

## HEALTH BUSINESS LICENSING FREQUENTLY ASKED QUESTIONS

### 1. What is health business licensing?

Health business licensing is a regulatory process that sets standards and criteria for healthcare-related businesses that operate legally within a country. This is similar to restaurants needing a license to operate that ensures they meet health and safety standards. Likewise, health business licensing ensures that health businesses adhere to specific requirements to safeguard the well-being of the public. This involves setting guidelines, conducting inspections, and collecting essential data to maintain a high standard of care and protect the interests of both providers and patients. Licensing is not intended to be a deterrent to the development or expansion of health businesses. Rather, it will be a mechanism to ensure that the health business environment is sustainable and adequately considers the whole system (including the actual healthcare needs of our residents) when changes are made at the individual business level. It should be noted that health business licensing is different than professional regulation (see Question 3).

### 2. What is the difference between a “health business” and a “health service provider”?

For the purposes of health business licensing in Bermuda, “health business” and “health service provider” are equivalent. This is distinct from, and should not be confused with, the definition of a “health professional”. A “health service provider” is a legally defined term that, under the legislation, can be seen as equivalent to a “health business”. A health business/health service provider engages in the exchange of goods and services in some way that involves a consumer’s health. They can do so as an individual or sole proprietor; or as a group, such as a partnership; or as an organisation, such as a registered company or charity. For clarity, and in respect to solo-run health businesses, an individual health professional is primarily focused on delivering direct patient care. A solo-run business involves a single person who takes on both the role of the health professional and the role of the health business owner, overseeing the broader aspects of running a health business. Such solo-run businesses would be included in the health business licensing process.

### 3. What is the difference between health business licensing and professional registration?

Health business licensing applies to the legal entity – be it an individual, group, or organisation – that is engaged in the exchange of healthcare goods and services. The regulations for health business licensing will generally cover those health businesses that are recognised within OECD’s listing of Health Care Provider types and adapted for Bermuda. Health professional registration applies to the education and training a person must have to work in healthcare in Bermuda. As an example, a registered charity may provide a service that requires a doctor to be engaged by that charity. Per the Health Council Act, the charity is an organisation carrying on a business as a health service provider. The Council will license the charity. The professional registration of the doctor who is dispensing healthcare services to the charity’s patients is the responsibility of the Bermuda Medical Council (“BMC”). The BMC is the statutory body responsible for assessing the doctor’s education and training, and determining whether that doctor can be registered to work in Bermuda.

#### 4. Why does Bermuda need health business licensing?

Individual level patient safety and quality care are impacted by the standards used by health businesses in the delivery of services. For example, infection rates are impacted by the infection protocols a facility has in place and this, in turn, impacts the delivery of services. It is also important to consider the contribution of health business licensing to general population health outcomes. The more that is known about the health businesses that operate in Bermuda, the more quickly policy and funding decisions can be made that support better access or needed changes in service standards. Accurate and up-to-date data enables more timely decision making versus the current situation where, for example, regulatory and strategy bodies can only react to issues such as service availability gaps after the fact. Having a better understanding about how the pieces of the healthcare system fit together and how that matches with Bermuda's population health demands will ultimately allow people to receive the right care at the right time. This is a key part of creating a more affordable and efficient health system. It will also give health businesses important data to optimise their own role within the health system.

#### 5. Does health business licensing already exist in law?

Yes. The Bermuda Health Council Act 2004 ("the Act") became operative on 1 January 2006, except for section 13, which required a Notice in the Official Gazette. The Act established the Bermuda Health Council ("the Council") as a body corporate with the general purpose "to regulate, coordinate and enhance the provision of health services in Bermuda." Section 13 of the Act addresses the licensing of health businesses and states "No person, group of persons or organization shall carry on a business as a health service provider unless licensed to do so under regulations made under section 15." Currently, select health businesses such as clinical laboratories, pharmacies and health insurers are subject to licensing. However, to date, section 13 has not been gazetted and thus, broad health business licensing has not yet been implemented. That process is currently underway.

#### 6. Why is health business licensing being implemented now?

Bermuda is at a critical juncture of having a rapidly changing and aging population, a situation that is exacerbated by high costs and uneven access to care. It is imperative to ensure the Island's health system can meet the forecasted demand for healthcare through data-driven decision-making in a sustainable and cost-effective way. This is currently hampered due to significant gaps in data about the local health system. Health business licensing will provide the means for collecting some of the necessary data and, importantly, foster the ability to make data-driven decisions efficiently. Health business licensing is an important step towards improving our knowledge and understanding of health businesses and the products and services they provide for our Bermuda community. This and other initiatives will help to make sure our health system is fit for Bermuda's future. The goal is a health system that is strong, efficient, cost-effective and sustainable, and that also produces better overall population health outcomes.

#### 7. What is the process for drafting the Regulations for health business licensing?

The Ministry of Health prepares instructions for the Attorney General's Chambers on what the Ministry seeks to include in the regulations. These instructions are informed by feedback obtained during past (within the last five years) and current stakeholder consultation sessions and by stakeholder interviews. It is expected that drafting instructions in respect to the required regulations will be provided to the Attorney General's Chambers in Q4 2023.

**8. What is the process for actually implementing health business licensing?**

The Bermuda Health Council Act 2004 established Bermuda Health Council (operative 1 January 2006) as the body corporate “to regulate, coordinate and enhance the provision of health services in Bermuda”. The initial formal step to enact health business licensing is the gazetting of section 13 of the Act by Notice in the Official Gazette. The regulations will set out the health businesses to be licensed, the application process and applicable fees, the licence period, any reporting requirements, and what constitutes non-compliance with the provisions of the regulations. Draft regulations will be finalised and presented to the House of Assembly for consideration and debated at the earliest opportunity. The Ministry of Health (“the Ministry”) and the Council are committed to continuing the collaborative approach that is currently underway as health business licensing moves into the implementation phase.

**9. What is the proposed timing for implementing health business licensing?**

The Ministry and Council are in the process of developing the implementation timeline for health business licensing. It is expected, however, that drafting instructions for new regulations will be provided to the Attorney General’s Chambers in Q4, 2023. Implementation would be undertaken in a phased approach thereafter. The Ministry and Council’s approach to implementation will continue to be undertaken collaboratively with our health business stakeholders.

**10. How does health business licensing help to create a more unified healthcare community?**

Expanding health business licensing is a significant step towards improving the services that residents rely on. Creating a user-friendly, comprehensive online directory of licensed health businesses that meet best practice health business standards will contribute to residents, service providers, and health insurers being able to make informed decisions about healthcare. Health business licensing also helps overcome siloed working, provides an ‘early warning’ system for healthcare workforce challenges, and leads to better understanding of how to reimburse for essential preventive and effective treatments. Through health business licensing, our health system leaders will gain an improved understanding of where we need to enhance our services and how we can make healthcare more efficient and cost-effective for both businesses and consumers. It is all about providing better choices, better care, and potential savings for everyone.

**11. How does health business licensing benefit Bermuda’s overall health system?**

Health business licensing ensures that health businesses are meeting minimum safety and operational business standards. While health business licensing does not duplicate health professional registration, it may require verification that the people delivering health services within a business are registered by the appropriate statutory body. It may also include provisions that require health technologies used by the health business to be properly maintained and monitored. By establishing these types of business standards, the public is provided with more transparency on key aspects of a business’s ability to produce high quality care and services. Licensing carries within it a validation of the business being carried out. It can be leveraged to make better comparisons with respect to the delivery of services between Bermuda and other countries through the use of standard measures. This can bolster consumer trust in the local provision of care. It can also offer the opportunity for emerging and innovative health services to enter the health sector.

**12. What is the benefit of health business licensing to the health business themselves?**

Regulatory methods such as health business licensing influence healthcare provision by enforcing standards, thus raising the overall reputation of those businesses that maintain their licence through compliance with those agreed upon standards. Also, healthcare payors will often rely on licensing and other credentialing tools to assist them in defining eligibility for coverage and the level of reimbursement for health services.

**13. What data is the Health Council going to collect as part of the licensing process?**

The actual data to be collected is currently being determined and forms part of the feedback the Ministry and Council are seeking from health businesses within the 14 October and 28 November 2023 engagement sessions. Also, data collected may change over time based on the needs of the health system in the future. In the first phase of health business licensing, two areas of focus for data collection are anticipated. The first will be data that will allow the Council to create a comprehensive online directory of health businesses for public use. The second will be data pertaining to general health business costs to better understand the factors that contribute to health service co-payments, as this presents a significant barrier to care for our vulnerable populations. Ultimately, a thoughtful approach is being taken to ensure the data collected in the new health business licensing programme is relevant to the decision-making needs and to the purpose of understanding Bermuda's health business landscape.

**14. What is the Health Council going to do with the data it collects?**

The Health Council will use the data collected to create a user-friendly, comprehensive online directory of licensed health businesses for the public's use. Also, as outlined in the 2023 Throne Speech, data will be collected on health business costs to better facilitate insurance reimbursement and better manage medical co-payments for our vulnerable populations. The Ministry anticipates phased implementation of the data collection associated with health business licensing. The data collection process will build on the base data that is being collected now within the voluntary health business registration process. It acknowledges, however, the Government's decision to, in due course, consider and review data in respect of financially vested referrals, and also, to consider and review data to determine whether an assessment of health system need in the form of 'Certificate of Need' becomes a requirement. With respect to financially vested referrals, the purpose would be to bring transparency to potential conflicts of interest and the impacts thereof. With respect to the Certificate of Need, the purpose would be to help manage supply in our healthcare market, where excess supply may contribute to system waste and non-medically necessary utilisation.

**15. How will the collected data be kept safe and private?**

The Health Council, in alignment with the Personal Information Privacy Act 2016 (PIPA) will adhere to standards in respect to data privacy, data management and storage, cybersecurity, and data access. The Council currently manages tens of millions of units of data under these principles and will make every effort to continue to strengthen its infrastructure and provide a safe and private data environment.

**16. What assistance will the Ministry of Health and/or the Health Council provide to health businesses as they navigate the process of health business licensing? Will there be a dedicated resource?**

The Ministry and Council look forward to learning from healthcare stakeholders as to what assistance might be needed. During the implementation period, the Health Council will have dedicated personnel and materials available to help make sure the requirements are understood and to provide guidance on how best to administratively comply with the requirements. On an ongoing basis, the Council will provide appropriate support, as it currently does, to businesses who have challenges with completing digital forms that may be required during licensing, registration processes, or gathering required documents.

**17. Who will be responsible for vetting the information provided by health businesses and carrying out facility inspections?**

The Health Council will be resourced to vet information provided by health businesses and to carry out facility inspections. It has been working with international organisations such as the Care Quality Commission in the UK and the Pan American Health Organisation on health technology assessment, health facility standards, health business capacity, and health technology management.

**18. What and when will additional consultation take place?**

The Ministry and Council see the 14 October 2023 session as part of a series of engagements with health businesses as we work together not only to develop these licensing regulations and supporting policies, but to more generally implement health system improvements. We are committed to reaching as many stakeholders as possible through a mixture of approaches to facilitate feedback both prior to and after implementing health system change. This may include formally facilitated sessions, profession-specific discussions, invitations to provide written feedback and evidence-based recommendations, and other less formal sessions, amongst other approaches.

To create well-rounded health business licensing regulations, we encourage membership supported entities to share the information and invitations as they come out so that we can speak with as many and as diverse a group of health businesses as possible. The public will also be made aware of these discussions, which will ensure individuals who may be intending to operate health businesses in the future are aware of this licensing journey. Updates will continue to be provided to the full health business stakeholder group. Additional information will be provided in due course on [www.healthstrategy.bm](http://www.healthstrategy.bm), the main Government website ([www.gov.bm](http://www.gov.bm)), the Health Council website ([www.healthcouncil.bm](http://www.healthcouncil.bm)), and the Health Council e-newsletter. Additional communication mediums may also be used as we begin to roll out a more robust communications strategy in support of overall health system strengthening.

Ongoing engagement in this area will create the opportunity to implement a productive health business licensing programme that balances the needs of the overall health system and those of the health businesses that fall within the scope of the regulations. We want to ensure the regulations are right-sized to Bermuda and do not mire the regulated businesses in unnecessary and burdensome red-tape. Hence the importance of ongoing engagement.