consistently across all of the HSA's pharmacy locations, as they depend on the availability of staff. The main pharmacy is able to properly carry out the required checks, as it has a number of staff working at all times. West Bay pharmacy is also able to do this, as it has a pharmacist and a pharmacy assistant on site, although the procedure specifies that a pharmacy technician prepares the medication (before being checked). However, in some pharmacy locations, for example East End and North Side, it is impossible to carry out these checks because there is only one member of staff working at any time.

137. In addition, pharmacy services are also required to prepare 'near-miss reports' when incidents arise. We found that this is being done only at the main pharmacy. The main pharmacy 'near-miss reports' are collated and analysed to determine strategies to prevent near-misses from recurring. The reports are submitted to the HSA's Quality Assurance/Risk Manager, and ultimately to the Risk Committee; but these reports are incomplete, as they do not include information on incidents occurring outside the main pharmacy. We found that near-miss incidents are captured in some but not all pharmacy locations; and none of the district pharmacies submits 'near-miss reports' to pharmacy management.

Recommendation 17: Pharmacy management should ensure that 'near-misses' and errors are being captured and reported consistently for every location. The trends and results should be analysed to formulate improvements and effectively manage risks.

Recommendation 18: Pharmacy management should consider the feasibility of implementing independent quality checks on the dispensing process at all locations.

IT IS NOT CLEAR HOW MANY CUSTOMERS ARE AFFECTED BY THE UNAVAILABILITY OF MEDICINES

138. We reported earlier that, as a result of improvements to Pharmacy Stores and the supply chain, stock-outs have been minimal over the last five years. Pharmacy Stores communicates to all dispensaries, including district clinics, any anticipated medicine shortages, in which case pharmacists are required to ration the quantity of medicines dispensed (e.g. by dispensing two weeks' supply as opposed to a month's supply) until stocks are replenished.

139. The Pharmacy Stores Manager reports any medicine shortages to the Medical Director in the monthly pharmacy stores report. We found that, between 2017 and 2020, no more than five medicine shortages were reported in any one month. The reports stated that all of the shortages were due to external factors outside the control of the HSA. For example, the June 2020 monthly report highlighted a shortage of thiopental sodium 500 mg injection, a general anaesthetic, because its German manufacturer lost its good manufacturing practice status in the summer of 2018 and no

other available sources of the medicine could be found despite searches by all suppliers. We were told that an alternative anaesthetic on the formulary was used during this time.

140. However, we found that the information in the pharmacy stores monthly reports is not always accurate, and stock-outs observed and reported at dispensary locations are not always recorded in the reports. Patients responding to our surveys also reported that on one or more occasions they did not receive essential medicines such as blood pressure medication because they were out of stock. It is unclear how many people have been affected by dispensary stock-outs because this information is not tracked; this is essential management information and could be set as a KPI. The new Cerner pharmacy system has the capability to monitor inventory levels at all dispensary locations and, if used appropriately, could lead to better management of inventory levels at satellite pharmacies.

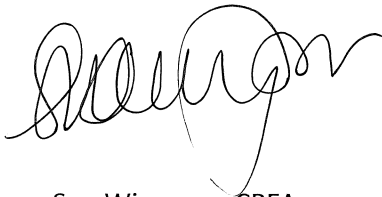
141. In the event of a stock-out at a pharmacy dispensary, customers are normally told to go to a private pharmacy to obtain their medicines. However, this is inconvenient for customers, as they need to then visit another pharmacy, pay for the medicines and, depending on their health insurance, claim back costs from their insurer, which may also involve the completion of forms and additional visits to health insurance offices. It is not clear if the pharmacy service considers whether it should obtain medicines from private pharmacies to meet customers' needs.

Recommendation 19: Pharmacy management should ensure that all stock-outs at the point of dispensing are captured, followed up in a timely manner and resolved, and that trends in, causes of and solutions for stock-outs are reported to appropriate levels of management.

CONCLUSION

142. The Health Services Authority (HSA) is the main provider of outpatient pharmacy services in the Cayman Islands. This is a vital service for a large proportion of the population, including many of the most vulnerable people in our society. It is therefore essential that the pharmacy service is high quality, while providing value for money.
143. Despite allowing nearly two months of clearance time, I have not had a response to this report and its recommendations from the Ministry of Health and Wellness. This is both highly unusual and disappointing especially when I previously reported in 2017 and more recently in 2021 that there are significant gaps at the national level for healthcare as the legislative framework is outdated and there is no overarching strategic plan. The *Pharmacy Act* is the principal legislation for pharmacy in the Cayman Islands but it dates back to 1979 and has not been updated since. This outdated legislation means that there is no national safety standard for medicines. This presents a significant risk to the safety, efficacy and quality of medicines that are able to be imported and dispensed in the islands, and needs to be addressed immediately. The legislative framework also established the Pharmacy Council, which provides the important role of registering pharmacists and publishing a code of ethics for pharmacists. However, loopholes in the legislation mean that there is currently no code of standards for other pharmacy staff, such as pharmacy technicians.
144. Despite the outdated legislation it is good to be able to report that the HSA has put in place measures to ensure that it uses and dispenses high-quality and safe medicines. The HSA has its own formulary of approved medicines that its medical practitioners are authorised to prescribe. A committee of experienced and skilled professionals ensures that all medicines on the HSA formulary meet a range of quality, safety and efficacy standards.
145. The HSA spends around \$9 million a year on medicines and it is essential that it can maintain a good supply of medicines while obtaining value for money through its procurement and contracts with suppliers. At the time of our audit the HSA had started a new procurement exercise for medicines but we found significant deficiencies in the process. Some of these challenges had been experienced in the previous procurement exercise in 2017 but HSA did not appear to have learned lessons from that. The procurement exercise was started in December 2019, which was far too late as contracts were due to expire at the end of 2019. The business case for the procurement was late and included a poor quality options appraisal, and the evaluation of tenders took too long. By the time tenders were received, we were in the midst of the COVID-19 pandemic, which affected the supply chain and prices that suppliers were able to commit to. The HSA cancelled the procurement in early 2021 and has recently started this again, aiming to complete it by January 2022. In the meantime, the existing contracts, which do not ensure value for money, have been extended multiple times and are now in place until March 2022.

146. The HSA provides a good quality pharmacy service, which has improved over recent years, including improvement to the internal supply chain, which means that customers are less likely to experience their medicines being out of stock. The COVID-19 pandemic in 2020 created challenges for the pharmacy service and they introduced some new approaches that helped alleviate these and allowed them to continue to serve the public. However, there is scope to improve the service further. Some of the facilities need to be improved and a performance measurement framework needs to be formally adopted that ensures the regular monitoring and reporting of key performance indicators that measure waiting times, customer satisfaction, the impact of the unavailability of medicines, and other financial information.



Sue Winspear, CPFA
Auditor General
George Town, Grand Cayman
Cayman Islands

5 November 2021

APPENDIX 1 – ABOUT THE AUDIT

AUDIT OBJECTIVE AND QUESTIONS

1. The objective of the audit was to evaluate the efficiency and effectiveness of the HSA’s outpatient pharmacy services.
2. The audit sought to answer the following questions:
 - Are the legal framework and oversight arrangements sufficient for efficient and effective pharmacy services?
 - How effective is HSA Pharmacy at ensuring the availability, safety and quality of medicines while delivering value for money?
 - How efficiently is HSA Pharmacy delivering dispensary services?

AUDIT CRITERIA

3. Audit criteria set out the expectations against which an audit can assess observed performance in order to develop findings, make recommendations as appropriate and conclude on audit objectives.
4. The seven criteria below were shared with the HSA and the Ministry of Health at the conclusion of the planning phase of the audit. The criteria against which the audit proposed to assess the efficiency and effectiveness of HSA’s Pharmacy services are set out below:
 - AC1: The Cayman Islands legal framework and government policies support the delivery of efficient and high-quality pharmacy services.
 - AC2: HSA’s board of directors and senior management team give good strategic direction and exercise effective oversight of pharmacy services to ensure that the HSA delivers on its mandate.
 - AC3: Structures, processes and bodies meant to provide support to delivering pharmacy services delivery are working well.
 - AC4: Strategic goals for pharmacy services are clear and linked to the Government’s broad outcomes, and are supported by detailed plans.
 - AC5: Pharmacy services are focused on meeting the needs of its customers, particularly in terms of service accessibility and the availability, quality and safety of medicines.
 - AC 6: Pharmacy services are organised well and operate efficiently.
 - AC 7: Pharmacy services achieve their performance objectives and this is monitored effectively.

AUDIT SCOPE AND APPROACH

5. The audit focused on HSA outpatient pharmacy operations across Grand Cayman and Cayman Brac including Pharmacy Stores (warehouse) and eight outpatient pharmacy locations:

- Cayman Islands Hospital main pharmacy
 - Cayman Island Hospital GP pharmacy
 - Smith Road Centre pharmacy
 - West Bay Health Centre pharmacy
 - Bodden Town Health Centre pharmacy
 - East End Health Centre pharmacy
 - North Side Health Centre pharmacy
 - Faith Hospital pharmacy.
6. Our audit focused on dispensary operations only. HSA clinical pharmacies and private sector pharmacies were not within the scope of the audit. Although HSA clinical pharmacies were out of scope, their informatics and quality coordination functions support dispensary operations and were therefore touched upon. The Pharmacy Stores Department ensures the availability, safety and quality of medicines and is therefore within the audit scope.
7. The audit was conducted in accordance with International Standards on Assurance Engagements. The approach to the audit included drawing on a range of evidence to inform our findings and conclusion, including these specific methods to answer the audit questions:
- Conducting interviews with key stakeholders, including Ministry of Health officials, the HSA board of directors, HSA senior management, pharmacy operations management (Pharmacy Stores Manager and Chief Pharmacist) and other lead pharmacists and pharmacy staff.
 - Reviewing documents, including legislation, guidance, budget documents, financial reports and statements, strategic, corporate and operational plans, minutes of board and committee meetings, financial metrics, staffing information and performance expectations for significant programmes.
 - Site visits, observation and process walkthroughs.
 - Analysing financial and performance information by each location, including understanding how information is collected, reported and used for management decisions. In the absence of robust information on profit, we analysed financial information for the four years 2017 to 2020, which included all pharmacy service revenues and costs, including salaries, freight, utilities and other direct costs.
 - Researching international leading practices, e.g. pharmacy service standards and performing gap analyses between actual and good practice.
 - Conducting a small survey of pharmacy dispensary customers at main and district dispensary locations. We surveyed a total of 63 customers across all locations between 27 January and 1 February 2021. Surveys were conducted in person and by email and phone.

- Analysing audit evidence and assessing against agreed criteria to develop findings, recommendations and a conclusion on the audit objective.
- Providing a draft report to relevant government officials for review of factual accuracy and obtaining responses to the report's recommendations (see Appendix 2).
- Presenting a final report of the audit to the Parliament.

AUDIT STAFF

8. The audit was carried out under the direction of Angela Cullen, Deputy Auditor General (Performance Audit), and undertaken by Julius Aurelio (Audit Manager), Ruel Huet (Audit Project Leader) and Jasmine Williams (Audit Project Leader).

APPENDIX 2 – RECOMMENDATIONS

Recommendation	Management response	Responsibility	Date of planned implementation
<p>1. The Government should ensure that a revised <i>Pharmacy Act</i>, one that reflects international good practice, including national standards for medicines, is finalised, enacted and brought into force as soon as possible.</p>	<p>The Ministry of Health and Wellness has not responded to the report or recommendations.</p> <p><u>Management comment received from HSA:</u></p> <p>Agreed. The HSA provided the new Honourable Minister of Health (MoH) with a briefing on the challenges experienced across the local Pharmacy industry in June of this year. We also took the opportunity to address the need to update a national health policy and include guidance for best practices. Updates to the Pharmacy Law should:</p> <ul style="list-style-type: none"> • include a framework to allow for compliance with international due diligence requirements; • provide a national regulatory body to govern the registrants within the industry; and • ensure robust quality and safety protocols governing the prescription of pharmaceuticals. 		
<p>2. The Pharmacy Council should ensure that standards of practice for pharmacy technicians are finalised, published and brought into force as soon as possible.</p>	<p>The Ministry of Health and Wellness has not responded to the report or recommendations.</p>		

Recommendation	Management response	Responsibility	Date of planned implementation
<p>3. The Ministry of Health and Wellness should prioritise the development of a new national strategy for health, one that provides overarching direction for pharmacy services and the use of medicines, and publish this as soon as possible.</p>	<p>The Ministry of Health and Wellness has not responded to the report or recommendations.</p> <p><u>Management comment received from HSA:</u></p> <p>Agreed. HSA provided the MoH with a briefing which addressed the need for an updated National Health Policy.</p>		
<p>4. The Health Services Authority should ensure that its strategic plan clearly aligns with the Government’s priorities and Strategic Broad Outcomes for healthcare, and provides clarity on how departments, including pharmacy services, are expected to contribute to the Government’s strategic objectives.</p>	<p>The HSA’s strategic plan allows for flexibility and directional change in an ever evolving and dynamic healthcare environment. While the strategic plan does not provide specific objectives for each of its cost centres, the senior management team meets to discuss and review the plans and objectives of each area of service. In addition, the Board is kept informed at least monthly of what is happening across the organization, via written Board Reports and Board Sub-committee meetings. In 2020-2021, the strategic direction for the pharmacy was to expand the outpatient pharmacy to Smith Road Centre. In addition to ad-hoc meetings with the pharmacy’s leadership, the Medical Directorate holds bi-monthly meetings (alternate Thursdays) with the managers of the Pharmacy and Pharmacy Stores to address any areas of concern. There have also been retreats with key stakeholders designed at setting strategic goals aimed at improvements in service delivery.</p>	<p>Chief Executive Officer Director of Corporate Services</p>	<p>None</p>

Recommendation	Management response	Responsibility	Date of planned implementation
<p>5. HSA Pharmacy should develop a business plan that sets out how pharmacy services will be delivered efficiently and effectively to meet current and future needs, sets success measures that allow performance to be monitored, and demonstrates how pharmacy services will contribute to the HSA's strategic objectives.</p>	<p>Senior Management has already taken steps to implement and monitor performance of the pharmacy overall. Senior Management will take under review the implementation of a formal business plan to document this.</p>	<p>Chief Pharmacist Deputy Medical Director (DMD)</p>	<p>April 2022</p>
<p>6. HSA Pharmacy should improve its reporting on pharmacy, by including performance information and ensuring that the information included is consistent and covers all locations to better inform decision-making at the senior management and board levels.</p>	<p>With reference to Key Performance Indicators, the HSA's Medical Director and clinical team utilize a business intelligence software and other tools to monitor performance of the pharmacy team, pharmaceutical usage, and pricing passed on to patients.</p>	<p>Chief Pharmacist Deputy Medical Director (DMD)</p>	<p>April 2022</p>
<p>7. The Drug & Therapeutics Committee should ensure that it carries out all of the functions specified in its terms of reference.</p>	<p>In relation to 'Commission, organize and approve clinical audit of medicines prescribed in the hospital' This has not been implemented officially. Investigative audits are carried out if needed for a specific drug. This process requires a dedicated staff/team, which is able to perform systematic audits and correlate data. Unfortunately, the Drug & Therapeutics committee is made up of all clinical staff, who have busy daily schedules.</p>	<p>Drug & Therapeutics Committee</p>	<p>None</p>

Recommendation	Management response	Responsibility	Date of planned implementation
	<p>In relation to 'Conduct medicine utilization reviews in the hospital': The D&T Committee has indicated its intention to request a Clinical Pharmacist FTE (via the Director of Corporate Services), in the next financial years staffing plans, who will be responsible for Pharmacovigilance. The incumbent will oversee medication reviews, which will include:</p> <ul style="list-style-type: none"> • Prospective - evaluation of a patient's drug therapy before medication is dispensed • Concurrent - ongoing monitoring of drug therapy during the course of treatment • Retrospective - review of drug therapy after the patient has received the medication • At present drug history and evaluation checks are done by pharmacists during the final check. This is a mandated element of the checking process for pharmacists. 		
<p>8. The Health Services Authority should ensure that pharmacy procurement is planned and overseen effectively to ensure that the process is completed in a timely manner.</p>	<p>Agreed. A new business case incorporating the interim and future procurement plans has been finalized and approved by the Entity Procurement Committee. It was submitted for public tender on 16 September 2021. The ultimate goal is to potentially issue new awards by the beginning of 2022, time allowing, as the clinical teams are once again under pressure further to the recent community outbreaks of COVID-19.</p> <p>The HSA's next steps include:</p> <ul style="list-style-type: none"> • Receive tender bids by midday, 12 November 2021; 	<p>HSA Procurement Committee Procurement Manager Chief Pharmacist</p>	<p>Ongoing</p>

Recommendation	Management response	Responsibility	Date of planned implementation
	<ul style="list-style-type: none"> • Complete evaluation of bids by 3 December 2021; • Submit contract award for consideration to Public Procurement Committee for the January 2022 meeting. 		
<p>9. The Health Services Authority should explore alternative contract options that would allow for better control of price increases from suppliers.</p>	<p>A number of options have since been explored in the context of the procurement regulatory framework and the ongoing need for supplies in a COVID-19 influenced operating environment. With reference to the extension of contracts earlier this year, in most cases vendors confirmed that they were only able to provide pricing based on what they themselves are able to source due to current market situation. We anticipate that the global supply chain will begin to settle once the effects of current vaccination programs improve the landscape, which should put us in a better position to receive meaningful bids from vendors and, more importantly, stabler prices. The HSA team have already seen some pricing settle back down to levels closer to 2019 pricing, though not in all instances. Vendor reluctance to provide firm pricing (given current global market issues) remains an ongoing risk. The contract template will contain provisions which we anticipate should sufficiently protect the HSA.</p> <p>However, contextually, we are a small customer in a very large market, and ultimately if vendors do not wish to continue doing business with the HSA (due to export restrictions or higher demand from larger buyers), we will be limited as to our recourse unless we are able to partner with a much larger buyer (e.g., NHS).</p>	<p>HSA Procurement Committee Procurement Manager Chief Pharmacist</p>	<p>Ongoing</p>

Recommendation	Management response	Responsibility	Date of planned implementation
<p>10. In light of improvements made to the management of pharmacy stocks, the Pharmacy Service should reconsider whether recommendations made by the consultant in 2014 to improve patient services, through increasing the volume of medicines dispensed and reducing the number of times that customers need to visit the pharmacy, are now able to be implemented.</p>	<p>There is difficulty with this proposal, given the uncertainties of drug availability due to COVID-19 and the growing demands in larger overseas markets.</p> <p>In addition –</p> <ul style="list-style-type: none"> • Larger volumes dispensed to patients depletes HSA stock more quickly than is necessary, and puts other patients at risk if this larger dispensing creates or contributes to HSA stock shortages; • Dispensing larger quantities is also highly dependent upon availability of replacement drugs from overseas suppliers. <p>Our current process/controls allow for more fair and even availability of medicines to the overall population.</p>		<p>Not feasible under current market conditions</p>
<p>11. The pharmacy service should formally adopt a performance management framework and continue to improve this, ensuring that performance is regularly monitored and reported against its key performance indicators.</p>	<p>The existing framework was developed and approved by the Medical Director and his senior team.</p> <p>The HSA’s Medical Director and clinical team utilize a business intelligence software and other tools to monitor performance of the pharmacy team, pharmaceutical usage, and pricing passed on to patients.</p> <p>The Medical Director, along with the CFO, are working with IT Business Analysts to develop the capability to report on pharmacy performance at a cost centre level, as pharmaceuticals are disbursed not only at the retail Pharmacy locations. In the meantime, some KPIs are monitored by the Pharmacy’s clinical team.</p>	<p>Chief Pharmacist Deputy Medical Director (DMD)</p>	<p>May 2021</p>

Recommendation	Management response	Responsibility	Date of planned implementation
<p>12. The Pharmacy Service should develop a workforce plan to ensure that it can meet current and future demands and deliver effective services to its customers.</p>	<p>There is a workforce plan in place, initially created in 2018, and updated in 2020.</p> <p>The requirement for adequate staff has been a long-standing concern for many years, which directed much of our attention and efforts to ensuring proper coverage of our services. The actual number needed was identified, calculated using benchmarks, FTE requirements and requested at various times (financial year requests). However, those needs were often partially approved by senior management, but did not fit the overall budget approvals by government, and so the cycle shortages continued.</p> <p>In many instances HSA incurs overtime to cover shifts during absences. Along with this, there is no locum budget for the Pharmacy and complications arise when faced with unforeseen situations in tandem with any existing authorized absence. HSA has managed to circumvent this issue but not without sacrifices e.g., staff may voluntarily defer their vacation plans to provide coverage in emergency or urgent situations, which may then lead to persons carrying leave over into the following year. This situation touches all staff and has led to coverage of several shifts for oncology/hematology clinics, weekend and weekly Inpatient and Outpatient Pharmacy and at times the districts by the Chief Pharmacist and Team Leaders. This coverage by the Chief Pharmacy presents the most economic, convenient option for coverage, especially on weekends, since no overtime payment is involved and it permits the ability for staff to take at least a full 24 hours</p>	<p>Chief Pharmacist Deputy Medical Director (DMD) Chief HR Officer</p>	

Recommendation	Management response	Responsibility	Date of planned implementation
	off in accordance with Section 23 (1) of the Labour Act (2021 Revision).		
13. The Health Services Authority should provide regular customer service training for all frontline staff members.	The Pharmacy facilitated training of all existing staff during a Pharmacy weekend retreat held in June 2021. In addition to customer service training, patient drug information counselling was also added to the agenda. This training is scheduled to be an annual event.	Chief Pharmacist Chief Human Resources Officer	June 2021
14. The Health Services Authority should ensure that it has sufficient financial information to monitor and report the profitability of the entire pharmacy service, including individual district clinic dispensaries.	Agreed. The HSA's Medical Director and clinical team utilize a business intelligence software and other tools to monitor performance of the pharmacy team, pharmaceutical usage, and pricing passed on to patients. Medical Director along with Finance are working with IT Business Analysts to develop capability to report on pharmacy performance at a cost centre level, as pharmaceuticals are disbursed not only at the retail Pharmacy locations.	Chief Pharmacist Deputy Medical Director (DMD) Medical Director Chief Information Officer Patient Financial Services Manager	Ongoing
15. Pharmacy management should review and assess the resourcing implications of new and existing services and ensure that these are taken into account when developing the workforce plan.	Agreed. This is already in place, and review was done when considering 2022/2023 staffing plan.	Chief Pharmacist Deputy Medical Director (DMD)	None
16. Pharmacy management should ensure that systems in place are used to measure, monitor and report on waiting times.	Daily measurement and tracking of waiting times will be readily available using the new 'Qmatic' automatic queuing system to be installed at both Smith Road and Main Pharmacy. Procurement of this new system is in progress.	Chief Pharmacist	Dec 2021

Recommendation	Management response	Responsibility	Date of planned implementation
<p>17. Pharmacy management should ensure that ‘near-misses’ and errors are being captured and reported consistently for every location. The trends and results should be analysed to formulate improvements and effectively manage risks.</p>	<p>Agreed. Pharmacy management has reviewed this process with the team and a new process has been rolled out to all dispensing areas to capture these instances. This will be facilitated by a new reporting form designed to capture all relevant information.</p>	<p>Chief Pharmacist Deputy Medical Director (DMD) Risk Manager</p>	<p>Jan 2020</p>
<p>18. Pharmacy management should consider the feasibility of implementing independent quality checks on the dispensing process at all locations.</p>	<p>Agreed. This process has already been implemented, and was put in place further to discussions with team leaders at the June 2021 weekend retreat.</p>	<p>Chief Pharmacist Deputy Medical Director (DMD)</p>	<p>June 2021</p>
<p>19. Pharmacy management should ensure that all stock-outs at the point of dispensing are captured, followed up in a timely manner and resolved, and that trends in, causes of and solutions for stock-outs are reported to appropriate levels of management.</p>	<p>Agreed. Pharmacy management has created a team in Microsoft Teams where relevant staff has been instructed to note stock outages at the point of discovery to allow for timely management and information sharing with patients who may be impacted by these shortages. In addition, a WhatsApp group was created to include all relevant staff which works in a similar way to the Teams group. The effect of these groups is to allow for efficient and timely dissemination of information throughout the hospital.</p>	<p>Chief Pharmacist Deputy Medical Director (DMD)</p>	<p>Jan 2021</p>

APPENDIX 3 – 2014 CONSULTANT’S RECOMMENDATIONS

Focus area	Conclusions and recommendations	Progress report – management response	Status
Pharmacy pricing policy	1. The recently approved changes to the pharmacy pricing policy will smooth pharmacy charges and will avoid excessively low charges on low-cost items and excessively high charges on high-cost items. This will improve the link between the overall charge and the work involved.	This policy was created and has since been updated to provide better market pricing to patients. Prior to development of the policy, a number of market surveys were conducted by pharmacy staff and senior management to better understand the markups and pricing trends applied in the private sector.	Implemented
	2. The impact of the new pricing model on total income should be assessed (if not done so already). It was not possible to complete this analysis from the data provided during site visits.		Implemented
Pharmacy – patient services	Main outpatient dispensary 3. Consideration should be given to coordinating regular supplies of medicines for each patient into a single monthly dispensing episode. This will reduce patient waiting times and will reduce the need for multiple patient visits to be processed in clinic, in pharmacy and through finance/administration. NB. This model appears to have been successfully implemented at West Bay pharmacy.	A policy of dispensing enough medication to last two months or more was implemented but this practice was subsequently discontinued for several reasons: <ul style="list-style-type: none"> Supply issues – it was not possible to secure orders of sufficient size to consistently dispense large enough quantities of medicines. Patients were found to be hoarding large amounts of unused medicines because their prescription for some reason was either changed or stopped. This led to wastage or misuse of medicines, which was revealed mainly by the West Bay process. Patients who are travelling overseas – especially for medical care – are permitted to get two to four weeks’ supply of their chronic medications. Pharmacy cannot implement these actions.	Scoped out – cannot be implemented
	4. Consideration should be given to increasing the amount of stable repeat medications dispensed per prescription from one month’s supply to two to three months’ supply		Scoped out – cannot be implemented
	5. Consideration should be given to all non-specialist regular medication being prescribed by a single ‘general’ prescriber.		Scoped out – cannot be implemented

Focus area	Conclusions and recommendations	Progress report – management response	Status
	<p>6. The high proportion of uncollected outpatient prescriptions (up to 40% of the total) must be reduced. Consideration should be given to initiatives to achieve this.</p>	<p>The following actions have been taken:</p> <ul style="list-style-type: none"> • Patients are encouraged to wait for their medicines and pharmacies are encouraged to give patients realistic waiting times and to stick to them. • Liquid medications are not dispensed until patients present to collect their medication. On receipt of a prescription, labels are typed and placed on the appropriate size (volume) of container, which is bagged on a shelf. The containers are then filled and the prescription rechecked only once the patient arrives to collect their medication. This reduces the chance of having to discard some uncollected liquid preparations for sanitary reasons. • The length of time for which some uncollected items are kept has been reduced to 72 hours, after which the items are returned to stock. This does not include medications for chronic diseases and other serious illness but does apply to over-the-counter products and, in some cases, antibiotics. • A daily prescription delivery service has been introduced. This initially covered only the GAB and George Town and the surrounding areas, but since the acquisition of a donated vehicle has been expanded to deliver island-wide to elderly and vulnerable patients. • HSA Pharmacy has embarked on an education drive via the media encouraging patients to collect their medications. 	Implemented
	<p>7. Patient and clinical representatives should be consulted to determine the most effective methods to implement an improved model of repeat outpatient medicine supply, i.e. single monthly dispensing, increased duration of supply or a single ‘general’ prescriber for all regular medicines for each patient.</p>	<p>This was not done officially. However, patients did indicate in previous surveys that they prefer to receive more than one month’s supply of medicine. The factors already listed did not support this.</p>	Scoped out – cannot be implemented
	<p>8. Increased use of ‘original packs’ for outpatient dispensing should be pursued to improve dispensing efficiency.</p>	<p>This was implemented, and accurate dose packs are sourced whenever possible.</p>	Partially implemented

Focus area	Conclusions and recommendations	Progress report – management response	Status
	9. Consideration should be given to establishing training and staff development to enhance the roles and skills of staff in the outpatient pharmacy. In particular, consideration should be given to establishing dispensing pharmacy assistants and accredited checking pharmacy technicians.	Staff technician and assistant numbers have been increased and internal training is ongoing, with entry-level staff being trained to technical professional levels. Some staff are also sent overseas to attend job-specific training courses.	Implemented
	10. The suitability and use of the Suvarna IT system should be urgently reviewed, as at present it appears to make the dispensing process less efficient while delivering limited benefits – see below for more Suvarna recommendations.	The Suvarna system was taken out of service. The older Encom system was reinstated until a suitable replacement was selected and installed. A request for information was issued, following which an RFP for a new IT system was published. The procurement process was carried out and all deadlines were adhered to. The Cerner outpatient system was selected and is now in use throughout the pharmacy services, including in Faith Hospital.	Implemented
	West Bay pharmacy 11. The West Bay pharmacy space is inadequate to safely meet the service demand. Consideration should be given to expanding the pharmacy into the apparently underused ‘laboratory’ situated next to the pharmacy.	This suggestion was explored by facilities and senior management. Expansion has not been done.	Not implemented
	12. The West Bay staffing model of a lone pharmacist is inadequate to safely meet the service demands. Expansion of the physical pharmacy space should be accompanied by the addition of a pharmacy technician/assistant post to incorporate a double-check into the dispensing process.	One pharmacy assistant or technician was added to the schedule after this suggestion was made. Staff were asked to provide better coverage during leave. New positions have been recently approved to meet this need.	Implemented
	13. West Bay operates an efficient model of outpatient medicine prescribing and dispensing in that most patients collect all regular medicines at a single visit and receive two months’ supply at each visit. This model should be applied more widely across other HSA repeat dispensing areas.	The model mentioned was instituted to reduce numbers of patients attending the small clinic space daily, as well as the workload. This could not be sustained owing to variations in supply levels.	Not implemented

Focus area	Conclusions and recommendations	Progress report – management response	Status
		See also 3.	
	<p><i>Inpatient dispensary</i> 14. The establishment of the inpatient dispensary has been very successful. It has improved the medicines supply service to inpatients (including the fulfilment of discharge prescriptions) and the links between pharmacy and ward staff. All discharge prescriptions should be processed through the inpatient dispensary.</p>	Discharge prescriptions are processed at the inpatient pharmacy.	Implemented
Pharmacy management structure and leadership	<p>15. The current pharmacy management structure should be reviewed to clarify roles and responsibilities to assist the organisation, the staff and the pharmacy service.</p> <p>The current pharmacy structure is overcomplicated and does not provide clear leadership in each area of the service. A potential structure is suggested in Appendix 1.</p>	<p>Management structure was revised to provide oversight in four key areas.</p> <p>Team leaders were assigned to existing subsections: revenue, clinical, dispensary operations, product information management, etc.</p>	Implemented
	16. The management structure should be clearly defined for each area of the pharmacy service and built into job descriptions to ensure broad understanding among all staff.	<p>Team leaders were appointed and assigned to specific areas:</p> <ol style="list-style-type: none"> 1. clinical services 2. dispensing operations 3. revenue 4. QA 5. Information (pharmacy information system – PIMS). 	Implemented
	17. All staff (irrespective of contract status) should have an annual appraisal with their manager with objectives agreed for the coming year.	All staff receive regular appraisals (led by the chief pharmacist accompanied by the appropriate team leader) and are set objectives.	Partially implemented
	18. The senior pharmacy team and its members (including the chief pharmacist) would benefit from some team-building and leadership development.	A two-week planning exercise was conducted (led by a senior manager), in which the necessary structure for team-building was implemented and various directives to facilitate this process were given.	Implemented

Focus area	Conclusions and recommendations	Progress report – management response	Status
	19. Consideration should be given to greater organisational recognition of the importance of the leadership role for pharmacy in medicines optimisation and medication safety.	This was highlighted in the Joint Commission International recommendations and subsequent policy expectations. ²⁷	Not implemented
Suvarna and pharmacy IT	20. Suvarna implementation is directly linked with an increased staffing requirement in the main outpatient pharmacy and a reduction in service level. It is likely that, even with optimisation of the set-up of Suvarna, this situation will continue.	<ul style="list-style-type: none"> The Suvarna system was taken out of use and the previous system, Encom, was reinstated. We now have the new Cerner system. 	Not applicable – the Suvarna system was discontinued
	21. It is likely that implementation of Suvarna across other pharmacy areas will have a detrimental impact upon efficiency and service levels. Further roll-out should not continue until the likely impact is established and consideration given as to whether this is desirable.	See 20 above.	Not applicable – the Suvarna system was discontinued
	22. The ability of Suvarna to meet the requirements of the HSA pharmacy service is uncertain. The IT procurement process did not match Suvarna against the pharmacy requirements specification. Before further implementation of Suvarna, an urgent comparison of Suvarna against an updated pharmacy requirements specification should be conducted.	See 20 above.	Not applicable – the Suvarna system was discontinued
	23. Suvarna offers potentially useful functionality to enhance patient safety, operational delivery and financial data capture. However, the system is inflexible, labour-intensive and unproven, with no reference sites worldwide. As such, much of the required functionality requires development before implementation in the HSA. Serious consideration should be given to whether the potential benefits of Suvarna are outweighed by the disadvantages of the system in the short, medium and long terms.	See 20 above.	Not applicable – the Suvarna system was discontinued

²⁷ The Joint Commission is the oldest and largest health care standards-setting and accrediting body in the United States.

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	<p>24. If, following consideration, further roll-out of Suvarna is planned, serious consideration should be given to:</p> <ul style="list-style-type: none"> • The resource needed to support development, testing, implementation and ongoing management of the system. It is likely that this will require dedicated on-site supplier support for a minimum of six months to ensure that the system is optimised and functionality is developed in line with service requirements. • The staffing levels required in pharmacy to run the system and the pharmacy service. 	See 20 above.	Not applicable – the Suvarna system was discontinued
	<p>25. The legacy pharmacy system, Encom, has limited functionality and is old technology. However, until a decision is made on Suvarna roll-out, continued use of Encom is advised. If a decision is taken not to pursue roll-out of Suvarna, a contemporary pharmacy system should be sourced that delivers core pharmacy requirements and is able to demonstrate successful implementations in pharmacies similar to those run by the Jamaica HSA.</p>	See 20 above.	Not applicable – the Suvarna system was discontinued
Pharmacy Stores	<p>Medicines supply chain</p> <p>26. Medicine shortages are commonplace in the HSA. Contracted medicine suppliers perform poorly, often failing to inform the HSA of the original source of the medicine or to provide details of the particular brand of medicine supplied. There is an urgent need for a more secure medicines supply chain to meet the needs of the Cayman Islands population. The absence of such an arrangement increases the risk of medicine shortages and of counterfeit or unacceptably low-quality medicines appearing in the medicines supply chain.</p> <p>The HSA (or Cayman Islands Government) should explore developing strategic agreements (possibly by government-to-government contact) to establish a secure medicines supply chain to the HSA with reputable suppliers in the UK, USA, Europe or Canada. This element of the medicines supply problem appears to be outside the direct control of HSA Pharmacy.</p>	<p>Pharmacy Stores was made a separate entity to permit the creation of a purchasing department with the ability to focus on all aspects of pharmaceutical procurement, working closely with the Procurement Unit. This relationship focuses on creation and maintenance of directives and policies, which determine the best suitable source, quality and consistency of pharmaceuticals/related products purchased for the HSA. Additionally, medicines are selected only based on approvals/recommendations made by the FDA (USA), the MHRA (UK), the Therapeutic Goods Administration (Australia), Health Canada (Canada) and the European Medicines Agency (European Union). Other regulatory bodies are considered depending on the circumstance or need.</p> <p>Pharmacy Stores and the HSA, as a whole, have forged strong working relationships with credible suppliers in all of the regions listed, as well as with some in Central America and the Caribbean, which that medicines of sufficient quality are available for purchase. However, government-to-government</p>	Partially implemented

Focus area	Conclusions and recommendations	Progress report – management response	Status
		partnerships have been utilised mainly during crises (e.g. hurricanes, the H1N1 flu epidemic, COVID-19). There is presently no ongoing supply relationship of this sort.	
	27. Pharmacy QA principles should be applied to procured medicines to ensure they are of an appropriate quality. This will require pharmacy QA input into medicines tendering and contracting and more detailed assessment of 'high-risk' medicines or medicines sourced from 'higher-risk' suppliers or originating from 'high-risk' markets.	See 26 above. The HSA refuses to purchase some medicines sourced from some countries and companies because data on material origins or manufacturers are incomplete.	Implemented
	For the avoidance of doubt, this recommendation relates to structured assessment of procured medicines (e.g. licensed status, certificates of analysis, demonstration of authenticity) and the suppliers of those medicines (e.g. local regulatory approval as medicines suppliers). It does not mean widespread laboratory testing of medicines.	Samples of medicines are now sent to the Caribbean Public Health Agency Drug Testing Laboratory for quality testing free of cost.	
	Medicines contracting 28. Consideration should be given to improving HSA medicines supply by implementing the following measures:		Partially implemented
	Incorporating into medicines supply contract penalties for supplier failure (e.g. 'clawback' allowing compensation for off-contract expenses).	This is difficult to maintain, since the Cayman Islands purchases medicines from several overseas jurisdictions, which may not be answerable to restrictions or penalties imposed. This measure may also have undesirable consequences for the HSA in the competitive market, for example if suppliers stop providing services by simply stating that stock is unavailable.	
	Contracts should be preferentially awarded to suppliers sourcing medicines licensed in the UK, the USA, Europe or Canada (or similar high-quality markets)	This has been done.	
	Contracts should be preferentially awarded to suppliers providing medicines in 'patient packs'.	This cannot be maintained owing to availability issues. Not all manufacturers use blister packs.	

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	Contracts should include a clear statement of the country of origin of medicines and whether the medicine supplied is licensed in the country of origin.	This information is sought mainly from suppliers at the point of ordering, since the HSA seeks to avoid uncertain manufacturing sources.	
	Contracts should include a requirement for provision of minimum quality assurance documents to support pharmacy QA assessment.	Because the HSA makes purchasing decisions based on the assurances and product information of established regulatory bodies (e.g. FDA, the UK National Health Service, etc.), it seeks the same standards of information before purchasing medicines from other sources, although these are seldom used. The HSA is also now able to submit samples of all medicines for random quality assurance testing to the Caribbean Public Health Agency in Jamaica.	
	Pharmacy Stores operations 29. Pharmacy Stores staffing is at present inadequate to meet demands placed on the service. The agreed additional staff should be recruited to an updated stores management structure to enable provision of a much improved service.	Pharmacy Stores was restructured in April 2015 and made a separate entity/cost centre from Pharmacy, with its own management and team. The staffing level was increased from three team members to six: one manager, one pharmacist, two pharmacy technicians and two inventory clerks.	Implemented
	30. The leadership and management structure of Pharmacy Stores and the Procurement Department should be reviewed and an appropriately skilled and experienced Pharmacy Stores and procurement lead should be identified and tasked with responsibility for all aspects of this service.	See 31 above.	Implemented
	31. A series of KPIs should be agreed to monitor Pharmacy Stores' performance and medicines availability.	KPI's include customer satisfaction, financial performance, waiting times, staffing and quality.	Partially implemented
	32. Pharmacy Stores processes should be reviewed to ensure that all stock movements are recorded in real time on the pharmacy computer stock control system.	This has been addressed with the implementation of the Cerner system module to manage the supply chain. All stock movements in Pharmacy Stores are now recorded in real time.	Implemented
	33. Industry-standard stock control practices (e.g. rolling stock checks, stock rotation) should be implemented to ensure that stock levels are accurate and to reduce the risk of stock-outs and loss of stock through expiry.	The FEFO (first expired, first out) or FIFO (first in, first out) principle is currently used. In addition, periodic stock checks are carried out – the goal is to carry out cycle counts (this functionality exists in the Cerner system) between the half-year and year-end stock count exercises.	Implemented

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	<p>34. A formal system should be implemented to record and enable follow-up of both supplier failure to the HSA and failure of stores to supply internal customers.</p>	<p>Supplier failure:</p> <ul style="list-style-type: none"> Currently, follow-up, when needed, is by email or telephone. However, a formal evaluation form could be developed to assess the performance of vendors to the HSA. <p>Supply to internal customers:</p> <ul style="list-style-type: none"> An out-of-stock logbook is currently used to track when items go out of stock and when they return. Regular emails and/or stock update memos are circulated to all pharmacy staff as needed 	Partially implemented
	<p>35. The IT needs of Pharmacy Stores should be considered as a key part of any future pharmacy IT plans, including any review of Suvarna. Future IT systems should support paperless internal medicines requisitions and enable livestock control in all pharmacy locations as a minimum.</p>	<p>The Cerner system has the functionality required and when fully implemented HSA will be able to make paperless medicines requisitions..</p> <p>Live stock control is now a reality as a result of the real-time inventory/stock movement functionality in the Cerner system.</p>	Partially implemented
Clinical guidelines and formulary	<p>36. Responsibility and capacity for managing the HSA formulary should be established as part of pharmacy management structure review. It is recommended that dedicated time should be given to this role, which will sit most comfortably within the clinical pharmacy service.</p>	<p>The clinical team has responsibility for the formulary in collaboration with the D&TC.</p>	Implemented
	<p>37. The HSA formulary and D&TC represent a sound mechanism to promote cost-effective and evidence-based prescribing practice. However, owing to workload pressures, the current HSA formulary is in need of updating, and appropriate resources are not committed to ensuring that the D&TC is provided with the necessary analyses of new medicines to support evidence-based decision-making.</p> <p>Once this resource is identified, the formulary should be updated and relaunched in 2015.</p>	<p>The task of evidence-based research has been delegated to the lead D&T pharmacist, who provides detailed medicine information on newly requested or queried medicines</p>	Implemented

Focus area	Conclusions and recommendations	Progress report – management response	Status
	<p>38. Consideration should be given, in discussion with commissioners, to extending the formulary to include approved indications in addition to approved medicines. This could deliver improvements in cost-effective and evidence-based prescribing, particularly when applied to high-risk and or high-cost medicines. The resultant savings could be reinvested in the pharmacy service to deliver quality improvements.</p>	<ul style="list-style-type: none"> The hospital formulary now covers all therapeutic medicine categories. The formulary is available online and is due for an update, which will include links to access medicine and formulary information within the HSA website. A committee is in the selection stages to initiate this work. 	Partially implemented
Pharmacy end-user experience	<p>Patients</p> <p>39. Customers of the main outpatient pharmacy experience poor service: long ‘on the day’ waits and frequent failures to supply (either complete or partial). The causes of this are multifactorial, and consideration should be given to involving patients in developing the solutions.</p> <p>These solutions will relate to in-pharmacy actions (IT, process, stores operations), in-hospital actions (repeat prescribing practices), patient actions (reduction in uncollected medicines, coordinated repeat medicines visits); and HSA actions (international strategic medicines supply chain agreements).</p>	<ul style="list-style-type: none"> Stock outages have reduced quite considerably since this study, as a result of a number of measures put in place by the senior manager. These included establishing Pharmacy Stores as a separate entity and providing a dedicated team to focus on sourcing and purchasing medicines. Worldwide medicine availability has also improved. Patients’ suggestions were entertained and considered. It is important to note that the current COVID-19 situation is already presenting a number of challenges related to medicine availability and acquisition. The new Cerner PIMS in HSA Pharmacy and Pharmacy Stores has improved the IT situation considerably. Changes in the repeat prescribing practice would need to be initiated at the medical director level after much consideration of advantages and disadvantages to patients. There has been a reduction in uncollected medicines, since the hospital conducted a media campaign to remind patients of the importance of timely collection of medicines. It is difficult to coordinate repeat medicines visits to the pharmacy since patients tend to see multiple physicians for various conditions at different times. This presents a problem with single visits. No international strategic arrangements or agreements have been implemented to date. 	Partially implemented

Contact us

Physical Address:

3rd Floor Anderson Square
64 Shedden Road, George Town Grand Cayman

Mailing Address:

Office of the Auditor General
P. O. Box 2583 Grand Cayman KY1– 1103
CAYMAN ISLANDS
Email: auditorgeneral@oag.gov.ky
T: (345) 244 3211 Fax: (345) 945 7738

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To make a complaint about one of the organisations we audit or about the OAG itself, please contact Katrina Thomas at our address, telephone or fax number or alternatively email: katrina.thomas@oag.gov.ky

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Media enquiries

For enquiries from journalists please contact Angela Cullen at phone number (345) 244 3220 or email: Angela.Cullen@oag.gov.ky

www.auditorgeneral.gov.ky



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