
Health legislation and policy

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The radically transforming terrain of health services demands a high degree of policy coherence, as well as visionary stewardship from government in a participatory and inclusive national effort.

In 2019, the National Health Insurance Bill was tabled, initiating the legislative steps necessary to enable Universal Health Coverage in South Africa. The Bill includes consequential amendments to many other Acts, including the National Health Act of 2003.

This chapter provides a detailed and critical examination of the Bill. The implications for existing constitutional allocations of responsibility for health are examined, with particular focus on the existing and anticipated arrangements for financing, governance and management, as well as public participation and engagement. The implications for the private sector are

explored, with additional consideration given to the final report and recommendations of the Competition Commission Health Market Inquiry.

A brief summary is provided of other health-related primary health legislation (in the form of Bills or Acts of Parliament), selected secondary legislation (Regulations published by the Minister of Health) and tertiary legislation (Board Notices issued by statutory health councils). Relevant major health-related jurisprudence is discussed, with a focus on the Constitutional Court's judgment with regard to cannabis use and its implications for drug policy.

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Introduction

The Sustainable Development Goals (SDGs), which were agreed to by the United Nations in 2015, set 17 broad areas of development and targets to be achieved by 2030.¹ In the area of ‘Health’ (SDG3), Goal 3.8 includes a commitment to achieve universal health coverage (UHC).² The South African response to this challenge is encompassed in the proposals for National Health Insurance (NHI).

There were no attempts to create a unified health system for all citizens of the country during the apartheid era, and the proposals of the 1940s Gluckman Commission were never implemented.³ One of the first major policy documents issued in the democratic era was the 1997 White Paper on the Transformation of the Health System in South Africa.⁴ The preface to the White Paper opened with a clear statement of intent, but also a recognition of the enormity of the task ahead: “We have set ourselves the task of developing a unified health system capable of delivering quality health care to all our citizens efficiently and in a caring environment”. In addition to a commitment to Comprehensive Primary Health Care, the White Paper expressed a preference for decentralised management, in the form of a district health system, and sought to “integrate the activities of the public and private health sectors, including NGOs and traditional healers” and to “foster community participation across the health sector”.

The path from the 1997 White Paper to the current stage of development of NHI has not been simple, linear or uncontested. Various ministerially appointed policy committees have developed proposals for Social Health Insurance, Comprehensive Social Services, and ultimately for NHI. This process has been interwoven with the equally contested, and protracted, process of replacing apartheid-era health legislation with, inter alia, the National Health Act (61 of 2003).⁵ Although the National Health Act (NHA) has already been amended once,⁶ it has not yet been brought into effect in its entirety. In particular, the highly contested chapter 6 (sections 36 - 40) was prematurely promulgated, before the necessary regulations were in place, and that promulgation was reversed by the Constitutional Court in 2015.⁷ No further attempt to bring these provisions into effect has yet been made.

After the publication of a Green Paper on National Health Insurance in 2011,⁸ a White Paper followed in 2015.⁹ Somewhat unusually, a subsequent policy document followed in 2017,¹⁰ accompanied by a Gazette notice about the “institutions, bodies and commissions” to be created to enable its implementation.¹¹ Although these structures have not been appointed, the internal policy development process within government has continued. In particular, the central role of the Minister and the National Department of Health (NDoH) has been shifted to the Presidency, and an

‘NHI War Room’, headed by a previous Director-General.¹² Senior staff of the NDoH have been seconded to the ‘War Room’, with the expected challenges to lines of reporting and authority.¹³ More recently, Dr Nicholas Crisp has been appointed by the Minister of Health to manage a new NHI office.¹⁴

This analysis focuses, primarily, on the content of the NHI Bill (11 of 2019), published on 6 August 2019.¹⁵ A draft NHI Bill was published for public comment in June 2018,¹⁶ and elicited 197 written submissions. The Bill has been proposed as a section 76 Bill (an ordinary Bill affecting the provinces), which implies that public hearings will not only be held by the National Assembly Portfolio Committee on Health, but also in the provinces.

National Health Insurance Bill, 2019

This analysis of the NHI Bill focuses specifically on the provisions describing the governance of the proposed NHI Fund and its relationship with governance and management bodies created in terms of the NHA. In addition, it draws on two publicly accessible inputs: the Hospital Association of South Africa’s (HASA) input on the White Paper,¹⁷ and the SECTION27/Treatment Action Campaign (TAC) submission on the draft Bill.¹⁸ Unlike the Competition Commission’s Health Market Inquiry (HMI), the NDoH does not make submissions received in response to policy documents or draft Bills publicly accessible.⁹ The two submissions cited represent widely differing positions on key issues.

Following publication of the NHI Bill, numerous opinions have been proffered, both in favour of and in opposition to its contents. Two other documents are inextricably linked with the Bill: the report on the Presidential Health Compact,¹⁹ released in July 2019, and the external evaluation report on the phase 1 NHI pilot projects,²⁰ released in the same month. Importantly, the latter noted that “[t]he first phase of NHI did not involve developing new funding arrangements for health care in South Africa, but rather piloted various health system strengthening interventions focused at the primary health care (PHC) level”. Attempting to predict the feasibility of the proposed NHI reforms on the basis of these limited health systems strengthening interventions in 10 districts is therefore questionable. Lastly, in late September 2019, the final findings report and recommendations of the HMI were released.²¹

Preamble and definitions

The preamble to the Bill echoes the key elements of UHC (access to quality services, and financial protection), but also of the 1997 White Paper, in that it seeks to “create a single framework throughout the Republic for the public funding

a The submissions received in response to the Competition Commission’s HMI provisional report are accessible at <http://www.compcom.co.za/12138-2/>

and public purchasing of health care services, medicines, health goods and health related products, and to eliminate as far as is reasonably possible the fragmentation of health care funding in South Africa”.

The definitions in a Bill should, where possible, be in concert with the terminology in related legislation. The Bill includes a new variant to the term “health care provider” (defined in the NHA as a registered health professional), namely “health care service provider”, defined as “a natural or juristic person in the public or private sector providing health care services in terms of any law”.

Two other definitions are key to understanding the Bill: “‘health goods’, in respect of the delivery of healthcare services, includes medical equipment, medical devices and supplies, health technology or health research intended for use or consumption by, application to, or for the promotion, preservation, diagnosis or improvement of, the health status of a human being”; and “‘health related product’ means any commodity other than orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance which is produced by human effort or some mechanical, chemical, electrical or other human engineering process for medicinal purposes or other preventive, curative, therapeutic or diagnostic purposes in connection with human health”. Unless these terms and their definitions are aligned and standardised by consequent amendments to the Bill and related legislation, these anomalies will continue to cause confusion or, worse, result in litigation.

Purpose and application

Chapter 1 of the Bill deals with the purpose and application of the Act, re-stating the goal of a single purchaser and single payer system, applicable to all health establishments other than those serving the military and State Security Agency. Section 3(3) proposes a hierarchy of legislation, in that “If any conflict, relating to the matters dealt with in this Act, arises between this Act and the provisions of any other law, except the Constitution and the Public Finance Management Act or any Act expressly amending this Act, the provisions of this Act prevail”. This immediately challenges the status of the NHA, as the overarching piece of health legislation defining the structure and function of the health system, despite the following section: “The Act does not in any way amend, change or affect the funding and functions of any organs of state in respect of health care services until legislation contemplated in sections 77 and 214, read with section 227, of the Constitution and any other relevant legislation have been enacted or amended”.

Section 77 of the Constitution deals with money Bills, whereas section 214 governs the allocation of resources in terms of the equitable share concept and section 227 covers sources of provincial and local government funding. The Constitution has allocated concurrent competency for “Health services” to the national and provincial spheres, with the NHA clarifying what is meant by “municipal health services”, allocated to the local government sphere.²²

The 2016 HASA input on the White Paper focused on the restrictions to be placed on the private sector, argued that these “infringe upon or unduly limit fundamental rights contemplated in the Constitution”, including “the right to freedom of association in section 18 of the Constitution as well as the rights to self-determination and security of a person in section 12”.¹⁷

The SECTION27/TAC response to the draft Bill took a different line, arguing that the “proposals are neither coherent nor are they reasonably conceived”, and therefore that implementation as proposed “risks regression in access to health care services, a violation of section 27 of the Constitution”.¹⁸ The most significant change regarding the provinces is the proposed shift of the provincial equitable share of funds to the NHI Fund. The current situation has been criticised for the inability of the NDoH to monitor and direct appropriate distribution of these funds to pressing health needs, such as human resources, hospital maintenance and outreach services.²³ The proposed shift holds the prospect of improved allocation for urgent health interventions, particularly in resource-poor settings.

Access to services

Chapter 2 of the Bill describes access to healthcare services funded by NHI, and specifically limits access for asylum seekers and “illegal foreigners” to emergency medical services and those required for “notifiable conditions of public health concern”. Visitors without health insurance would also have access only to these limited services. The most contentious component of the chapter is that related to the future role of medical schemes. In terms of section 6(o) a user may purchase services that are not covered by the Fund through a “complementary voluntary medical insurance scheme register in terms of the Medical Schemes Act, any other private health insurance scheme or out of pocket payment”. Section 58 of the Bill enables consequent amendments to other legislation, as listed in the Schedule. The proposed amendment to the Medical Schemes Act (131 of 1998) would alter the definition of the “business of a medical scheme”, restricting such schemes to services “not covered by” NHI. This change would fundamentally alter the functioning of medical schemes over time (section 58 is also subject to the phased transition covered in section 57 of the Bill). Section 33 states: “Once National Health Insurance has been fully implemented as determined by the Minister through regulations in the Gazette, medical schemes may only offer complementary cover to services not reimbursable by the Fund”. Importantly, section 3(5) of the Bill states that the Competition Act (89 of 1998) is not applicable to any transactions concluded in terms of the NHI Act, presumably clearing the way for tariff-setting and collective engagement with healthcare service providers.

Governance of the NHI Fund

The key institution created by chapter 3 of the Bill is the NHI Fund, established as an “autonomous public entity”, in accordance with Schedule 3A of the Public Finance

Management Act (1 of 1999). Whether the Fund, as proposed, fundamentally alters the co-operative governance of health, as required by the Constitution and enshrined in the NHA, is open to question. Governance of the NHI Fund is to be entrusted to an independent Board, that is, nonetheless, “accountable to the Minister” (section 12). Whereas the draft Bill stated that members of the Board would be “recommended by the Minister of Health and appointed by the Cabinet” (section 14), the final Bill now entrusts this process entirely to the Minister (section 13), following a process of public nominations.

The question that arises is whether this process would yield a Board that is truly independent, and free from any political influence. In particular, one of the Board members is specifically appointed to represent the Minister. The requirements for appointment are largely technical (“appropriate technical expertise, skills and knowledge or experience, including health care financing, health economics, public health planning, monitoring and evaluation, law, labour, actuarial sciences, information technology and communication”). While the draft Bill stated that the chairperson and deputy would be chosen by the Board, the final Bill now enables the Minister to appoint the chairperson. Neither option is sufficient to ensure that no ‘sand’ fouls the gears of this multi-billion Rand Fund. There are other tell-tale signs of intended close engagement: for example, the Board is enjoined to “inform the Minister of any advice it gives to the Chief Executive Officer” (section 15(4)(d)). The Board may only determine its own procedures “in consultation with the Minister” (section 17).

One possible alternative is to construct a Board from representatives of key stakeholders. A 2017 input prepared for the High Level Panel on the Assessment of Key Legislation and the Acceleration of Fundamental Change argued that “[a]s the NHIF will be tax funded, it is not appropriate to appoint members representing specific interest groups”.²⁴ The source for that advice was a World Bank document that described the elements of effective governance as including, among others, that “[s]takeholders have effective representation in the governing bodies”.²⁵ This source recommended that the governance structures of mandatory health insurance (MHI) bodies include “representatives of government agencies, regulatory bodies, MHI entities, unions, employers’ organizations, beneficiaries, providers, and independent experts”. The authors recognised the risks, stating: “The representation of stakeholder interests can be functional or dysfunctional depending on which groups it includes and in what proportion; beneficiaries, employers, and medical professionals each often bring different perspectives regarding cost containment and financial sustainability versus service provision. To be successful, representation should attempt to achieve inclusiveness, participation, and consensus orientation”.

Principle 7 in the King IV Report would seem to offer a way forward: “The governing body should comprise the appropriate balance of knowledge, skills, experience, diversity and independence for it to discharge its governance role and responsibilities objectively and effectively”.²⁶ It would seem premature, therefore, to construct a governance body only of technical experts, and preclude the balancing inputs of stakeholders, including government agencies and regulatory bodies, such as the Council for Medical Schemes, let alone beneficiaries and healthcare providers. Nonetheless, the principle that needs to be emphasised is that the required “objectivity and effectiveness” can only be achieved if the appointees (whether “expert” or drawn from particular stakeholders) bring their experience and expertise into, but leave their stakeholder interests outside, the boardroom.

Management and structures

The Chief Executive Officer (CEO) of the Board is to be appointed through a convoluted process. After interviewing shortlisted candidates, the Board would forward recommendations to the Minister “for approval by the Cabinet”. The Minister would inform Parliament of the appointment within 30 days, and give notice in the Government Gazette. The notion of overly close engagement is continued in section 21, which requires the CEO to meet with the Minister, Director-General of Health and CEO of the Office of Health Standards Compliance (OHSC) at least four times per year, yet still be accountable to the Board. The CEO may not appoint or dismiss executive management staff without the prior written approval of the Board (section 22). The CEO is also enjoined to report to Parliament annually (section 20(1)(d)). Confusingly, section 51(1) requires the Board to submit an annual report to the Minister and Parliament, and section 51(4) requires the Minister to “without delay” table a copy of the report in both the National Assembly and National Council of Provinces.

The degree to which community participation in planning and decision-making is enabled by the Bill can be explored with reference to the proposed ministerial committees. How these would differ from the technical committees that the Board is entitled to appoint (section 24) is unclear, as these would not be sub-committees of the Board, composed only of Board members, but would involve external appointees. Chapter 7 of the Bill (sections 25 - 30) outlines three specified committees, and then the ability to establish additional technical committees. Section 29 requires the Minister to gazette the “composition, functions and working procedures” for any committee established under this chapter. While no size is stipulated for the Benefits Advisory Committee or the Stakeholder Advisory Committee, the Health Care Benefits Pricing Committee is to be composed of no fewer than 16 members and no more than 24. The remit of each committee and the requirements for membership/representation are shown in Table 1.

The role of these advisory structures is complicated by the additional structures outlined in the transitional arrangements (section 57). A particularly ill-advised decision has seen the inclusion of timelines in the Act itself (Phase 1: 2017 - 2022; Phase 2: 2022 - 2026). In Phase 1, the following interim structures are prescribed:

- National Tertiary Services Committee;
- National Governing Body on Training and Development;
- Ministerial Advisory Committee on Health Care Benefits for NHI (as a precursor to the Benefits Advisory Committee); and
- Ministerial Advisory Committee on Health Technology Assessment for NHI (as a precursor to the Health Technology Assessment Agency, which is mentioned nowhere else in the Bill).

It is only in Phase 2 that “selective contracting of health care services from private providers” will commence.

Interestingly, while the Stakeholder Advisory Committee appeared to be an optional structure in terms of the draft Bill (the Minister “may appoint”), and its remit also appears to be limited to advice and comments without any decision-making power, the composition is now to be prescribed, and the remit is unstated. In addition, it is unclear how this body would differ from the National Consultative Health Forum already established in terms of the NHA.

In the draft Bill, the appointment of technical committees was not only optional, but would occur only “after consultation with” the National Health Council (NHC). That the private sector has no representation on the NHC, as constituted by the NHA, was seemingly ignored. A larger

question was left unanswered, namely: what is the place of the NHC in a health system unified under NHI where the majority of funds for healthcare services are not disbursed by means of the equitable share formula to the provinces? The attempt in the final Bill to resolve this conundrum is less than convincing. Firstly, section 31 attempts to define the role of the Minister as being “governance and stewardship of the national health system” and “governance and stewardship of the Fund”. These two allocations are followed by an instruction that the Minister “must clearly delineate in appropriate legislation the respective roles and responsibilities of the Fund and the national and provincial Departments, taking into consideration the Constitution, this Act and the National Health Act”.

SECTION27/TAC expressed their concern directly in relation to the construct in the draft Bill: “Having all health funding and most decisions on health largely in the hands of one politician is dangerous”.¹⁸ The powers of the NDoH are described as being those provided by the NHA (section 32). However, it is the powers of the provincial Departments of Health that seem to be most severely constrained, although the detail is left for later amendments: “Without derogating from the Constitution or any other law, the functions of a provincial Department must be amended to comply with the purpose and provisions of this Act, subject to the provisions of section 57”. The Minister of Health is enabled to intervene directly in provincial affairs, by for example, designating “provincial tertiary and regional hospitals or groups of hospitals as autonomous legal entities accountable to the Minister through regulation” (section 32(2)(b)). Most importantly, the Minister will establish the District Health Management Offices (DHMOs) as “government components

Table 1: Ministerial Advisory Committees for the NHI Fund to be established in terms of Chapter 7 of the NHI Bill, South Africa, 2019

Ministerial Advisory Committee	Membership	Remit
Benefits Advisory Committee	Persons with expertise in medicine, public health, health economics, epidemiology, and the rights of patients. One member to represent the Minister.	To determine, in consultation with the Minister and Board, the health service benefits provided by the NHI Fund, at each level of care. To “determine and review” “detailed and cost-effective treatment guidelines that take into account the emergence of new technologies”.
Health Care Benefits Pricing Committee	Persons with expertise in actuarial science, medicine, epidemiology, health management, health economics, health financing, labour and rights of patients. One member to represent the Minister.	To recommend the prices of health service benefits to the Fund.
Stakeholder Advisory Committee	Representatives from the statutory health professions councils, health public entities, organised labour, civil society organisations, associations of health professionals and providers as well as patient advocacy groups.	Not explicitly stated.

to manage personal and non-personal health care services” (section 32(2)(c)). Section 36 further emphasises that the DHMOs are a “national government component”, established by a new section of the NHA (section 31A), and entrusted to “manage, facilitate, support and coordinate the provision of primary health care services” at district level. Whereas the NHA required the head of a provincial department to “control the quality of all health services and facilities” in the province, this is altered to read “assist the District Health Management Office in controlling” such quality.

Contracting for services

A key design feature of the proposed Fund is that of a purchaser-provider split. Section 35(2) indicates that the Fund must transfer funds directly to “accredited and contracted central, provincial, regional, specialised and district hospitals based on a global budget or Diagnosis Related Groups”. In addition, funds for primary health care services must be transferred to Contracting Units for Primary Health Care (CUPs) “at the sub-district level”. The proposed disbursement mechanism specifically excludes the provincial authorities. How private hospitals might fit into this process is unclear, as their designation fits none of the categories listed.

It is at the primary health care level that the proposed system is most difficult to fathom. Section 35(3) stipulates that at the sub-district level funds are to be transferred to CUPs. Section 36 then describes the role of the DHMOs, which do not yet exist (being introduced by the consequent amendment to the NHA). Section 37 returns to the role of the CUPs, described as being “comprised of a district hospital, clinics or community health centres and ward-based outreach teams and private providers organised in horizontal networks within a specified geographical sub-district area”. As the SECTION27/TAC input notes, “the national structure (the Fund) pays a sub-district level structure (the CUP) which then pays contracted providers (owned privately, by the province, or by the municipality)”.¹⁸

SECTION27/TAC further notes that the CUPs will need to be “sophisticated and multi-skilled structures, capable of performing an extensive role”. The Bill therefore describes the CUPs as including the full range of potential contracted providers, not a structure capable of a highly technical role. The confusion between which body is contracted by the Fund and which body is engaged in the process of the contracting of providers (both public and private) is also revealed in section 41(3)(a), which states that “an accredited primary health care provider must be contracted by” a CUP. In contrast, section 39(3) states that the “Fund must conclude a legally binding contract with a health establishment certified by the Office of Health Standards Compliance”.

Clearly the CUPs are an integral element of the Fund, but they are also the structures to be contracted to deliver services. Further confusion appears in section 31B(6) inserted into the NHA: “To the extent that the Contracting Units for Primary Health Care are not adequately capacitated, the District Health Management Office must perform these functions on its behalf until such time as the Units have been sufficiently capacitated to fulfil their purpose as provided for in this section”. To date, neither the CUPs nor the DHMOs exist, nor have any such structures been explored or tested in the NHI pilot districts. To what extent contracting of providers will be centralised to the Fund or decentralised to DHMOs and/or CUPs therefore remains unclear.

A further new structure is to be created in the form of the Office of Health Products Procurement, to be established by the Board in consultation with the Minister, and “located within the Fund”. Confusingly, while the Benefits Advisory Committee is to be entrusted with developing “detailed and cost-effective treatment guidelines”, the Office of Health Products Procurement is tasked to “determine the selection of health related products to be procured” and “develop a national health products list”. It must also “coordinate the supply chain management process and price negotiations for health related products”. “Health related products” are specifically defined in the Bill as excluding medicines and medical devices, but “health products” are not defined (whereas “health goods” are and appear to include medicines and medical devices).

The process of selection is directly related to pricing, and the Fund is required to “negotiate the lowest possible prices for goods and health care services” (section 11(2)(e)). The Health Care Benefits Pricing Committee must “recommend the prices of health service benefits to the Fund” (section 26(3)). Section 38(4) attempts to outline the selection functions as follows: “The Office of Health Products Procurement must support the Benefits Advisory Committee in the development and maintenance of the Formulary, comprised of the Essential Medicine List and Essential Equipment List as well as a list of health related products used in the delivery of health care services as approved by the Minister in consultation with the National Health Council and the Fund”.

Importantly, section 38(6) states: “An accredited health care service provider and health establishment must procure according to the Formulary, and suppliers listed in the Formulary must deliver directly to the accredited and contracted health service provider and health establishment”. In this regard, the proposed amendment to the Medicines and Related Substances Act (Act 101 of 1965) has enormous implications for the procurement and supply of medicines in particular. Where previously the single exit

price (SEP) was defined in section 22G of that Act as being the “only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State”, this is amended to read “to the National Health Insurance Fund or any other person”.

The consequences for the current strict separation between state tender stock and private-sector medicines are wide-ranging and call into question the very *raison d’être* of the Centralised Chronic Medicines Dispensing and Distribution (CCMDD) programme. In the meantime, the current separation between the pricing of medicines for the public and private sectors continues, with recent Gazette notices providing for the SEP adjustment for 2019,²⁷ updated dispensing fees for pharmacists²⁸ and dispensing practitioners,²⁹ and exploring amendments to the methods of determining SEP adjustments in future.³⁰

Anticipated regulations

As is usual, the Bill lists an extensive set of regulations to be issued by the Minister, including on the “functions and power” of the DHMOs and CUPs. Two regulations raise questions: the requirement for regulations on the “relationship between public and private health establishments, and the optional contracting in of private health care providers”, and on the “relationship between the Fund and medical insurance schemes registered in terms of the Medical Schemes Act and other private health insurance schemes”. There is no clarity in the policy *per se*, in either the 2015 or 2017 versions, that can inform such regulations.

Consequential amendments

The NHI Bill also includes the proposed amendments to a number of other Acts once section 58 comes into effect (in the form of a listing of laws repealed or amended). Apart from the amendments already described, proposed amendments to the Health Professions Act and Allied Health Professions Act (but not to the Nursing Act or Pharmacy Act) are included, and deal with informing patients about services, and fees to be charged, that are “complementary” in that they are “not covered by the National Health Insurance Fund”.

What is not clear from the NHI Bill is whether medical schemes will be restricted to “complementary” services or allowed to provide “supplementary” or even “duplicative” services. Whether, as is argued in the HASA submission, the Constitution would allow the restriction of existing rights is open to question.¹⁷ It may well be that, as in the United Kingdom, those who wish to may be able to procure all healthcare services privately, and insure against such costs, provided that they also make a full contribution to the NHI Fund, however that will eventually be funded.

Congruence with the HMI?

Although the final findings report of the Competition Commission’s HMI is at pains to point out that its terms of reference were specific to the private sector, the report is clearly cognisant of the NHI Bill and the extent to which its

recommendations need to dovetail with the structures and processes envisaged under NHI.²¹ Nonetheless, the HMI has recommended the establishment of key structures that are not catered for in the NHI Bill, and which in some cases could be duplicative.

The HMI found that the private healthcare sector is currently “subject to distortions which adversely affect competition”, at the level of health facilities, funders and practitioners (p. 201). In particular it noted a “fragmented, poorly enforced regulatory system with weak oversight” of the supply side (p. 212), and accordingly recommended the establishment of an Independent Supply-Side Regulator for Healthcare (SSRH), using the existing enabling provisions in the NHA (section 3, read with section 90(1)(f)).

The SSRH is, among other functions, to be responsible for a strengthened health facility licensing regimen (replacing the current provincial systems, which mostly rely on regulations issued in terms of previous Health Acts). The proposed system would largely supplant that envisaged in chapter 6 of the NHA, which is not yet in effect. The SSRH would also take over the practice code numbering system currently operated by the Board of Healthcare Funders (BHF). In making these proposals, the HMI carefully explained how they would complement, not duplicate, the accreditation and inspectorate role of the OHSC.

However, the recommendation that the SSRH also take on the role of “economic value assessments”, described as akin to health technology assessment (HTA), is less easily located in relation to the proposals included in the NHI Bill (which are also confusing). Likewise, although the need for extensive data on all aspects of the health system is clear, the best location for the proposed “national health data repository” is unclear. The SSRH is also to enable the creation of a multilateral negotiation forum (MLNF) on health services pricing, a process that is also covered in the NHI Bill. In this regard the recommendation that all medical schemes offer a “single, stand-alone, comprehensive, standardised, obligatory base benefit package” (p. 236) has considerable overlaps with the NHI proposals on benefit package design.

The second key new structure to be established, as recommended by the HMI, is the Outcome Measurement and Reporting Organisation (OMRO), described as “a platform for providers, patients and all other stakeholders in the provision of healthcare to generate patient-centred and scientifically robust information on outcomes of healthcare”. Where the SSRH is proposed as a Schedule 3A public entity, the OMRO is envisaged to be an independent and collaborative structure, in the private not-for-profit space (p. 232). Noting that the NHI Fund plans to engage in “strategic purchasing”, which would rely on accurate data on health outcomes and the costs of care, the HMI argued that “OMRO is not only consistent with, but also essential to the operation of the NHI” (p. 206).

Questions of actors, process and context

The degree of uncertainty outlined in the analysis above points to the extent to which engagement by actors outside of the NDoH and Presidency has been severely limited to date. Although material differences between the draft and final Bill are discernible, the existing National Consultative Health Forum has not been used to its maximum potential. Two processes have had the potential to alter this dynamic considerably. The first was the establishment of the Competition Commission's HMI in 2014, which has gathered considerable materials,³¹ issued a draft report,³² and issued its final report and recommendations on 30 September 2019.²¹ There are indications that a wholesale amendment of the Medical Schemes Act of 1998 will only occur in response to that final report. The HMI process, in stark contrast to the NDoH-driven policymaking process, has placed all submissions received in the public domain.

In October 2018, a Presidential Health Summit was held, attended by more than 600 delegates.¹⁹ The report of that Summit lists fine intentions:

- “A coherent and aligned network of ‘structures’ across the health system that spread responsibility downwards in the hierarchy must be developed to improve accountability in leadership and governance”;
- “The community, including health service users must be actively engaged in the processes of unifying the health system”.

As outlined above, the NHI Bill fails to deliver those “structures”, or to meet the requirement for community engagement. Whether the public participation required in a section 76 legislative process will be able to fundamentally alter the final shape of the NHI Fund remains to be seen.

The President's State of the Nation Address in February 2019 contained a relatively lengthy exposition on the state of play, and specifically linked the NHI process to the quality improvement plan.³³ The outlines of that plan were released, in hard copy only, to a consultative meeting with stakeholders held in August 2018. The Draft National Quality Improvement Plan (NQIP) has not been placed in the public domain by the NDoH, but a scanned version is available.³⁴

Implementing the National Health Act

The draft NQIP includes a clear description of the evolution of quality standards applicable to health facilities, from the establishment of the OHSC (by the 2013 amendment of the NHA), through the development of the National Core Standards, to the publication of the regulated standards in February 2018 (which came into effect a year later).

However, most importantly, it contains this statement: “the plan is to enhance the rigor and depth of the regulated standards as experience is gained in the field”. A key part of this development programme is the extension of the Ideal Clinic Realisation and Maintenance (ICRM) programme to the Ideal Hospital Realisation and Maintenance Framework.³⁵ That document and process are still in draft form.

From an actor and process perspective, one of the most intriguing lines in the draft NQIP is this one: “There is already an internationally recognised healthcare facility accreditation organisation in South Africa that could offer the NHI an accreditation system”. It is assumed that this refers to the Council for Health Service Accreditation of Southern Africa (COHSASA), whose founder serves on the OHSC board.³⁶ A rapprochement between the NDoH leadership and this not-for-profit organisation, which has already engaged with a number of public-sector health facilities over the years, is apparent. However, whether the OHSC will render COHSASA obsolete remains to be seen.

The NQIP recognises the scale of the challenge of ensuring that the full range of health establishments meet accreditation standards, in order to be eligible for an NHI contract. In this regard, the final publication of the report of the South African Lancet National Commission, linked to the Lancet Global Health Commission on High-Quality Health Systems in the Sustainable Development Goals Era, is eagerly awaited.^{37,38}

The development of systems at the OHSC continues apace, with the publication of a Code of Conduct for Inspectors in January 2019.³⁹ In March 2019, this was followed by the publication of a draft Enforcement Policy for public comment.⁴⁰ This document is the first to mention the impact of the Protection of Personal Information Act (POPIA) of 2013, which is gradually coming into operation. Explorations of how the POPIA will impact various elements of healthcare practice are beginning to be published.⁴¹

The issuing of regulations in terms of the NHA has, however, slowed down perceptibly. In April 2018, a correction was published to a previous policy guideline on the Licensing of Residential and/or Day Care Facilities for Persons with mental Illness or Severe or Profound Intellectual Disability.⁴² Although this update can be viewed as evidence of a tightening of regulatory measures in the aftermath of the Life Esidimeni tragedy, the consequences of non-adherence to such instruments cannot be ignored.⁴³ In September 2019, the Minister designated “health establishments to provide acute care, rehabilitation and palliative care for cerebral palsy”, the majority of which are central hospitals.⁴⁴ These hospitals and hospital complexes are to provide care “in collaboration with each other”, and “at no cost to the patients”. In July 2018, the format of the Material Transfer Agreement of Human Biological Materials was stipulated.⁴⁵

Other health-related legislation: unfinished business

Following the 2019 General Election, a number of health-related Bills have lapsed. The National Health Laboratory Service Amendment Bill, first introduced in 2017, was passed by Parliament in February 2019, and assented to by the President as Act No. 5 of 2019.⁴⁶ However, the linked National Public Health Institute of South Africa Bill, also introduced in 2017, which passed its Second Reading in the National Assembly in August 2018 and was referred to the National Council of Provinces, has not progressed further.⁴⁷ Both have been described in a previous issue of the *Review*.⁴³

Two Private Member's Bills seeking to amend the NHA have also lapsed but could be revived. Bill 29 of 2018 was introduced by Dr S Thembekwayo, MP (EFF).⁴⁸ The Bill seeks to amend section 4 of the NHA, by adding a subsection reading: "Clinics funded by the State must provide the services referred to in subsection (3) 24 hours a day and seven days a week". A more substantive proposed change has been tabled by Ms D Carter, MP (COPE), in the form of Bill 9 of 2019,⁴⁹ following the publication of an explanatory memorandum.⁵⁰ The Amendment Bill seeks to "provide for legal recognition, legal certainty and legal enforceability regarding advance health care directives such as the living will and the durable power of attorney for healthcare". It aims to "set out the purpose, scope and format for these advance health care directives and provide for the resolution of disputes related to such directives; clarify whether a 'living will' or a substitute decision-maker's decision may be overridden by a medical practitioner or family members in any circumstances; and clarify whether someone acting upon these directives is immune from criminal and civil prosecutions". The Bill appears to address some of the lacunae exposed by previous cases.⁵¹

No progress has been evident in relation to the draft Control of Tobacco Products and Electronic Delivery Systems Bill, published for comment in May 2018.⁵² However, it has been reported that the Bill has been referred to the state law advisors.⁵³ In this regard, South Africa has been rated as at high risk of interference from tobacco industry lobbying.⁵⁴

The State Liability Amendment Bill (16 of 2018) has also not progressed, after being tabled in the National Assembly in May 2018.⁵⁵ As noted in the last issue of the *Review*, "[w]hile ostensibly aimed at increasing the financial resources of state hospitals in order to provide healthcare services, this legislative attempt in no way addresses the fundamental issue of professional negligence that gives rise to the proliferation of malpractice suits".⁴³ As a section 76 Bill, this proposed amendment will need extensive debate in the provinces in order to pass constitutional muster.

Statutory health councils

In the year since the last *Review*, few legislative instruments have been issued by the statutory health councils, apart from those dealing with routine nominations/elections and the setting of fees. In March 2019, the Minister issued a confusing notice creating two categories of nurse practitioners, namely "enrolled nurse" and "general nurse", which do not appear to match previous categories established in terms of section 31 of the Nursing Act of 2005.⁵⁶ In April 2019, draft regulations were issued in terms of the Nursing Act, specifying the minimum requirements for education and training of learner/student midwives.⁵⁷ The same day saw the publication of the National Policy on Nursing Education and Training by the NDoH.⁵⁸

The South African Pharmacy Council (SAPC) published amendments to the Good Pharmacy Education Standards (Higher Education and Training) in March 2019,⁵⁹ as well as draft amendments covering the Occupational Qualification Sub-Framework.⁶⁰ An example of a change in the Higher Education standard is the insertion of the requirement: "A person who teaches pharmacy practice must be a pharmacist registered in South Africa". Perhaps of greater relevance to the implementation of NHI, the SAPC also updated the schedule of fees that a pharmacist may charge for professional services.⁶¹ As before, the fees relating to dispensing of finished pharmaceutical products are those published in terms of the Medicines and Related Substances Act of 1965. However, for any additional services, such as extemporaneous compounding, sterile preparations, pharmacokinetic consultations, medicines use reviews, chronic medicines authorisation, or pharmacist-initiated therapy, additional fee-for-service rates are prescribed. It is unclear how many of these fees are actually charged by pharmacists or reimbursed by medical schemes. Further draft amendments to the Good Pharmacy Practice standards were published in May 2019.⁶² Also issued in May 2019 were the final regulations governing continuing professional development for those registered with the SAPC.⁶³

Jurisprudence

The most pressing court decision in the past year has undoubtedly been the Constitutional Court judgment in the cannabis cases referred from the Cape High Court.⁶⁴ This judgment poses an existential challenge to the logic underpinning the regulation of so-called "drugs of abuse". That logic rests on the assumption that some substances with psychoactive properties can be deemed to have legitimate medicinal uses (and therefore regulated in terms of the Medicines and Related Substances Act of 1965), whereas others can be designated as having no legitimate

medicinal applications, allowing their possession and use to be proscribed (in terms of the Drugs and Drug Trafficking Act of 1992). In addition to the criminal sanctions applied, there are additional measures prescribed in terms of the Prevention of and Treatment for Substance Abuse Act of 2008.

In essence the Constitutional Court confirmed the ruling of the Cape High Court, finding the restrictions on the possession, cultivation and use of cannabis by an adult, in private, to be inconsistent with the right to privacy entrenched in section 14 of the Constitution. The court therefore found the definition of “deal in” in section 1 and section 4(b) of the Drugs and Drug Trafficking Act of 1992, and section 22A(9)(a)(i) of the Medicines and Related Substances Act of 1965, to be constitutionally invalid. The declaration of invalidity was, however, suspended for a period of 24 months from the date of the handing down of the judgment (18 September 2018), but with specific wording “read in” to the sections listed in the interim.

South Africa is a signatory to the United Nations Single Convention on Narcotic Drugs of 1961, which requires the country to take certain legislative steps to control the possession, use and trade in substances listed in the various Schedules to the Convention. Although amendments to the Schedules in relation to cannabis and cannabinoids were proposed by the World Health Organization Expert Committee on Drug Dependence (ECDD) to the Commission on Narcotic Drugs in March 2019,⁶⁵ and supported by the South African delegation, it appears that a decision to implement them was postponed to later in the year.

The Department of Justice is in the process of drafting a new Cannabis Regulation Bill, but no details are publicly accessible yet. The necessary amendments to the Medicines and Related Substances Act of 1965, have yet to be drafted. However, there is an ongoing process of updating the Schedules to that Act, and also of issuing licences for the cultivation of cannabis for medicinal purposes.⁶⁶ One consequence is that the Constitutional Court judgment has introduced considerable uncertainty, and resulted in a marked increase in the number of under-regulated cannabis-containing products reaching the market, including those that make medicinal claims that might not be justified or safe.⁶⁷ Despite the judgment, the marketing of cannabis-based medicinal products is still subject to the requirements of the Medicines Act.⁶⁸ In May 2019, specified cannabidiol-containing medicinal preparations were exempted from the operation of Schedule 4 to the Medicines Act.⁶⁹

The broader question of how South Africa will approach the question of non-medicinal use of drugs remains unresolved and awaits the update to the National Drug Master Plan (NDMP). The Cabinet statement of 27 March 2019 noted that the evaluation report on the National Drug Master Plan

2013 - 2018 had been approved, and that “the setting up of an Anti-Drug Council, structured similarly to the South African National AIDS Council, to drive the fight against drug addiction” was approved.⁷⁰ The Cabinet noted that the “revised master plan will now be referred to as [the] Anti-Drug Master Plan”, an unfortunate echo of the discredited “war on drugs” rhetoric.

In August 2019, the Supreme Court of Appeal dismissed an appeal against a previous High Court judgment which found that a mother had failed to prove that the damage sustained by her child (due to hypoxaemia during childbirth) was due to the negligent failure of the hospital staff involved in the child’s delivery.⁷¹ Nonetheless, the court expressed its displeasure with the quality of care delivered in the province in question: “Far too often this court is confronted with serious and serial negligence in hospitals falling under the respondent. Whether or not the negligence can be said to have caused harm in the delictual sense, it is clear that studied neglect of standards has become pervasive in many such hospitals” (para. 28).

A recent decision in the Western Cape Division of the High Court⁷² could have far-reaching implications for the way in which amendments are made to schedules to an Act of Parliament, such as the schedules to the Medicines Act. In opposing an application for his extradition to the United Kingdom, where he was suspected of having committed certain criminal offences relating to the production, cultivation, possession, and supply of cannabis, the person concerned challenged, among others, the constitutionality of section 63 of the the Drugs and Drug Trafficking Act (140 of 1992) (Drugs Act). This provision empowers the Minister of Justice and Correctional Services to amend the schedules to the Drugs Act. This authority was challenged as an impermissible delegation of power and a breach of the separation of powers doctrine, on the basis that Minister’s power encroached on the function of parliament to promulgate primary legislation, which, it was argued, included the schedules to the Drugs Act. A single judge bench found that the section was indeed unconstitutional, and ruled that all amendments made pursuant to the passing of the Drugs Act stood to be impugned. However, as the scheduling of cannabis was done concurrently with the promulgation of the Drugs Act, its scheduling was not affected with regard to this case.

Section 37A of the Medicines Act contains a similar provision: “Amendment of Schedules – Notwithstanding the provisions of section 35(2), the Minister may, on the recommendation of the Authority, from time to time by notice in the Gazette amend any Schedule prescribed under section 22A(2) by the inclusion therein or deletion therefrom of any medicine or other substance, or in any other manner”. As amendments to the schedules to the Medicines Act are much more frequent, striking down such a provision could lead to the absurd result of having

to resort to parliament every time an item is added to, or deleted from, the schedule. On the other hand, an important principle of our constitutional democracy has been raised, namely whether a schedule that may be considered an integral part of legislation may be amended without resort to parliament. Ultimately, the Constitutional Court will be required to pronounce on the constitutionality of section 63 of the Drugs Act (and indeed all other similar provisions) and provide directions on the remedy to a possible legal impasse.

Conclusions

South Africa has been poised on the brink of fundamental reform of its health system for a number of years. Many of the principles underpinning the attempt to create a unified health system for the country have remained unchanged since the first health-related White Paper in 1997. That they have proven so difficult to implement is testament not only to the scale of the challenge, but also to the consequences of the quasi-federal Constitutional order confirmed in 1996, and in particular the impact of fiscal federalism. Following the tabling of the NHI Bill, and the recommendations of the almost five-year Health Market Inquiry, it is critical that these processes be aligned, especially in terms of the phased changes envisaged by both sets of proposals. Whether these reforms will see re-invigorated public participation in the planning and provision of healthcare services is also open to question, but such participation is equally crucial to a meaningful application of Comprehensive Primary Health Care, a critical pillar of our healthcare system. The Presidential Health Summit cannot merely be an event, but must signal a new approach to meaningful engagement with all stakeholders.

The radically transforming terrain of health services demands a high degree of policy coherence, as well as visionary stewardship from government in a participatory and inclusive national effort.

References

1. United Nations. Sustainable Development Goals, 2015. URL: <https://www.un.org/sustainabledevelopment/>
2. United Nations. SDG 3: Ensure healthy lives and promote wellbeing for all at all ages. URL: <https://www.who.int/sdg/targets/en/>
3. Harrison D. The National Health Services Commission, 1942-1944 - its origins and outcome. *S Afr Med J*. 1993;83(9):679-84.
4. Minister of Health. White Paper on the Transformation of the Health System in South Africa. General Notice No. 667, Government Gazette No. 17910, 16 April 1997. URL: https://www.gov.za/sites/default/files/gcis_document/201409/17910gen6670.pdf
5. Republic of South Africa. National Health Act (Act No. 61 of 2003). URL: https://www.gov.za/sites/default/files/gcis_document/201409/a61-03.pdf
6. Republic of South Africa. National Health Amendment Act (Act No. 12 of 2013). URL: https://www.gov.za/sites/default/files/gcis_document/201409/36702gon529_1.pdf
7. President of the Republic of South Africa and Others v South African Dental Association and Another [2015] ZACC 2. URL: [https://collections.concourt.org.za/bitstream/handle/20.500.12144/3779/Full%20judgment%20Official%20version%20\(130%20Kb\)-22580.pdf?sequence=1&isAllowed=y](https://collections.concourt.org.za/bitstream/handle/20.500.12144/3779/Full%20judgment%20Official%20version%20(130%20Kb)-22580.pdf?sequence=1&isAllowed=y)
8. Minister of Health. National Health Insurance in South Africa. Policy Paper. 12 August 2011. URL: https://www.gov.za/sites/default/files/gcis_document/201409/nationalhealthinsurance2.pdf
9. Minister of Health. White Paper on National Health Insurance. 11 December 2015. URL: https://www.gov.za/sites/default/files/gcis_document/201512/39506gon1230.pdf
10. Minister of Health. National Health Insurance Policy: Towards universal health coverage. 30 June 2017. URL: https://www.gov.za/sites/default/files/gcis_document/201707/40955gon627.pdf
11. Minister of Health. NHI Implementation: Institutions, bodies and commissions that must be established. Government Notice No. 660, Government Gazette No. 40969, 7 July 2017. URL: https://www.gov.za/sites/default/files/gcis_document/201707/40969gon660.pdf
12. Hunter Q. 'We'll call it Ramaphosa-care': Health minister Motsoaledi wants the president to make NHI happen. *TimesLive*, 31 March 2019. URL: <https://www.timeslive.co.za/politics/2019-03-31-well-call-it-ramaphosa-care-health-minister-motsoaledi-wants-the-president-to-make-nhi-happen/>

13. Kahn T. Health DG kept in the dark on revisions to NHI Bill. BDLive, 23 November 2018. URL: <https://www.businesslive.co.za/bd/national/health/2018-11-23-health-dg-kept-in-the-dark-on-revisions-to-nhi-bill/>
14. Heywood M. Nicholas Crisp: A man on a mission to make NHI work. Daily Maverick, 19 August 2019. URL: <https://www.dailymaverick.co.za/article/2019-08-19-nicholas-crisp-a-man-on-a-mission-to-make-nhi-work/>
15. Minister of Health. National Health Insurance Bill (Bill No. 11 of 2019). 6 August 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf
16. Minister of Health. Draft National Health Insurance Bill. Government Notice No. 635, Government Gazette No. 41725, 21 June 2018. URL: https://www.gov.za/sites/default/files/gcis_document/201806/41725gon635s.pdf
17. Hospital Association of South Africa. Input on the National Health Insurance White Paper, prepared by Werksman's Attorneys, 2016. URL: <https://www.hasa.co.za/wp-content/uploads/2016/07/Werksmans-Report-HASA-NHI-White-Paper-Submission.pdf>
18. SECTION27/Treatment Action Campaign. Submission on Draft National Health Insurance Bill, 2018, Draft Medical Schemes Amendment Bill, 2018, and Draft National Quality Improvement Plan, 2018. 21 September 2018. URL: <http://section27.org.za/wp-content/uploads/2018/09/NHI-submission-from-SECTION27-and-TAC-21-September-2018.pdf>
19. Presidential Health Summit 2018. Strengthening the South African health system towards an integrated and unified health system. Birchwood Conference Centre, Johannesburg, 19-20 October 2018. URL: <http://www.thepresidency.gov.za/download/file/fid/1493>
20. South African National Department of Health. Evaluation of Phase 1 implementation of interventions in the National Health Insurance (NHI) pilot districts in South Africa. July 2019. URL: <http://www.health.gov.za/index.php/2014-03-17-09-09-38/reports/category/573-reports-new-2019?download=3548:evaluation-of-phase-1-implementation-of-interventions-in-the-national-health-insurance-nhi>
21. Competition Commission South Africa. Health Market Inquiry. Final Findings and Recommendations Report. September 2019. URL: <http://www.compcom.co.za/wp-content/uploads/2014/09/Health-Market-Inquiry-Report.pdf>
22. Republic of South Africa. Constitution of the Republic of South Africa (Act No. 108 of 1996), as amended. URL: <https://www.gov.za/sites/default/files/images/a108-96.pdf>
23. Rensburg R. The power, the purse strings and the National Health Insurance. Mail and Guardian. 20 September 2019. URL: <https://mg.co.za/article/2019-09-20-00-the-power-the-purse-strings-and-the-nhi>
24. McIntyre D, Ataguba J. Access to quality health care in South Africa: Is the health sector contributing to addressing the inequality challenge? Input to the High-Level Panel on the Assessment of Key Legislation and the Acceleration of Fundamental Change, 2017. URL: https://www.parliament.gov.za/storage/app/media/Pages/2017/october/High_Level_Panel/Commissioned_reports_for_triple_challenges_of_poverty_unemployment_and_inequality/Diagnostic_Report_on_Access_to_Quality_Healthcare.pdf
25. Hansl B, Rahol A, Gottret P, Leive A. Good governance dimensions in mandatory health insurance: A framework for performance assessment. In: Savedoff WD, Gottret P, editors. Governing Mandatory Health Insurance. Learning from Experience. Washington: The World Bank; 2008. URL: <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/Peer-Reviewed-Publications/GovMandatoryHlthIns.pdf>
26. Institute of Directors in Southern Africa. King IV Report on Corporate Governance for South Africa, 2016. URL: https://c.ymcdn.com/sites/iodsa.site-ym.com/resource/collection/684B68A7-B768-465C-8214-E3A007F15A5A/IoDSA_King_IV_Report_-_WebVersion.pdf
27. Minister of Health. Annual Single Exit Price Adjustment of medicines and scheduled substances for the year 2019. Government Notice No. 29, Government Gazette No. 42183, 23 January 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201901/42183gon29.pdf
28. Minister of Health. Transparent pricing system for medicines and scheduled substances: Dispensing fee for pharmacists. Government Notice No. 28, Government Gazette No. 42183, 23 January 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201901/42183gon28.pdf
29. Minister of Health. Transparent pricing system for medicines and scheduled substances: Dispensing fee for dispensing practitioners. Government Notice No. 27, Government Gazette No. 42183, 23 January 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201901/42183gon27.pdf
30. Minister of Health. Annual single exit prices adjustment of medicines and scheduled substances for 2020. Government Notice No. 3014, Government Gazette No. 42286, 8 March 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201903/42286gon304.pdf
31. Competition Commission South Africa. Market Inquiry into the Private Healthcare Sector. 27 September 2019. URL: <http://www.compcom.co.za/healthcare-inquiry/>
32. Competition Commission South Africa. Health Market Inquiry. Provisional Findings and Recommendations Report. 5 July 2018. URL: <http://www.compcom.co.za/provisional-findings-and-recommendations-report/>

33. President of the Republic of South Africa. 2019 State of the Nation Address, 7 February 2019. URL: <https://www.gov.za/speeches/president-cyril-ramaphosa-2019-state-nation-address-7-feb-2019-0000>
34. South African National Department of Health. Draft National Quality Improvement Plan. Draft Plan for consultation, 24 August 2018. URL: <https://www.spotlightnsp.co.za/wp-content/uploads/2019/04/Draft-National-Quality-Improvement-Plan-24-August-2018.pdf>
35. South African National Department of Health. Ideal Hospital Realisation and Maintenance Framework Manual 2018. URL: <https://www.idealhealthfacility.org.za/docs/hospital/v1/Ideal%20Hospital%20Realisation%20And%20Maintenance%20Framework%20Manual.pdf>
36. Council for Health Service Accreditation of Southern Africa (COHSASA). URL: <http://cohsasa.co.za/>
37. National Commissioners on High Quality Health Systems. National Commissions on High Quality Health Systems: activities, challenges, and future directions. *Lancet Glob Health*. 2019;7(2):e179-80.
38. Matsoso MP, Hunter JR, Brijjal V. Embedding quality at the core of universal health coverage in South Africa. *Lancet Glob Health*. 2018;6(11):e1153-4.
39. Office of Health Standards Compliance. Code of conduct for inspectors. Government Notice No. 11, Government Gazette No. 42162, 18 January 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201901/42162gon11.pdf
40. Office of Health Standards Compliance. Draft Enforcement Policy, Government Notice No. 478, Government Gazette No. 42337, 29 March 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201903/42337gon478.pdf
41. Staunton C, de Stadler E. Protection of Personal Information Act No. 4 of 2013: implications for biobanks. *S Afr Med J*. 2019;109(4):232-4.
42. Minister of Health. Policy guidelines for licensing of residential and/or day care facilities for persons with mental illness and/or severe or profound intellectual disability: Correction. Government Notice No. 424, Government Gazette No. 41571, 13 April 2018. URL: https://www.gov.za/sites/default/files/gcis_document/201804/41571gon424.pdf
43. Gray A, Vawda Y. Health legislation and policy. In: Rispel LC, Padarath A, editors. *South African Health Review 2018*. Durban: Health Systems Trust; 2018.
44. Minister of Health. Designation of health establishments to provide acute care, rehabilitation and palliative care for cerebral palsy. Government Notice No. 1146, Government Gazette No. 42687, 5 September 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201909/42687gon1146.pdf
45. Minister of Health. Material transfer agreement of human biological materials. Government Notice No. 719, Government Gazette No. 41781, 20 July 2018. URL: https://www.gov.za/sites/default/files/gcis_document/201808/41781gon719.pdf
46. Republic of South Africa. National Health Laboratory Service Amendment Act (Act No. 5 of 2019). URL: https://www.gov.za/sites/default/files/gcis_document/201905/42442gon5nationalhealthlaboratoryserviceamendmentact5of2019.pdf
47. Minister of Health. National Public Health Institute of South Africa Bill (Bill No. 16B of 2017). URL: https://www.gov.za/sites/default/files/gcis_document/201808/b16b-2017a.pdf
48. Dr S Thembekwayo, MP. National Health Amendment Bill (Bill No. 29 of 2018). URL: https://www.gov.za/sites/default/files/gcis_document/201809/b29-2018nationalhealtha.pdf
49. Ms D Carter, MP. National Health Amendment Bill (Bill No. 8 of 2019). URL: https://www.gov.za/sites/default/files/gcis_document/201903/b8-2019healthbill.pdf
50. Ms D Carter, MP. Notice of intent to introduce a Private Member's Bill and invitation for comment on the Draft National Health Amendment Bill, 2018. Government Notice No. 408 of 2018, Government Gazette No. 41789, 24 July 2018. URL: https://www.gov.za/sites/default/files/gcis_document/201808/41789gen408.pdf
51. McQuoid-Mason DJ. Assisted suicide and assisted voluntary euthanasia: Stransham-Ford High Court case overruled by the Appeal Court - but the door is left open. *S Afr Med J*. 2017;107(5):381-2.
52. Minister of Health. Control of Tobacco Products and Electronic Delivery Systems Bill: draft. Government Notice No. 475, Government Gazette No. 41617, 9 May 2018. URL: https://www.gov.za/sites/default/files/gcis_document/201805/41617gon475re.pdf
53. Kahn T. SA has little capacity to fend off tobacco lobby, report finds. *BDLive*, 10 October 2019. URL: <https://www.businesslive.co.za/bd/national/health/2019-10-10-sa-has-little-capacity-to-fend-off-tobacco-lobby-report-finds/>
54. Assunta M. Global Tobacco Industry Interference Index 2019. Global Center for Good Governance in Tobacco Control, Bangkok, Thailand. September 2019. URL: https://exposetobacco.org/wp-content/uploads/2019/10/GlobalTIIndex_Report_2019.pdf
55. Minister of Justice and Correctional Services. State Liability Amendment Bill (Bill No. 16 of 2018). URL: https://www.gov.za/sites/default/files/gcis_document/201806/b16-stateliabilitya.pdf
56. Minister of Health. Categories of persons to be registered to practice nursing. Government Notice No. 402. Government Gazette No. 42308, 14 March 2019. URL: https://www.gov.za/sites/default/files/gcis_document/201903/42308gon402.pdf