Dr MB Goqwana

Chairperson of the Portfolio Committee on Health

Send via email to the secretary of the Committee, Ms Vuyokazi Majalamba, vmajalamba@parliament.gov.za

Comments by Dr Kim Faure on the National Health Amendment Bill, Section 76 Bill

Dear Dr Goqwana

I am very pleased to provide the Health Portfolio Committee with comments on the proposed National Health Amendment Bill as put out for public comment on 15 February 2012. These comments represent my own views and opinions along with those of a number of individuals within the healthcare sector who are unable to comment in their individual capacity but have contributed their insights towards this submission.

Having been integrally involved in the implementation of a large number of aspects of the current National Core Standards for Health Establishments, the strategic documents and plans for the future Office of Health Standards Compliance (the Office), provincial support plans and proposals on the regulatory framework, I feel very passionate about ensuring that this new regulatory body is able to achieve its mandate in a way that adds integrity to the health system and more importantly achieves its aims for users of health services.

I would be most willing to do an oral presentation to the Committee on Tuesday the 13th March or Friday the 16th March when the time suits them. Please do not hesitate to contact me should you have any additional queries.

Kind regards

Dr Kim Faure

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COMMENTS ON THE DRAFT NATIONAL HEALTH AMENDMENT BILL

This submission will highlight some areas of concern which may hamper the Office of Health Standards Compliance (the Office) from delivering against this its mandate as presented in the updated Bill published for comment on the 15 February 2012.

In summary, there are five main areas which this submission will comment on the:

1. The Mandate of protecting the users;
2. Powers;
3. Governance provisions;
4. Inspectors risk based inspection strategy for efficient use of resources; and
5. Regulatory coordination and co-regulation.

Each area will be looked at in more detail now and some recommendations will be provided.

1. MANDATE

We are encouraged to see that the mandate of the Office is more clearly spelt out in this iteration of the Bill "**to protect and promote the health and safety of users of health services"**.

This mandate should be reflected in the core functions of the Office; inspect or investigate for compliance to standards and manage complaints against standards, promote compliance through enforcement and provision of information to the public. In accomplishing this mandate the Office should identify risks to user's[1] safety, inform the public of their rights to safe quality care and seek user opinions and get their involvement in discharging some of its functions.

a. Identification of **risks to user's safety** is addressed clearly in the current iteration in terms of inspector's functions to monitor compliance to the standards and norms. The Bill also alludes to proactive early warning indicator monitoring which can be used to determine these risk profiles for each health establishment and identify deteriorations or critical events before they escalate;
b. Users should have **access to information** on compliance reports and health outcomes which facilitate their ability to make informed choices or put pressure on service providers to improve the quality of their service offerings.
   In the current iteration of the Bill, the role of the Office and Minister remains somewhat unclear in the reporting on the quality of healthcare services.

[1] User – means any person who utilises the health services such as patients, their families, visitors and carers.

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Section 79D (5) (a) requires that the Office will furnish the Minister with all information and reports related in respect of any case, matter or subject dealt with by the Office. It further requires that the CEO provide the Minister with reasons for any decisions taken by the CEO or the staff of the Office. However, it is unclear what the Minister will do with such information. A key question that still remains unanswered is whether the Minister will approve reports. This implies that the Minister will first sanction reports before publication. If this is the intention of the Bill, then the transparency and autonomy of the Office becomes questionable. Moreover, the ability of the Office to provide the public with credible information will likely be compromised.

In addition, the bill remains silent on public reporting. This raises questions of whether the office will be able to publish their final reports for use by the general public. In our opinion, the bill should allow that summaries of final compliance reports are made public by the Office while having informed the Minister of Health.

Disseminating appropriate information in the public domain is an important way of engendering accountability within the healthcare system. Here, lessons from international experience may provide valuable insights. In my opinion, the approach to public reporting adopted by the Care Quality Commission (CQC) in the United Kingdom sets the benchmark for reporting on the quality of care. Under the UK dispensation, the CQC publishes reports on inspections without sanction by the Minister. The requirement is to inform the Minister of any non compliant healthcare establishments prior to the publication of the report. This collaborative relationship with the Department supports the promotion of change in the system (a non blame culture) and improvement in quality and never compromises transparency.

c. **User's opinions** can be well sought through annual patient satisfaction surveys or patient forums conducted by the Office. The aim is to understand the needs of the users in terms of safe, quality care in order to meet their expectations. These expectations can be met by incorporating the requirements for patient centred care into norms and standards and also by educating users in terms of their rights to quality of care. In garnering user opinions the view of healthcare professional's should also be sought as they act in most instances as the patients advocate.

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2. POWERS

In order to discharge on its mandate effectively, the Office should be given clear powers to act. While the bill does empower the Office with a myriad of powers, they are in some cases not sufficient and in other perhaps not appropriate for a body with regulatory powers to certify compliance with standards. We highlight four areas where the powers of the Office require review:

1. Standards and norms development
2. Enforcement for inspectors
3. Enforcement for Ombudsman

2.1. Standards and norms development

Good regulatory practice suggests that the compliance and enforcement functions should be separated from the standard setting function. This separation avoids a situation where the regulator inspects against its own standards (therefore acting as both "player and referee"). This raises a number of problems within the system. First, it allows the regulator to influence the outcomes of his performance. For example, the Office could lower the standards in order to achieve political imperatives of demonstrating compliance for more facilities. Second, this situation undermines the credibility of the reports issued by the regulator. Finally, conflating the standards setting function with the compliance functions can lead to regulator capture. That is where the regulator is lobbied or encouraged to set lower standard if his funding depends on industry.

The Bill does not clearly define what the Office will do in only *advising* the Minister of Health on standards and norms.

While, there are regulators in the South African healthcare context who do set standards and inspect against them[2], the success of this approach is not readily evident Moreover, expertise required for standard setting may not necessarily lie within the Office and will need to be sought in a collaborative fashion.

This collaboration should occur with the appropriate experts from the NDOH, public and private sector, academia and international experts where relevant. This would require specialist advisory committees to be formed within the NDoH. As mentioned before, user involvement in expressing their needs of quality care, and providing input into areas of compliance breaches, should be incorporated into standards development processes.

[2] Council for Medical Schemes, HPCSA, SANC and outside the health sector

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This submission therefore recommends that the Bill:

- Limits the Office's powers to advising and supporting the development of standards and norms;
- That the advisory role includes the ability to give recommendations on what should be done in terms of the development and setting of standards and norms;
- Includes a provision with a requirement that the Office is consulted on all healthcare standards that have legal repercussions on their work;
- Includes a provision that requires the Office to participate in the review of all healthcare standards.

2.2. Enforcement for Inspectors

In the current iteration of the Bill, the powers of the Inspectorate unit allow then to fulfil their functions in terms of protecting and promoting the safety of user.

The Bill however has only limited enforcement provisions of a fine or referral to the National Prosecuting Authority. Such harsh sanctions may give rise to health establishments "gaming" the system in order to appear compliant and hence prejudicing the care of patients to meet desktop compliance. It will also compromise the establishment of a learning and improvement culture for quality.

We suggest a progressive approach to dealing with non-compliance including:

a. Negotiating a grace period to rectify the problems and challenges (which should be agreed with the regulator)
b. Reporting any misconduct by practitioners in healthcare establishments to the HPCSA or SANC as relevant.
c. Setting progressive fines for continued gross non-compliance with standards based on the level of non compliance
d. Suspending management and the Chief Executive or Head of Department as relevant for not adhering to vital healthcare standards (which may require renegotiating of employment contracts to include relevant performance targets).
e. Recommending the closure of non-compliant wards within healthcare establishments for non-compliance with vital healthcare standards. This can only be used in extreme circumstances and provided the alternative is with easy access and provides better service that this unit.

We therefore recommend that these provisions around enforcement are included in the Bill.

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2.3. Independence and Enforcement Powers of the Ombudsman

In order for the Ombudsman to perform the functions of "consideration, investigation and disposal of complaints relating to non compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner" it assumes a need for an adjudicative role or function. This adjudicative function requires that the Ombudsman will settle matters judicially. The current iteration of the Bill requires the Ombudsman to submit a report with a recommendation to the CEO of the Office who may then request the intervention by the Minister of Health. This implies that the Ombudsman has no power of adjudication. In other words, it is not able to enforce remedies to ensure redress for the complainant. In effect it functions more like a Commission with its current legislative powers, allowing to only make a recommendation on what should be done.

The Ombudsman proposed by the Bill appears to have investigative functions as well. This poses a structural concern that there may not be a clear distinction between the investigative functions and the recommendation functions, thereby limiting the objectivity of the findings and reducing the integrity of any recommendations coming therefore.

Given the above insights, it appears that the Ombudsman function proposed is more along the lines of a Complaints Investigations unit which can be called on to investigate serious events or breaches in compliance reported through complaints. This unit would then need to utilise the services of the Consumer Protection Commission, which has higher enforcement and determinative powers than it to seek redress for the complainant.

Although in principle a Complaints Investigations Unit may meet some of the requirements of considering and disposing of complaints, it poses a serious risk to the Minister of Health. Patients will now have access to the "free" investigative functions of the Ombudsman in the Office to investigate their complaint and then through the Access to Information Act request the investigation information is made available to them. This information can then be utilised by them to institute formal medico-legal claims against the NDOH and the specific health establishment or healthcare professional. The Ombudsman therefore becomes a vehicle by which the NDOH is facilitating potentially expensive legal action against itself rather than assisting in disposing of complaints in an expeditious and economical manner.

The Bill also appears to imply that the Ombudsman will investigate **all** complaints related to standards and norms. This places serious resource demands on the Ombudsman. Good regulatory practice suggests the need for a progressive complaints management system. This begins with ensuring that complaints are first dealt with within facilities and by their governance bodies (hospital boards). The Ombudsman should only see escalated complaints, high risk complaints and those particularly related to quality of care standards compliance issues. Therefore a selection process will need to occur which risk stratifies all complaints received by the NDOH. The Bill should therefore provide for a comprehensive

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complaints and disputes resolution process under the sections that relate to the Ombudsman.

Research done by the Human Rights Commission shows that patient expectations are that their complaints are handled fairly in hospitals, and the function of the Ombudsman would be to ensure that this occurs.

We therefore are recommending that the Ombudsman be created in an "independent authoritative approach" whereby it is essentially an alternative to going to the courts for the complainants wherein they will get a resolution to their complaint.

The Ombudsman therefore is someone who has an interest in resolving the complaint and also the power to take a decision and impose a sanction or reparation.

3. GOVERNANCE PROVISIONS

The Bill indicates that the Office will be a juristic person at national sphere of government under the control of a Chief Executive Director. The CEO will be appointed by the Minister and the Minister exercises final responsibility over the Office. The CEO is also appointed as the Accounting Officer in terms of the Public Finance Management Act (1999) and therefore is responsible and accountable for the management of revenue and expenditure within the Office.

The exact organ of state is not elaborated on in the Bill, however, given the above statements in the Bill, we have assumed that the Office is a National Government Component based on the PFMA and DPSA definitions.

This organisational form allows the NDOH to delegate the functions of assessment of compliance to the Office without having to assign functions to a separate public entity outside the public service. This institutional arrangement makes sense in the light of limited resources. The NDOH can exercise oversight over a government component from a policy implementation, performance, integrated planning, budgeting and service delivery point of view. It is also useful when the aim is to affect service delivery changes as close as possible to the point of service operations. So collaboration between the government component and the NDOH can effectively happen easier.

However, the OHSC given its certification powers is not directly involved in service delivery. The Act clearly confers on the Office two important regulatory functions: the power to certify compliance and the power to investigate and resolve complaints. Moreover, the Office can primarily be seen as a regulator as its main function is not to deliver services but to **protect and promote the health and safety of users of health services**. Regulators are by definition agencies or entities that safeguard the health and safety of the citizens of its country. Such agencies are only effective when they are empowered with the appropriate enforcement tools to discharge their mandate.

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One of the key shortcomings of the current bill is that it lacks a clear governance framework. In developing appropriate governance arrangements, it is important that one adheres to the principles of good regulation as well as King 3 principles. We therefore propose two options for the entity and highlight the advantages and disadvantages of each option:

- Option 1: Public entity
- Option 2: Government component with a mandatory council

3.1. Option 1: Establish a public entity

The first option would be to establish the Office as a Public Entity in terms of Schedule 3A of the PFMA. This organisational form is widely accepted as the most appropriate for a regulator. It provides greater autonomy in its functions and decisions and hence promotes public confidence in the reports and outcomes. Other regulators in South Africa formed as a public entity include the Council for Medical Schemes, National Health Laboratory Service, Financial Services Boards, NERSA, ICASA to name a few.

For the Office to be a national public entity it would require a Board or Council appointed by the Minister. This Board or Council would be responsible for setting the strategic agenda of the Office after consultation with relevant parties, approving reports, deciding on enforcement measures. An Chief Executive Officer would then be appointed to manage the day to day operations of the Office. Perhaps, the main advantage of this form is that it provides some level of separation that may shield the Executive Authority (Minister) from extensive litigation resulting from medico-legal claims of poor quality care.

Perhaps one of the disadvantages of this approach is that Boards have often been at odds with the executive authority. However, this problem is symptomatic of poor internal governance arrangements rather than a structural problem with the organisational form. We therefore suggest that should this option be adopted, the Minister should:

- Sign performance agreements with Board Members
- Meet on a quarterly or biannual basis to ensure that the Board's work is properly targeted

The Bill would also provide for the Minister and Department to have first sight of any non compliant reports drafted by the Office.

The diagram shows a suggested organogram.

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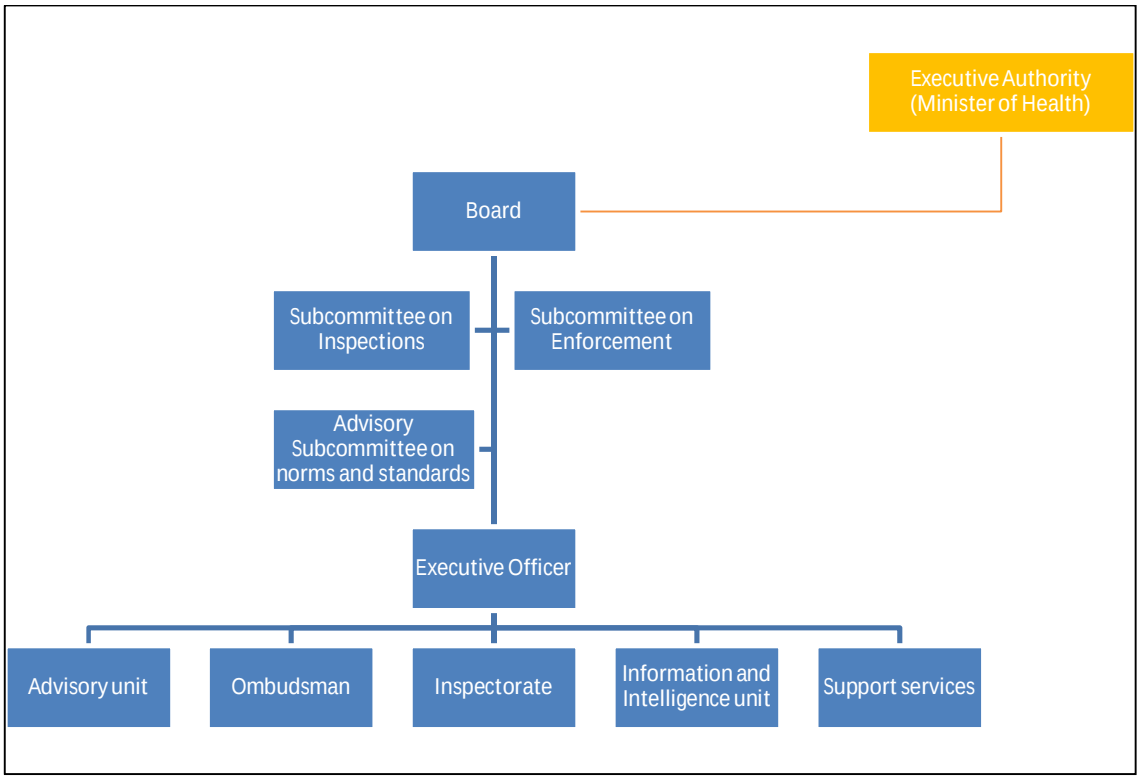
Figure 2 - Suggested Governance Framework for Option 1



3.2. Option 2: Government component with a mandatory council

A government component is often established where an aspect of service delivery needs to be ring-fenced. It therefore has no governance framework of its own as it is often really an extension of the department.

On the whole, this option is not really suitable for a body with regulatory functions. This option hinders the Office's ability to play a patient advocacy role, provide transparent, credible reports, and remain accountable to the public for improving the quality of care and ensuring their safety.

Moreover, the lack of governance arrangements also leaves the Minister and Department open to litigation risk. This means that the work of the Office could be hamstrung by legal challenges from the outset.

Therefore, should the government component as an organisational form be adopted, we propose that a mandatory **Health Standards and Compliance Council (HSCC)** is also established. The Health Standards and Compliance Council would be responsible for:

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- Approving, amending or rejecting compliance reports recommended by the inspectorate;
- Ensure strict confidentiality and ethical behavior policies are followed for both the Executive Director and the inspectors;
- Approving appropriate enforcement measures.
- Hear appeals against enforcements or inspection reports and;
- Making recommendations on norms and standards to the NDOH.

The focus of the Health Standards and Compliance Council will be on compliance and enforcement matters. The Executive Director would remain the accounting officer in terms of the PFMA. And therefore, he would be responsible for:

i. Revenue and expenditure management;
ii. General compliance with the PFMA and PSA;
iii. Internal quality assurance systems;
iv. Confidentiality and ethical behavior policies;
v. Strategic planning and budgeting and;
vi. Organizational and strategic risk management assurances.

The Executive Director would have functional accountability to the Health Standards and Compliance Council however operational accountability would remain with the Minister. The diagram shows a suggested organogram.

By introducing a Health Standards and Compliance Council, the Office will sufficiently meet the requirements of autonomy, transparency, good governance and risk management. It also ensures that regulatory decisions are taken by persons with appropriate experience and skills in the sector. The Health Standards and Compliance Council should consist of internal and external members appointed:

i. from persons within the NDOH and some persons outside the NDOH (from the healthcare industry), who collectively have skills and expertise in patient advocacy and rights, medical expertise, legal matters, finances and accounting, medical ethics, public health, PHC and Hospital sectors both public and private;
ii. the chairperson of the Committee for Norms and Standards;
iii. the chairperson of the Committee for Inspectorate;
iv. the chairperson of the Advisory Panel for Ombudsman; and
v. the Chief Executive Officer of the Office ex officio.

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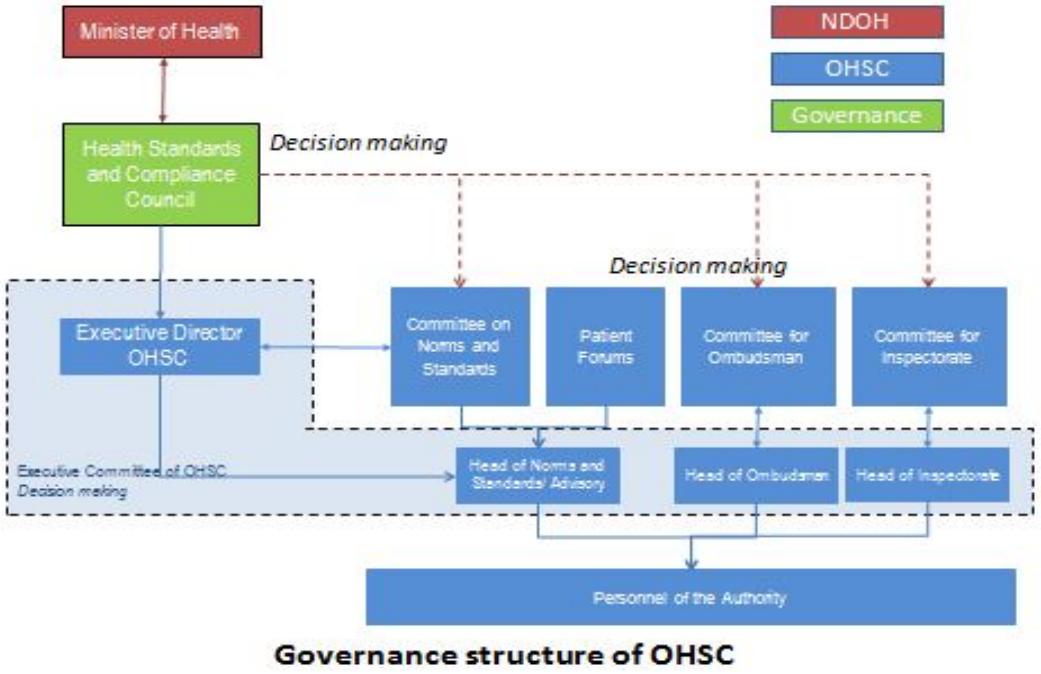
Figure 3 - Suggested Governance Framework for Option 2



There is agreement with the iteration of the Bill that the Office should submit an annual report on the quality of care and safety of patients using health services to the Minister of Health. We recommend that it should be stipulated in the Bill that this report should contain how effective the Office has been in protecting users and promoting quality of care, with summaries of the number and outcomes of all inspections and investigations conducted, including the type and severity of complaints received by the Ombudsman.

3.3. Competency of the Executive Director

The position of Executive Director should be seen as one of utmost importance. This person should be appointed by the Minister and Parliament taking into account the following competencies:

- The ability to operationalise this complex Office within the given resource constraints and deliver the services as contemplated within the Bill
- An excellent technical understanding and experience within the health system;
- Understanding of the quality regulatory environment;
- Have sound moral and ethical principles of work.

We advise the competencies described above are legislated in under the current Section 79 A.

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4. INSPECTION RISK BASED STRATEGY AND RESOURCE UTILISATION

In an ideal world with unlimited resources the Office should be able to assess every establishment in a 3 -5 year cycle, but given resourcing constraints it is my opinion that the Office should initially focus on those establishments most at risk of having quality failures. These at risk establishments would be determined through the proactive risk system mentioned earlier (Early Warning System). More directed and frequent inspections should then be performed on these high risk establishments to prevent patient safety events from occurring. Those establishments that are low risk will be only be sampled for assessment, in order to focus resources on the high risk establishments. This exact model is utilised by the CQC in the United Kingdom. We therefore recommend that the Regulations broadly define the parameters of an inspection strategy. This would include the powers of the Office to:

- Risk profile each health establishments based on a defined set of indicators that are regularly submitted;
- Set rules for inspections based on this risk profiling;
- Define timeframes for the carrying out of inspections;
- Set guidelines for self assessment; and
- Develop self assessment tools.

5. CONCURRENT JURISDICTION

There are a number of areas of concurrent jurisdiction contained in the Bill. For example there is concurrent jurisdiction and overlapping provisions between the Bill and the Consumer Protection Act. There is considerable overlap between the objectives of the acts in the areas of:

- Establishing norms and standards on reporting and access to information by patients.
- Protecting consumers (patients from hazards to their well being).
- Investigating complaints and developing dispute resolution mechanisms.
- Facilitating consumer (patient) advocacy.

These overlaps mean that patients, as end users in the health care services, have a right to the remedies set out in the Consumer Protection Act. This provision could have serious implications on the budget of public sector hospitals and bottom line of private sector participants.

The Consumer Protection Act tasks the Consumer Commission with receiving notice of consumer complaints regarding hazards and safety issues, to monitor and investigate these complaints. This overlaps with the function of the Ombudsman in Section 81A of the Bill.

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Other areas of concurrent jurisdiction include the Medicines and Related Substance Control Act, Pharmacy Council as regulator of pharmacies.

Overlaps with the Health Professionals Act and the functions of the HPCSA include the Ombudsman judging professional conduct related to complaints of health professionals it investigates. The Bill also mentions certifying health professional's practices as compliant with standards again overlapping with the HPCSA.

Given these areas of concurrent jurisdiction, we suggest that provision is made for a legal resolution mechanism within the Bill in the case of jurisdictional conflicts. This would require the following coordinating instruments to be implemented:

- Memorandums of association (MOUs) between the Office and other regulators. Priority should be given to those regulators with large areas of concurrent jurisdiction and complex regulatory issues. These include the HPSCA, SAPC, and SANC, Public Protector, Human Rights Council and Auditor General. In particular, for health sector regulators, regulating quality standards has indirect impacts on the health professionals they oversee. Therefore, the memorandum of understanding should:
    - Provide clarity on the process in case of jurisdictional conflicts.
    - Identify the possible areas of jurisdictional conflicts based on the mapping exercise
    - Agree on a process of information sharing
    - Describe a process of referral and coordinated enforcement action between the OHSC inspectors and the relevant regulatory bodies compliance staff

- Information Sharing Protocols (ISPs) support the memorandum of associations. These ISP identify the types of information regulators should share, the frequency at which it is shared, the approach to triangulation and validation if required. It is recommended that ISP's are signed with the HPSCA, SAPC, SANC, MCC, NDoH and Auditor General.
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6. CONCLUSION

This submission provides an overview of some key concerns related to the current Health Amendment Bill published for public comment. We trust that these concerns will be given due consideration during the revision process. As mentioned in the cover, Dr Kim Faure will be willing to do an oral presentation to the Committee on Tuesday the 13th or Friday the 16th March.

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GLOSSARY OF TERMS

Users – means people who utilise the health services such as patients, their families and care givers.

Providers – means people who care for users either through provision and management of establishments, professional expertise (healthcare professionals) or funding of healthcare (medical schemes and administrators)

Stakeholders – includes other regulatory bodies within the healthcare sector, the NDOH, provincial DOH, HPCSA, SANC, Pharmacy Council, doctors and specialist Associations, Unions,

NDOH – National Department of Health

Department – National and Provincial Department of Health

PFMA – Public Finance Management Act

DPSA – Department of Public Service Administration

HPCSA – Health Professions Council of South Africa

SANC – South African Nursing Council

SAPC – South African Pharmacy Council

National Public Entity - A board, commission, company, corporation, fund or other entity (other than a national business enterprise) which is-

(i) established in terms of national legislation;

(ii) fully or substantially funded from either the National Revenue Fund or by way of tax, levy or other money imposed in terms of national legislation; and

(iii) accountable to Parliament.

Advise – recommend or give an opinion as to the suitability and requirement for norms and standards

Develop – build up, extend or increase from new the standards and norms

Sentinel event – defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness

Ombudsman - an intermediary between the health facility and the people using the facility. They investigate and address complaints and make recommendations to resolve them

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