SAFEGUARDING PATIENT SAFETY IN HEALTHCARE SETTINGS IN NAMIBIA: AN APPRAISAL OF THE REGULATORY FRAMEWORK GOVERNING HEALTHCARE PROFESSIONALS' CONDUCT AND PRACTICE

A DISSERTATION SUBMITTED IN FULFILMENT

OF THE REQUIREMENTS FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY IN LAW

OF

THE UNIVERSITY OF NAMIBIA

BY

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OCTOBER 2022

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ABSTRACT

Patient safety refers to a framework of organised activities that creates cultures, processes, procedures, behaviours, technologies, and environments in healthcare, which consistently and sustainably lowers risks, reduces the occurrence of avoidable harm, makes error less likely, and reduces its impact when it does occur. The overall aim of the study was to evaluate the appropriateness of the Namibian regulatory framework for healthcare professions to contribute to the improvement of patient safety and, if not, how it can be enhanced. A mixed method approach was used in this study as quantitative, qualitative, exploratory, and descriptive research methods were employed. The necessary data were collected through literature review and analysis of relevant legislations, case law as well as government and regulatory authorities' reports. The finding of this study is that Namibia has adopted a hybrid form of a traditional model of professional self-regulation, which is predominantly person-centred and premised on individual accountability with little or no regard for systemic and organisational factors such as bad policies and procedures, lack of resources and poor organisational culture that may compromise patient safety. In this respect, the Namibian regulatory framework for healthcare professions may be regarded as appropriate, but inadequate to improve patient safety. The study recommends a shift from the traditional way of regulating healthcare professions that focuses exclusively on individual healthcare practitioners to one that includes systemic and organisational determinants of patient safety, and simultaneously ensures that both individuals and systems can be held accountable when appropriate.

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LIST OF ABBREVIATIONS/ACRONYMS

AIDS	Acquired immunodeficiency syndrome
AG	Administrator General
AHRQ	Agency for Health Research and Quality
CCL	Cabinet Committee on Legislation
CPD	Continuing professional development.
GMC	General Medical Council
EU	European Union
GG	Government Gazette
GN	Government Notice
HIV	Human immunodeficiency virus
HPCNA	Health Professions Councils of Namibia
HPCSA	Health Professions Council of South Africa
IAMRA	International Association of Medical Regulatory Authorities
ICPS	International Classification for Patient Safety
ICN	International Council of Nurses
LAC	Legal Assistance Centre
NHS	National Health Services

NMRC	Namibia Medicines Control Council
OAVT	Ontario Association of Veterinary Technologists
PCC	Professional Conduct Committee
PIC	Preliminary Investigation Committee
SWA	South West Africa
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

ACKNOWLEDGEMENTS

I am greatly indebted to my supervisors, Professor John Baloro and Dr Tapiwa Victor Warikandwa for their academic support, guidance, and nurturance during my study. Their patience and the interest they showed in this work were the source of inspiration.

Sincere gratitude is due to Leonie Munro from MarLeo's Communication Services, for agreeing to edit the text.

Last but not least, I wish to thank my dearest wife Selma for her constant encouragement and loyal support. Had it not been for her, I would not have come this far.

DEDICATION

This dissertation is dedicated to my children, Collin and Ena.

SUPERVISOR'S CERTIFICATE

Main Supervisor

I, Professor John Baloro, hereby certify that the research and writing of the Dissertation was carried out under my supervision

…… ……

Prof. John Baloro Date

Co-Supervisor

I, Dr Tapiwa Victor Warikandwa, hereby certify that the research and writing of the Dissertation was carried out under my supervision**.**

…… ……

Dr Tapiwa Warikandwa Date

DECLARATION

I, Cornelius Vataleni Weyulu, hereby declare that this study is my own work and is a true reflection of my research, and that this work, or any part thereof has not been submitted for a degree at any other institution.

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CHAPTER ONE

INTRODUCTION

1.1 Background of the study

This study evaluates the appropriateness of the Namibia regulatory framework for healthcare professions to contribute to the improvement of patient safety. The provision of healthcare in Namibia is guided by the Namibian Constitution[1] and relevant Acts.[2] Article 95 of the Constitution provides that "the state shall actively promote and maintain the welfare of the people by adopting, *inter alia*, policies aimed at …e) ensuring that every citizen has a right to fair and reasonable access to public facilities and services in accordance with the law." The provision of healthcare is also inspired by Article 8 of the Constitution on respect of human dignity which states in sub-article 2(b) that "No person shall be subjected to torture or cruel, inhuman or degrading treatment or punishment." [3]

The regulation of healthcare professions does not only influence the lives of registered professionals, but also those who receive healthcare services.[4] The main purpose of regulating healthcare professions is to ensure public protection.[5] This is achieved through nurturing the acceptable standards of practice and behaviour and thereby minimising the need for disciplinary actions to be taken against registered healthcare professionals whose conduct falls

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1 The Constitution of the Republic of Namibia Act 1 of 1990.

2 Public and Environmental Health Act 1 of 2015, Hospitals and Health Facilities Act 36 of 1994, Abortion and Sterilisation Act 2 of 1975, Medicines and Relates Substances Control Act 13 of 2003, National Health Act 2 of 2015.

Ex Parte: Attorney-General In Re: Corporal Punishment by Organs of State (SA-1990/14) [1991] NASC 2 (05 April 1991).

4 Aldridge, S. (2008). The regulation of health professionals: an overview of the British Columbia experience. *Journal of Medical Imaging and Radiation Sciences*. 39: 4-10. p. 5 .https://www.jmirs.org/article/S1939 8654 (08)00002-7/pdf (Date of use: 14 July 2019).

5 Allison, M, J. (2015). The role of health profession regulation in health services improvement (unpublished thesis for a of Doctor of Philosophy) Victoria University of Wellington. p. 96.

short of the required knowledge, skills, and care.[6] Regulation of healthcare professions is therefore one element of a much wider public health system to ensure quality of healthcare. In a broader context, the primary target of professional regulation is not the system or organisation but individual healthcare professionals.[7]

There are five regulatory bodies responsible for regulating 75 healthcare professions in Namibia, and approximately 22 568 registered healthcare professionals.[8] The five regulatory bodies are: Social Work and Psychology Council,[9] Allied Health Professions Council,[10] Nursing Council,[11] Pharmacy Council,[12] and Medical and Dental Council.[13] They all have the same overarching functions which are: 1) to set standards of professional conduct, practice, education and training; to investigate all complaints, accusations or allegations relating to conduct of registered healthcare professionals or whose fitness to practice the profession is in doubt; 2) to deal firmly, fairly and promptly with a registered healthcare professional against whom a charge, complaint or allegation of unprofessional conduct has been laid; 3) to guide healthcare professionals with respect to the codes of conduct and ethical standards relating to their professions; 4) to keep the register of healthcare professionals who are fit to practice and remove from the register names of whose conduct was found wanting; and 5) to assist in the

6 Health care professionals are expected to possess and display the same degree of skill, knowledge and care as would a reasonably competent healthcare professional in the same professional discipline and under the same circumstances. See Carstens, P.A., & Pearmain, D. (2007). *Foundational Principles of South African Medical Law.* Durban : LexisNexis. p. 602. The reasonable person is merely a fictitious person, a concept coined by law to have a workable objective norm for conduct in society. Accordingly, the reasonable healthcare professional is not an exceptionally gifted, careful, or developed person, neither is he/she underdeveloped nor someone who recklessly takes chances or who has no prudence. See Neethling, J., & Potgieter, J. M. (2010). *Neethling-Potgieter – Visser Law of Delict* (6th ed). Durban: LexisNexis. p. 135.

7 Department of Health. (2015). *Regulation of Health Care Professionals, Regulating of Social Care Professionals in England*. www.gov.uk/government/pulications. (Date of use: 21 April 2019).

8 HPCNA. 2020. *Annual Report 2019/2020.* Windhoek: Health Professions Councils of Namibia.

9 Established by S 3 of the Social Work and Psychology Act 6 of 2004.

10 Established by S 3 of the Allied Health Professions Act 7 of 2004.

11 Established by S 3 of the Nursing Act 8 of 2004.

12 Established by S 3 of the Pharmacy Act 9 of 2004.

13 Established by S 3 of the Medical and Dental Act 10 of 2004.

promotion of the health of the Namibian population.[14] It is in the interest of the health and welfare of the citizens of Namibia that these functions are executed by these regulators.

Patient safety refers to a state of freedom from accidental or preventable harm in healthcare settings caused by healthcare practitioners.[15] However, this study has adopted a broader definition by the World Health Organisation (WHO) which refers to "a framework of organised activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur."[16] Improving patients' safety requires implementation of strategies that reduce the likelihood of errors from occurring and increasing possibilities of interrupting them.[17]

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14 See SS 5 of the Social Work and Psychology Act 6 of 2004, Allied Health Professions Act 7 of 2004, Nursing Act 8 of 2004, Pharmacy Act 9 of 2004 and Medical and Dental Act 10 of 2004.

15 AHRQ. 2016. *Patient safety network, glossary*. http://psnet.ahrg.gov/glossary/p (Date of use: 27 April 2019). This statement underlines the test for medical negligence formulated in the English decision by Chief Justice Tindall in *Lanphier v Phipos* (1938) 8 C & P 475 479 that "Every person who enters into a learned profession undertakes to bring to the exercise of it, a reasonable degree of care. He does not undertake, if he is an attorney, that at all events you shall gain your case, nor does a surgeon undertake that he will perform a cure, nor does he undertake to use the highest possible degree of skill. There may be persons who have higher education and greater advantages than he has, but he undertakes to bring a fair, reasonable and competent degree of skill, and you will say whether, in this case, the injury was occasioned by want of skill in the defendant". The South African formulation of the test for inept is found in *Mitchell v Dixson* 1914 Ad 519 525 where the court stated that "A medical practitioner is not expected to bring to bear upon the case entrusted to him the highest possible degree of professional skill, but he is bound to employ reasonable skill and care, and he is liable for consequences if he does not". Patient safety concerns should therefore be approached with caution as in *Medi-Clinic v Vermeulen* 2015 (1) SA 241 (SCA) where Zondi JA at para 33 referred with approval to a remark by Denning LJ in the matter *Roe v Ministry of Health & others*; *Woolley v Same* [1954] EWCA Civ 7; [1954] 2 All ER 131 CA at 139: 'But we should be doing a disservice to the community at large if we were to impose liability on hospitals and doctors for everything that happens to go wrong. Doctors would be led to think more of their own safety than of the good of their patients. Initiative would be stifled, and confidence shaken. A proper sense of proportion requires us to have regard to the conditions in which hospitals and doctors have to work. We must insist on due care for the patient at every point, but we must not condemn as negligence that which is only a misadventure.'

16 WHO. (2021). Global Patient Safety Action Plan 2021-2030. Towards Eliminating Avoidable Harm in Health Care. Geneva: World Health Organisation. p. 6.

17 Yu A, *et al*. (2016). *Patient Safety 2030*. UK: NIHR Imperial Patient Safety Transitional Research Centre. Available from www.imperial.ac.uk/patient-safety-transilational-research-centre. (Date of use: 19 April 2019).

In Namibia, there has been an outcry that the public health sector has shown signs of deterioration in the delivery of healthcare services in the face of an increasing demand for its services.[18] As a result, in August 2012, the then President of the Republic of Namibia, His Excellency Hifikepunye Lucas Pohamba, appointed a commission of inquiry to investigate the activities, affairs, management and operation of the Ministry of Health and Social Services.[19] The commission released its final report on 31 January 2013 in which critical concerns in the areas of quality patient care and the conduct of healthcare professionals that calls for corrective measures were underscored.[20] The commission was particularly troubled by the conduct of some healthcare practitioners.[21] They were described as rude, careless, negligent or incompetent.[22] In some worse case scenarios, physical assaults of mothers giving birth were also documented.[23] The commission clearly recommended the intervention of the regulatory bodies in dealing with these matters.[24] However, there is no evidence indicating that regulatory

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18 Kisting reported about the ailing public health system and painted a negative picture of public health sector, especially in the field of maternal health, clinics, and hospitals in the state of decay, attitudes of health practitioners negatively impacted patients, long queues at public hospitals suggesting poor quality of care. Kisting, D. (2012 August 14). "Pohamba Orders Health Probe". *The Namibian*. p. 2.

19 See Proclamation No. 20 *Government Gazette* 5013 of 13 August 2012 regarding the announcement of appointment of the Commission of inquiry into activities, affairs, management and operations of Ministry of Health and Social Services, its terms of references, and regulations with reference to the Commission.

20 The Report indicates in paragraph 10 that the quality of patient care in public health facilities was generally described by public and healthcare professionals to be below the acceptable standard. The report also indicated that some of the factors compromising care were inadequate health care professionals and poor attitudes of healthcare professionals.Office of the President. 2013. *Report of Presidential Commission of Inquiry on Health and Social Services.* Windhoek: Government Printers, (hereafter "Report on Presidential Commission (2013)").

21 The Presidential Commission has invited public members to report bad conduct of healthcare professionals to the Health Professions Councils for appropriate disciplinary actions. See Report on Presidential Commission (2013), *supra* no 20. para. 70.

22 Report on Presidential Commission (2013), *supra* no 20. para. 72.

23 Report on Presidential Commission (2013), *supra* no 20. para. 73.8.

24 As part of its recommendations, the Commission believed the Health Professions Councils in Namibia must play a more active role in disciplinary matters, and acts on unethical behaviour of healthcare professionals reported to them. To achieve this, an effective disciplinary system should be introduced by such Councils capable of imposing punitive measures to offenders, including suspension and deregistration. Some other recommendations includes; promotion of professional ethics and professionalism among healthcare practitioners, the upgrading of dilapidated health facilities, replacement of obsolete medical equipment, fast tracking of recruitment process to deal with shortage of health professionals, harmonisation of clinical standards and protocols, devising strategies to attract, recruit and retain staff especially in rural areas, increasing the number of teaching facilities and training more healthcare professionals to meet the demand for both public and private sectors. See Report on Presidential Commission (2013), *supra* no 20 p. X para. 12 as well as p. 69.

bodies in Namibia have taken heed of the findings and recommendations contained in the report. This study is, to a certain extent, a response to a call for action made by the commission to address patient safety concerns in Namibia.

One area in which Namibia is still struggling to improve patient safety is maternal health. The country has a high maternal mortality ratio[25] estimated at 285 deaths per 100,000 live births.[26] Post-partum haemorrhage[27] is particularly associated with 39% of maternal deaths[28] while 21% of maternal deaths are linked to maternal sepsis.[29] The underlying causes of maternal deaths include lack of skilled personnel, long distances, and delays in seeking healthcare.[30] While delay in seeking care may be a critical issue, more has to do with the lack of quality care at the health facilities.[31] Access to healthcare therefore does not seem to be a major problem in Namibia as reflected by the high antenatal care attendance rate at 96% and that 87% of women give birth in health facilities, attended by healthcare practitioners.[32] This would therefore suggest that most maternal deaths occur whilst a woman is in a health facility.

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25 This refers to the number of women who die from pregnancy -related causes while pregnant or within 42 days of pregnancy termination per 100, 000 live births. WHO (2011). Evaluating the quality of care for severe pregnancy complications. The WHO near-miss approach for maternal health. Geneva: WHO.

26 Mbekele, E. (2019). *Nation's health experts look to improve women's health. Namibia* .UNFPA,Windhoek.Namibia.unfpa.or/en/news/nation's-health-experts-look-improve.womens-health. See also Ministry of Health and Social Services [MOHSS] (2014). *Namibia Demographic and health survey 2013*. Windhoek: MOHSS. p. 96.

27 Meaning bleeding after giving birth.

28 Sepsis refers to a life-threatening medical emergency caused the body's extreme response to an infection. Heemelaar, S., Kabongo, L., Iithindi, T., Luboya, C., Menetsi, F., Bauer, A., Dammann, A., Drewes, A., Stekelensburg, J., van den Akker, T., & Mackenzie, S. (2019). Measuring maternal near-miss in a middle-income country: Assessing the use of WHO and sub-Saharan Africa maternal near-miss criteria in Namibia. *Global Health Action.* 2019.12 (1): 1646036. pp.1-12. https://doi.org/ 10.10.1080/ 16549716.2019.1646036. p.1.

29 MOHSS (2019). Report on the prevalence and contributing factors of facility-based maternal and neonatal deaths in the five regions of Namibia (Erongo, Hardap, //Karas, Khomas, Omaheke) during 2010-2019. Namibia, MOHSS. Windhoek.

30 Mbekele, E (2019), *supra* note 26. p. 1.

31 MOHSS (2019), *supra* note 29. pp. 2-3.

32 Heemelaar, S., *et al* . (2019), *supra* note 28. P. 7.

1.2 Statement of the problem

While the public anticipates a high standard form of healthcare enjoyed by most people, especially in developed countries, the confidence of many people, especially in low and middle-income countries such as Namibia, has been shaken by reports of patient safety incidents, especially in state health facilities, and an alarming number of preventable adverse events perpetrated by the public healthcare system itself.[33] Several patient safety incidents, involving healthcare professionals, have been reported in Namibia over recent years; some have included elements of criminal behaviour.[34] The most recent of these is the case of a Swakopmund-based medical practitioner who was charged with three counts of rape after having allegedly drugged and raped his female patients.[35] Other notable reports of patient

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33 Healy, J. (2013). Improving patient safety through responsive regulation. The Health Foundation Inspiring Improvement http://www.patientsafety/healt/org/uk/sites/defaults/files/resources/improving_patient_safety_through_responsive_regulation_0.pdf. (Date of use: 21 April 2019). P.2.

34 Shortly after Namibia's independence in 1990 the court had to deal with a charge of culpable homicide in *S v Shivute 1991 (1) SACR 656 (Nm)* against a qualified nurse who administered an intramuscular injection of chloroquine to a four-year-old child as opposed to the prescribed chloroquine syrup which was to be administered orally. The child died. In this case, the court had to deal with the question of negligence and indicated that the accused ought reasonably to have foreseen the possibility of death resulting from her conduct and failed to take reasonable steps to avoid this eventuality. The court found that given the fact that the accused was a qualified and experienced nurse taken together with the fact that she said that she knew that to administer that quantity of chloroquine to a child would have been fatal, the only reasonable inferences to be drawn was that any reasonable person with the qualification and experience of the accused and in the position of the accused would have known at the time of the injection at least that such a course of action could have been fatal and therefore would have taken reasonable care to pursue a course of conduct which would have prevented such result. The court concluded that the accused has not done so and was therefore either reckless or negligent. See also Carstens & Pearmain (2007), *supra* note 6. p. 496. In the case of *Gomachab v Minister of Health and Social Services and Another((P) I 198/2007) [2001] NAHC 268 (16 September 2011)* an action in delict was instituted by the Plaintiff against the defendants based on the negligence against the second defendant – a medical practitioner and gynaecologist in the employ of the first defendant. The first defendant being sued vicariously, as the employer of the second defendant for the latter's alleged negligent conduct in the course of his employment. The claim was that the second defendant conducted himself negligently firstly, in performing a complicated appendectomy on the plaintiff knowing well that such a case should have been referred and managed by a specialist surgeon and secondly, for failing to provide the required post-surgical care and to refer the plaintiff to a tertiary level hospital at which such care could have been provided. The court found in favour of the plaintiff.

35 See Menges, W. (2018, October 24). Date set for doctor's rape trial. *The Namibian*, p 6. This article referred to a case of *S v Van Der Westhuizen (CC 11/2018) [2019] NAHCMD 267 (July 2019*) which the defendant in this case is a Psychiatrist charged with attempted murder, alternatively contravening section 16 of the Combating of Immoral Practice Act 21 of 1980 as amended, by using certain means to stupefy or overcome a female patient for immoral purpose. He was also charged with indecent assault and rape. The accused was acquitted at the end of the prosecution's case due to insufficient evidence. His defence was that he was suffering from an erectile dysfunction at the time of the alleged incident and had not been able to have penetrative intercourse since about 2010. Attempts by the prosecution to introduce new evidence in rebuttal were rejected by the court as unfair and prejudicial.

safety incidents are the nine immunisation related cases in 2018,[36] and cases of surgical sterilisation of HIV positive women without their consent.[37] Media articles on maternal healthcare have covered mothers who complained about losing their infants during labour due to alleged medical negligence.[38] While these incidents may be seen as proxy indicators of patient safety, they are likely to mirror unreported incidents in the Namibian health system and heighten concerns about patient safety and competency of healthcare professionals.

According to Downie *et al*[39] patient safety has become a significant policy issue worldwide as governments, health sectors, and the public, are increasingly becoming aware of the need to improve the safety of care delivered by their health systems. The pressure for change is not

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36 The Legal Assistance Centre (LAC) is handling eight cases relating to infants' deaths occurring a after six - weeks vaccination period at public health facilities. All these cases except two have undergone the judiciary case management to determine how to go about the trial process. The medical experts on both sides were requested by the managing Judge to provide the court with a joint report on the issues on which they agree and disagree. It was hoped that trial on these matters would start by the second semester of 2019. See page 03 of the LAC. 2018. *Annual Report,* 2018. Windhoek: Legal Assistance Centre. Available at lac.org.na /Pdf /annrep2018.pdf.

37 In the case of *LM and Others v Government of the Republic of Namibia (I 1603/2008 I 3518/2008 I 3007/2008) [2012] NAHC 211(30 July 2012*), three women instituted actions against the State alleging in their first claim to have been sterilised without consent by medical practitioners in the employ of the State which constituted a breach of duty of care the medical practitioners owed to them. In the second claim, they alleged that sterilizations were done as part of wrongful practice of discrimination against them based on their positive HIV status and therefore amounts to a breach of their basic human rights as guaranteed by the provisions of the Namibian Constitution. The judgement in this case was that the plaintiffs were successful in respect of the first claim, but the second claim was dismissed for lack of credible and convincing evidence. See pp. 82 - 83 of the judgement. These three cases were part of the eighteen sterilisation cases handled by the LAC. With regards to sixteen of these cases, litigation was stayed by the State, with the view that should the three cases gone to trial succeed, this success would apply to all those in similar position. See p. 5 of the LAC. 2017. *Annual Report,* 2017. Windhoek: Legal Assistance Centre. Retrieved from lac.org.na /Pdf /annrep2017.pdf. The sixteen cases were eventually settled out of court in early 2017, but the State did not immediately honour the agreement and kept stalling the agreed payment to the victims. These matters were later brought back in the court roll for contempt of court proceedings forcing the State to pay. In the end, all 18 women had received compensation for the pain and suffering emanating from forced sterilisations. See LAC (2018), *supra* note 36. p. 4.

38 See an article concerning medical negligence cases in maternity by Smith, J. M. (2018, October 19). Health faces multiple lawsuits. *Namibian Sun,* p 5. The LAC was also handling several cases of medical negligence such as the case of a deceased new-born delivered at a State Hospital after a full-term pregnant woman was admitted giving birth but did not receive medical attention from any hospital staff post admission. She was merely ordered to walk off her labour pain, and while doing so gave birth standing up and without assistance from the staff. The new-born fell from the womb in the course of this walk, hit the ground and died instantly. The other case is that of a severely dehydrated child as a result of diarrhoea who also needed an urgent blood transfusion. Shortly after the transfusion, he developed severe swelling and darkening of the skin surrounding the needle entry due to infection. The infection led to the amputation of the child's leg. See LAC (2018), *supra* note 36. p. 4.

39 Downie, J., *et al*. (2006) *Patient safety law: from silos to systems*. Canada, Ottawa: Health Policy Research Program.

only created by highly publicised incidents involving unsafe acts, but also by the massive costs such incidents can have on individuals, their families, communities, and the state.[40]

Professional regulation is regarded as one avenue through which governments can improve patient safety.[41] Sparrow[42] indicated that the main purpose of regulating healthcare professions is the abatement or control of risks to society: regulators must identify potential adverse events and fix them. However, with scandals surrounding patient safety, there has been growing scepticisms among scholars[43] and policymakers in some Anglo-American contexts such as the United Kingdom (UK) and Australia as to whether professional regulation really serves public interest or the interest of the professionals.[44] This scepticism about the role of professional regulation in protecting the public has ignited a complete restructuring of professional regulation in the fields of law and medicine in countries: the UK, Australia and the United States of America (USA), for example.[45]

Although there have not been public demands for legislative reform due to patient safety concerns in Namibia, the incidents of adverse events in the country, and the restructuring of professional regulation in other jurisdictions for the same reasons, raise a question as to whether the Namibian regulatory framework for healthcare professions is suitable to contribute to the improvement of patient safety. The primary purpose of this study was therefore to assess

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40 For example, the National Health Service in England is reported to have spent 1.63 billion pounds in litigation costs due to patient safety incidents in 2017-2018. WHO. (2021), *supra* note 16. p. 9.

41 Downie, J., *et al*. (2006), *supra* note 39. p.5.

42 Sparrow,M.K.(2000).*The regulatory craft: controlling risks, solving problems, and managing compliance*. Washington, DC: Brookings Institution Press. Available at www.amazon,com,Regulatory-Craft-Controlling-Problems-Compliance/dp/0815780656 (Date of use: 22 April 2019).

43 According to Adams, T. L. scholars such as Haug, 1980; cf.Saks, 1995a, 2012; and Murphy, 1988, clearly asserted that professional regulation is not about the public interest as professionals may claim, but rather about the monopolisation of rewards for self-gain. See Adams, T. L. (2016) "Professional Self-Regulation and the Public Interest in Canada". *Professions & Professionalism*, 6(3), 1-15.hpttp://dx.doi.org/10.7577/ pp. 1587. p. 2.

44 Adams, T. L. (2016), *supra* note 43. p. 2.

45 Gorman, E. H. (2014) "Professional self-regulation in North America: The Cases of Law and Accounting". *Sociology Compass* 8/5: 491-508.

whether the Namibian legal framework of regulating healthcare professions is appropriate to contribute to the improvement of patient safety; and if not, how it can be reformed. Secondly, given the dearth of research on the magnitude of patient safety incidents in Namibia and the potential economic losses of such incidents to the country, an effort was be made in this study to establish the prevalence of patient safety incidents reported to the regulatory authorities in Namibia and the value of such incidents to the taxpayers.

1.3 Study objectives

The objectives of this study are to:

1.4.1 evaluate the appropriateness of the Namibian regulatory framework for healthcare professions to contribute to the improvement of patient safety.

1.4.2 undertake a situational analysis of medical malpractice complaints reported to the regulatory authorities for healthcare professions in Namibia as well as the quantity and value of medical malpractice claims against the State between 2014 and 2019.

1.4.3 compare the Namibian regulatory framework for healthcare professions to South Africa and the UK with a view to identify similarities and differences in dealing with patient safety and draw best practices from these countries, and to

1.4.4 recommend a legal framework for improving patient safety in Namibia.

1.4 Significance of the study

The approach to improve patient safety has been primarily through the health system lens[46] to such an extent that legislative interventions to address the challenges of achieving improved patient safety have largely been underused and undervalued. This study contributes to a paradigm shift in thinking about patient safety from the legislative perspective, which focuses exclusively on individual healthcare practitioners, to one that includes systemic and

[46] WHO. (2021), *supra* note 16. p. 83

organisational determinants of patient safety. The study also advocates for a conducive environment in the health system for a just culture.[47]

Whilst other countries such as the UK, Australia and the USA have restructured their systems of professional regulation to improve patient safety, there is no evidence of research that looked at the efficacy of the Namibian legislative framework for the healthcare professions to contribute to the improvement of patient safety. It is this apparent gap in the Namibian-based research in this area, along with the chance to provide some locally based research, which is the driving force behind this study.

This study therefore contributes to the field of healthcare management, medical law, patient safety practice, and to the body of research in regulating healthcare professions in Namibia. The findings from this study would most likely assist the government of the Republic of Namibia, through the Ministry of Health and Social Services, to establish a national patient safety programme, supported by a patient safety policy, strategy, and implementation plan that are currently lacking.

The findings from the study may also be valuable to regulatory authorities in Namibia by providing an assessment of legal frameworks that focuses on patient safety and to serve as a pedestal for possible law reform. It is envisaged that the recommendations set out in this study will create a clear legal framework for the regulation of healthcare professions in Namibia, and elsewhere, to ensure patient safety now and in the future.

[47] According to WHO a just culture appreciates the complexity of situations and events and acknowledges that whilst most patient safety failures are the results of weak systems, there is a minority of situations where an individual who has been reckless in his or her behaviour or wilful misconduct should be held accountable. WHO. (2021), *supra* note 16. p. 34.

The study represents an opportunity to have baseline data on the number of reported fitness to practice complaints from members of the public, which were investigated by the regulatory authorities in Namibia, as well as the number and value of medical negligence claims against the State. This information will assist in narrowing the void of the required data upon which future research and strategies on patient safety can be grounded.

1.5 Limitation of the study

The study was limited by minimal availability and/or unavailability of the most recent secondary data in the Namibian health system. It is the first of this nature to be conducted connecting patient safety to the regulation of healthcare professions in Namibia. To that end, literature on similar studies in South Africa and the UK were reviewed. In addition, the number and value of medical litigation claims against the State in the aftermaths of medical negligence were determined. It was clear that some healthcare professions were more prone to fitness to practice complaints than others. As such, it might be biased to generalise the findings across all healthcare professions, even though in most cases the situation might be the same. This is largely a synthesis study. The researcher did not engage in any research on the effectiveness of a specific patient safety initiative.

1.6 Delimitation of the study

This study focused on legislative context for patient safety in the Namibian health system. There are many public and private actors that shape policy and practice in the Namibian health sector and the usage of a variety of tools to address patient safety issues. However, this study focuses on the role of only one actor, namely, the government. The focus is primarily on the use of one instrument: the laws regulating healthcare professions. This study excluded unregulated healthcare practitioners in Namibia such as traditional medical practitioners,

counsellors, community health workers, first aiders, home-based care providers and traditional birth attendants.

1.7 Theoretical framework of the study

According to Freidson,[48] earlier generations of sociologists postulated a theoretical model of professional self-regulation in the mid-20th century. It was based on an understanding that the practice of professions holds the propensity for negligence that can injure the public because those who have professional knowledge may exploit the obliviousness of their clients for their own benefit.[49] Cognisant of this danger, the state entered into an agreement with professions to regulate the behaviour of their members exclusively for public interest and in exchange for liberty from outside regulation.[50]

The theoretical model of professional self-regulation is grounded on three principles, namely, the "cultivation of distinctive ethical norms, socialisation of new practitioners, and social control of deviant behaviour."[51] The first principle posits that professions are like "communities within a community" that share a similar ethos and standard of professional behaviour which are different from that of the larger community.[52] The second principle suggests that professional communities have mechanisms of passing their ethical standards for education and practice to their neophytes.[53] The third principle underscores the ability of the professions to exert control over the behaviour of their members.[54] Collectively these three

48 Freidson, E. (2001). *Professionalism. The Third Logic*. Chicago, IL: University of Chicago Press.

49 Gorman, E.H. (2014), *supra* note 45.

50 Goode, W.J (1957). "Comm *supra* unity within a Community: The Professions." *America Sociological Review* 22:194 – 199. See also Gorman, E.H. (2014), *supra* note 45. p. 492.

51 Gorman, E.H. (2014), *supra* note 45. p. 2 and Wilensky, H. (1964). "The Professionalisation of everyone?" *American Journal of Sociology* 70: 137-158.

52 Goode, W.J (1957), *supra* note 50 and Van Maanen, J and Stephen, R.B. (1984) "Occupational Communities: Culture and Control in Organisations". *Research in Organisational Behaviour* 6: 287-365.

53 Cogen, M. (1953). "Towards a Definition of Professions." *Harvard Educational Review* 23: 33-50.

54 Freidson, E. (2001), *supra* note 48 and Reichstein, K.J. (1965). "Ambulance Cashing: A Case Study of Deviation and Control within the Legal Profession." *Social Problems* 13: 3-7.

characteristics form the rational model of professional self-regulation.[55] The model of professional self-regulation has been adopted as the theoretical framework for this study.

a) Cultivation of distinctive ethical standards

In this study, healthcare professionals represent a medical community within a bigger society which has similar standards of professional conduct and practice that differ from that of a larger society. In Namibia, individual healthcare professionals are only allowed into the medical community after meeting the prescribed minimum requirements of study and ethical standards by which they shall conduct themselves and practice their professions.[56] Entrance is only achieved through professional registration and certification after the display of appropriate knowledge, skills, and competence in a healthcare profession. As discussed in more details in chapter four, ethical standards may be shared informally within the medical community or codified.

b) Socialisation of new members

In the context of this study, this component of the theoretical framework refers to welcoming new members into the family of medical professionals and teaching them how to conduct themselves competently and ethically. In Namibia, socialisation of new members begins at educational institutions where formal teaching takes place and get cemented in hospitals and health facilities where professional norms and values are informally acquired through observation, role modelling and interaction with senior colleagues. This component is further discussed in chapter four.

55 Gorman, E.H. (2014), *supra* note 45. p. 493.

56. Such requirement is normally prescribed by way of regulation by the Minister responsible for health.

c) Social control of deviants

For purposes of this study, social control of deviants represents the continuous enforcement of acceptable standards of professional conduct and practice and disciplining those who violate them. This component exemplifies the disciplinary powers of the regulatory authority for healthcare professions in Namibia.

1.8 Literature review

Business transactions between individual members of society are normally a private affair. However, sometimes government must intervene when one of the parties to the transaction has some difficulties in appreciating the quality of the commodity being exchanged. To address such an imbalance, a government normally regulates the commercial activities within a society to create a more level playing field between experts and non-expert members of the public. This is equally true with regard to the provision of healthcare because healthcare professionals (HCPs) are generally more knowledgeable about medical conditions and procedures than their patients. A government is therefore expected to make sure that patients are protected against HCPs; one of the common methods used by government to create such protection is through regulation.[57]

The rationale for professional regulation in health is therefore patient protection.[58] Patients generally lack the knowledge, skills, or judgement to diagnose or treat diseases and ailments and therefore are inclined to rely on specialised knowledge and the expertise of HCPs for assistance.[59] Entrusting their care in the hands of HCPs is mostly beneficial. It is, however, difficult for a patient without any medical knowledge to competently evaluate the qualification,

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57 Randall, E. R. (2005) *Understanding Professional Self- Regulation*. Ontario Association of Veterinary Technologists (OAVT): Guelph, Ontario. p. 1.

58 Arrow, K.L. (1963) "Uuncertainty and the welfare of medical care". *Am Econ Rev*. 53(5): 941-197.

59 William, D. W. (2014). "Professional Self- Regulation in Medicine". *Virtual Mentor*; 16 (4):275-278.

skills, knowledge and competencies of a healthcare practitioner before being able to trust such a practitioner.[60] It is for this reason that regulating the conduct and practice of healthcare practitioners is imperative to identify individuals who may misrepresent their qualifications, make unfounded claims to cure various ailments, fail to exercise due diligence in providing care or engage in other forms of malfeasance to the detriment of patients.[61]

Patient safety will be compromised if regulation of the healthcare professions is ineffective, as this may result in persons who are not fit to practise in terms of providing care to patients.[62] Healthcare professions can be regulated through different models, for example: professional self-regulation; a regulatory authority responsible to a national or state government; and a regulatory authority within a national or state government.[63]

The focus of this study is on professional self-regulation as it is the most common approach used by governments to regulate the practice of HCPs.[64]The traditional model of professional self-regulation[65] was developed by sociologists during what is called the 'golden age' of the

60 William, D. W. (2014), *supra* note 59.

61 William, D. W. (2014), *supr*a note 59.

62 IAMRA (2018) Policy Statement on *Independence of Regulation: The Primacy of Patient Safety*. US, Texas: International Association of Medical Authorities. p. 1.

63 IAMRA (2018), *supra* note 62. p. 2.

64 Randall, E. R. (2005), *supra* note 57. p. 1.

65 Self-regulation which is also known as the professionalist-indepentent mode refers to the regulatory process whereby the regulatory body establishes and enforces the rules and standards relating to the conduct of the professionals and although some type of state regulation can co-exist with self-regulation, this definition entails that the core responsibility for the design and enforcement of the regulatory standards lies with the self-regulatory body rather than the state or some agency. Barbou Des Places, S. (2006). Self-regulation and the professions: A perspective from regulatory competition theory. In Cafaggi, F. (Ed), Reframing Self-regulation in European Private Law (pp. 215-235) Kluwer Law International. https://hal.archives-ouvertes.fr/hal-01615571. See Pearce, R. G., Semple, N., & Knake, R.N. (2014). A Taxonomy of Lawyer Regulation: How contrasting themes of regulations explain the divergent regulatory requirements in Australia, England/Wales, and North America. Legal Ethics, 16 (2). https://scholar.uwindsor.ca/lawpub/37.

professions in the mid-20th century.[66] At that time, self-regulation was, and probably still is, regarded as one of the characteristics of professionalism.[67] This model is premised on an understanding that because of the danger that those who possess expert knowledge will exploit the ignorance of clients for their own benefits, an occupational group has entered into an agreement with the society to formally take over the role of regulating the professional activities of its members.[68] In return, society has granted the occupational group freedom from external regulation.[69] The agreement normally takes the form an Act of parliament, which provides a legal framework for the regulation of a specified profession, and spells out the ambit of the legal authority delegated to the profession's regulatory body, while government maintains some control over the practice of a profession and services provided by its members.[70]

In exchange for self-regulatory status, a professional body is expected to develop, implement and enforce rules and regulations primarily aimed at public protection against its members.[71] This is normally achieved by putting in place strict registration requirements, rules governing the removal from the register, and standards on how the profession may be practiced competently and ethically.[72] A self-regulation model also requires a regulatory body to put in place a system of receiving and investigating complaints from patients and disciplining healthcare practitioners whose professional conduct may be found wanting.[73]

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66 Gorman, E. H. (2014), *supra* note 45. p. 49. see also Freidson, E. (2001), *supra* note 48.

67 Wilensky, H. (1964), *supra* note 51. Professionalism in health involves more than just a formal regulatory oversight. It includes the establishment of institutions for professional education and training, exchange of professional knowledge and expertise, and promotion of professional norms supportive of independent, knowledge – based decision making and acceptable professional behaviour.

68 Rueschemeyer, D. (1983). Professional autonomy and Social control expertise. In Dingwall, R & Lewis, P (Eds.), *The Sociology of Professions* (pp. 38 -58). Hong Kong: MacMillan.

69 Goode, W. J. (1957), *supra* note 50.

70 Randall, E. R. (2005), *supra* note 57. p. 1.

71 Randall, E. R. (2005), *supra* note 57. p. 1

72 Manitoba Law Reform Commission (1994), *Regulating professions and occupations*. Winnipeg: Manitoba Law Reform Commission.

73 Randall, E. R. (2005), *supra* note 57. p. 2.

Goode and Wilensky, as quoted by Gorman,[74] identified three components of professional self-regulation: cultivation of distinctive ethical norms; socialisation of new practitioners; and social control of deviant behaviour. First, the self-regulation model sees an occupational group as a smaller community within a broader community capable of developing its service cultures and standards of professional conduct different from the ethical norms of the larger community.[75] Second, the occupational group can develop systems for inspiring ethical standards in its new members through formal and informal education.[76] Third, the occupational group is able to exercise informal control over its members' behaviour by supporting good conduct and shunning unacceptable behaviour, and exercising formal control by establishing systems for monitoring and discipline.[77]

The provision of professional services such as medicine is customarily based on a model of self-regulation.[78] In this context, Bertkau *et al*[79] referred to the three principal tenets of self-regulation through which a regulatory body establishes the standards by which healthcare practitioners may enter the profession and by which they may then practice their professions, make registered healthcare practitioners responsible for teaching their neophytes on how to exercise those standards daily, and enforce those standards and decide when and how those who violate such standards will be disciplined.

Professional self-regulation ranges from the pure form where the profession alone regulates itself, to systems involving varying levels of collaborating with the government.[80] This means

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74 Gorman, H. E. (2014), *supr*a note 45. p. 492.

75 Gorman, H. E. (2014), *supr*a note 45. p. 492.

76 Cogan, M. (1953), *supra* note 53.

77 Gorman, H. E. (2014), *supr*a note 45. p. 493. See also Freidson, E., & Buford, R. (1963) "Process of Control in a Company of Equals." *Social Problems* 11: 119 – 131.

78 Barbou Des Place, S. (2006), *supra* note 65. p. 6

79 Bertkau, A. Halpern, J., & Yadla, S. (2005). "The Privileges and Demands of Professional Self-Regulation" AMA Journal of Ethics. *Virtual Mentor*. 2005; 7 (4): 267-269. Doi. 10.1001/vitualmentor.2005.7.4.fred1- 0504.

80 Affra, A. F., & Saif Al-Jabri, S. (2016). "Professional Self-Regulation for Nursing and Midwifery in Oman: Protecting the Public and Enhancing the Quality of Care". *Oman Medical Journal*. 2016 July; 31(4): 243 – 224. Doi: 10.5001/omj.2016.48.

that professional self-regulation, other than the pure form, works within both a professional and legal framework where legislation provides external controls, and the profession underwrites the internal control by way of standards, guidelines, and professional development.[81] Approaches to professional self-regulation array from minimal to extensive control, depending on the nature of activities performed by members of the profession, and the danger at which members of the public may be exposed should incompetent members of the profession be allowed to provide care to patients.[82] The common approaches for professional self-regulations include registration,[83] certification[84] or licensure.[85]

It is important to note that only a certified practitioner may use specific titles or professional designations such as nurse, midwife practitioner or medical practitioner.[86] Certification is also linked to recognised qualifications in that only those with recognised qualifications may be certified to practice a healthcare profession.[87] This is important in protecting the public from unqualified service providers. The licensure approach is more restrictive than other forms of professional regulation.[88] Only individuals who have met specific requirements to enter the profession may be licensed to practise the profession.[89] Licensing normally requires a specific level of competency and passing the licensing and re-licensing examination.[90] In addition, a licensed practitioner is normally required to maintain their professional knowledge, skills and

81 ICN. (2001). *Professional Self- Regulation for Nurses: Issues and Opportunities*. Geneva: International Council of Nurses. pp. 13-16.

82 Randall, E. R. (2005), *supra* note 57. p. 2.

83 Registration refers to the process of entering the name of a healthcare practitioner in the register after meeting the prescribed minimum requirements for registration. Neconchea, E. (2006).“*Building stronger Human Resources for Health through Licensure, certification, and accreditation*”. Capacity Project, Technical Brief 3.

84 Certification is essentially the stamp of approval given to a healthcare practitioner for meeting the prescribed requirements for registration. Neconchea, E. (2006), s*upra* note 83.

85 Randall, E. R. (2005), *supra* note 57. p. 2.

86 Jhpiego (n.d.) Registration, licensure, and certification: definition and requirements. resources.jhpiego.org/system/files/resource/01_RegLicCertfDefinRequirements-1.pdf. p. 1.

87 Neconchea, E. (2006), *supra* note 83.

88 Randall, E. R. (2005), *supra* note 57. p. 2.

89 Neconchea, E. (2006), *supra* note 83.

90 Jhpiego (n.d.), *supra* note 86.

competency through continuing professional development (CPD).[91] Taken together, these characteristics constitute an intelligible model of professional self-regulation.[92]

A government authority delegated to healthcare professions through self-regulation does not only give them a great deal of autonomy in determining how many and who would be allowed to enter the profession, but also serves as a control mechanism against oversupply of professionals, which ultimately translates into higher demand and income for individual members.[93] Greater autonomy and control gives individual members of the profession the right to independently carry out their professional activities with less supervision and interference from government.[94] Greater autonomy and control would also mean that a professional body is able to set professional standards[95] rather than having government or any other profession imposing such standards on its members.[96] A regulatory authority is also provided with direct access to government through submission of recommendations and expression of viewpoints on matters concerning the profession.[97] In addition to greater autonomy and occupational control, when an occupation becomes self-regulated it also gains professional prestige that comes from attaining the professional status and the benefits attached to such a status, and financial rewards for its members.[98]

The benefit accrued from professional self-regulation is not only limited to a regulatory authority and its members. Governments can also be viewed as having tried in protecting the public in a manner which does not require its direct involvement in the management of

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91 Randall, E. R. (2005), *supra* note 57.

92 Gorman, H. E. (2014), *supr*a note 45. p. 493.

93 Larkin, G. (1983). *Occupational monopoly and modern medicine*. London: Tavistock.

94 Manitoba Law Reform Commission (1994), *supra* note 72. p. 46.

95 This may include setting of entry requirements for registration and standards for practising the profession.

96 Randall, E. R. (2005), *supra* note 57. p 3.

97 Mostly rules and regulations are made by the minister on the recommendation of the regulatory authority. This avenue can also be used by the regulatory authority to negotiate with government for additional functions and powers should that be necessary. See Randall, E. R. (2005), *supra* note 57. p. 3.

98 The financial benefits come with an increased demand for the services rendered by healthcare practitioners and the assurance that the services they render are of high standards.

professional affairs.[99] This approach does not only impact on bureaucratic processes, which normally characterise government activities and slow down on delivery of services, but also saves government money in hiring experts to assist in creating profession specific rules and standards.[100] Members of a regulatory authority are experts in their professions, and professional self-regulation is their expertise, which is freely available to government in determining and monitoring the standards of practice for a profession.[101] The self-regulatory model also transfers the cost of regulating the profession from the government to the profession itself.[102] Seeing that a regulatory authority is normally a juristic person, through professional self-regulation, government is shielded from direct legal liabilities emanating from the conduct of a regulatory authority.[103]

The views that emerged from this discussion can be summarised as follows. Professional self-regulation has many benefits for members of the profession, but such members cannot be trusted to put the public interest above their own hence there is a need for more government oversight and public involvement.[104] Professional self-regulation can therefore best be described as a privilege, granted by a government to the profession, which can be taken away; to keep this privilege a profession must preserve the trust of the public.[105] This means the benefits to a profession and its members are secondary. Professional self-regulation can be trusted to regulate the public interest if there are effective processes in place for answerability and supervision.[106]

99 Randall, E. R. (2005), *supra* note 57. p. 4.
100 Randall, E. R. (2005), *supra* note 57. p. 4
101 Barbou Des Place, S. (2006), *supra* note 65. p. 6
102 Manitoba Law Reform Commission (1994), *supra* note 72. p. 48.
103 Randall, E. R. (2005), *supra* note 57. p. 4
104 Manitoba Law Reform Commission (1994), *supra* note 72. p. 46.
105 ICN.(2001), *supra* note 81.
106 Adams, T. L. (2006), *supra* note 43. p. 7.

Empowering a profession via professional self-regulation is justifiable only if the primary purpose of regulation is about improving services and protecting the public.[107] Public protection is mainly the function of the state therefore, despite the regulatory body having significant autonomy from the government in regulating the profession; the self-regulation model also provides avenues through which government can still ensure accountability for the powers and functions delegated to such a body.[108] This is normally achieved through a reporting requirement by a regulatory authority to government.[109] The regulatory authority is required to report to parliament through the sector minister on its activities and handling of finances.[110] A regulatory body, by tabling such report in parliament, is made to account to the public. It would therefore mean that while government is not expected to interfere with the day-to-day activities of a regulatory body, it often retains some ability to direct the regulatory body to do as it wishes otherwise its self-regulatory status may be removed.[111]

The other approach the government may use in holding a regulatory authority accountable to the public is through the appointment of public members to serve on such a regulatory authority.[112] The number of such members varies from country to country with some having only one member while others have many.[113] Some argue that having many public members serving on a regulatory authority would ensure effective public participation and the organisation is likely to make decisions that are in the interest of the public.[114] It can, however, also be argued that having many public representatives on a regulatory body runs contrary to

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107 Affra, A. F., & Saif Al-Jabri, S. (2016), *supra* note 80.

108 Balthazard, C. (2015). "What does it mean to be a regulated profession?". Canada: Human Resources Professional Association. p. 1.

109 Randall, E. R. (2005), *supra* note 57. p. 4.

110 Randall, E. R. (2005), *supra* note 57. p. 4.

111 Balthazard, C. (2015), *supra* note 108. p. 1.

112 Biggar, M.A., Lobigs, L. M., Fletcher, M., & Man, M. (2020). How can we make health regulation more humane? A quality improvement approach to understanding complaint and patient experience. *Journal of medical regulation*s. 106 (1): 7- 15. p. 7.

113 Balthazard, C. (2015), *supra* note 108. p. 2.

114 Manitoba Law Reform Commission (1994), *supra* note 72. p. 63.

the principle of self-regulation and may be referred to as more co-regulation than self-regulation.[115]

The main purpose of self-regulation is public protection against the activities of healthcare practitioners.[116] Departing from this premise, it can be accepted that if there is no risk of harm to the public, then there is no need for government to intervene through self-regulation.[117] However, should the risk of harm to the public exist from members of a specific occupation, then the public must be protected from such harm through self-regulation.[118]

The other qualification is that the occupational group to be regulated must be well defined and large enough to be able to finance its activities and implement the self-regulatory model.[119] In addition to adequate financial resources, the group should also have the required expertise and commitment to establish, maintain and implement the professional standards and rules that are required for the self-regulatory process.[120] Self-regulating professions are expected to fund their activities through membership fees; it is uncommon for government to allow smaller occupational groups to become self-regulated.[121] An occupational body is also expected to have a well-defined body of knowledge, which can be acquired through specified educational process and cannot be confused with that of another profession.[122] If the body of professional knowledge is already within the scope of another profession, it becomes difficult to set the scope of practice of a new profession and avoid conflicts emanating from the overlapping scopes of practice.[123]

115 Balthazard, C. (2015), *supra* note 108. p. 2.
116 Balthazard, C. (2015), *supra* note 108. p. 4.
117 Randall, E. R. (2005), *supra* note 57. p. 5.
118 Balthazard, C. (2015), s*upra* note 108. p. 5.
119 Randall, E. R. (2005), *supra* note 57. p. 5.
120 Randall, E. R. (2005), *supra* note 57 .p. 5.
121 Randall, E. R. (2005), *supra* note 57. p. 5.
122 Randall, E. R. (2005), *supra* note 57. p. 5.
123 Randall, E. R. (2005), *supra* note 57. p. 5.

The public interest theory, on which professional regulation is anchored, requires that the public be secured in its anticipation that those who are accepted in the profession are worthy of the trust and the confidence clients may realistically place in them.[124] Forming this theory are the market failure and the ethical public interest theories which rely on the argument that the purpose of regulation is to protect clients, third parties and interests of others as opposed to that of service providers.[125] According to Pearce *et al*, the market failure version of public interest theory suggests that regulation is imposed upon professional services to correct or mitigate market failures. Purchasers of services are regarded as consumers with interest in price, quality, and choice and who often are unable to discern the value of the services offered in the market in terms of their needs. This information asymmetry is premised on an understanding that the provider of expert service has a much better knowledge than the prospective customer.[126] On the other hand, the ethical version of the public interest theory relies on arguments that self-regulation is necessary to protect clients and society and is reflected in professional code of conduct and professional education. This version claims that professional independence is necessary to protect clients and public goods.[127]

Opposing views to professional regulation emerged from the field of economics with Adam Smith's Wealth of Nations in which he claimed that the purpose of regulating professionals is to supress competition by restricting the number of persons willing to enter the profession and denounced the self-regulating professions as platforms for collusion against the public and expediency to raise prices.[128] In support of this view is the classic captured theory pioneered by Stigler, who postulated that regulation is acquired by the profession primarily for its

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124 Pagliero, M. (2011). "What is the objective of professional licensing? Evidence from United States of America market for lawyers". *International Journal of Industrial Organisation.* 29. 473-483. p.473.www.sincedirect.com/science/journal/01677187.

125 Pearce, R.G., Semple, N., & Knake, R.N. (2014), *supra* note 64. p. 9.

126 Pearce, R.G., *et al* (2014*), supra* note 65. p. 9.

127 Pearce, R.G., *et al* (2014*), supra* note 65. p. 12.

128 Smith, A. (1776) "*An inquiry into the nature and causes of the Wealth of Nations*". Mathuen and Co, Ltd, London I. XC. 5.

benefits. He reasoned that economic groupings constantly pursue to enrich themselves by seeking state's coercive power to curtail rivalry and fix prices.[129] These sentiments of the classic capture theory also find application in the private interest theory which posits that professional regulation rules are created to protect the interest of members of the profession.[130] According to the classic captured theory, professional self-regulation is a platform through which an occupational group is given a leeway to sway regulation to enrich itself.

Although these perspectives did not particularly question the effectiveness of the occupation groups' control over their members, they have succeeded in raising the suspicion of the traditional model of professional self-regulation which remains alive today.[131] Over the past 50 years there have been considerable debates, especially amongst Anglo-American academics and policymakers, as to whether professional self-regulation is truly in the public interest or simply a means of advancing the professions' own interests in wealth, status and power.[132] From an economist's perspective, as Horowitz said it, self-regulation in the professions is self-serving with an ultimate goal to amass huge incomes beyond what professionals could have gained in competitive open markets.[133] These sentiments gave birth to demands for reforms or deregulation of professions and, in addition, the rising costs of professional services, together with scandals surrounding professional misconduct, provoked a complete restructuring of professional regulation in countries such as the United Kingdom (UK) and Australia.[134]

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129 Stigler, G. (1971) "The theory of economic regulation" *Bell Journal of economics*". 2, 3-21. pp. 4-7.

130 Pearce, R. G. *et al*, (2014), *supra* note 65. p. 4.

131 Abbott, A. (1983). " Professional Ethics." *The American Journal of Sociology* 88 : 855-855. See also Terry, L., Steve, M.., & Tahlia, G. (2012). "Adopting Regulatory Objectives for the Legal Professions." *Fordham Law Review* 80: 2685 – 2760.

132 Adams, T. L. (2016), *supra* note 43. p 1. Gorman, E.H. (2014), *supra* note 45. p. 493 and par: 1.2 above.

133 Horowitz, I. (1980). The Economic Foundation of Self-Regulation in the Professions. In Blair, D., & Rubin, S. (Eds). Regulating the Professions. Lexington Books. pp. 3-28. p. 16.

134 The UK and Australia have implemented new forms of professional regulation that place consumers and State appointed actors in the positions of regulatory authority. In the Australian case for example, co-regulation has become fashionable with professions being regulated by independent government appointed bodies with inputs from professionals. In the case of the UK, self-regulation in medicine has largely come to an end the principle of "protecting and promoting public interest" no longer the primary

In the field of medicine, professional self-regulation is founded on trust whereby the state and members of the public trust HCPs to act in the interest of citizens.[135] However, this trust has deteriorated over time due to incidents of medical malpractice, evidence of professional self-interest such as rising costs of professional services, negligence, and even crimes perpetrated by HCPs.[136] This prompted legislative changes in some countries that have reduced or eliminated professional self-regulation. For example, in the UK medical doctors are no longer self-regulating and, while they still have a voice in the regulatory process, the majority of the people on the General Medical Council are non-medical professionals.[137] Similarly in Australia, co-regulation has become more popular whereby professions are regulated by independent government appointed authorities with inputs from professionals.[138]

Besides the growing scepticism, professional self-regulation remains entrenched in countries such as Canada where legislation regulating professions still expects professional bodies to uphold the public interest. For this reason, Canada has been branded by some law scholars such as Rhode and Wooley as "the last bastion of unfettered self-regulation" in the world.[139]

The decline of self-regulation may not have eliminated the relevance of public protection claims[140] but has led to the transformation of the model particularly aimed at improving on

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objective of professional regulation but one amongst many other objectives. See Adams, T. L. (2006), *supra* note 43. p. 2. The UK case is discussed in chapter 5 of this dissertation.

135 Kuhlmann, E. & Saks, M. (2008). Changing patterns of health professional governance. In Kuhlmann, E. & Saks, M. (Eds) *Rethinking professional governance* (pp. 1-11). p. 2. Bristol: The Policy Press. http://dx.doi.org/10.1332/policypress/9781861349569.003.0001. See also Paton, P. (2008). Between a rock and hard plate: The future of self-regulation – Canada between the United State and the English/Australian experience. *Journal of Professional Lawyer*, Symp. Issues, 87-120.

136 Dixon-Woods, M. Yeung, K., & Bosk, C.L. (2011). Why is UK medicine no longer a self – regulating profession? The role of scandals involving "bad apple" doctors. *Social Science & Medicine,* 73, 1452-9.http://dx.doi.org/10.1016/j.socscimed.2011.08.031. (Date of use: 15 April 2019).

137 Dingwall, R. (2008). *A respectable profession'? Sociological and economic perspectives on the regulation of professional services. Essays on professions.* Aldershot, England: Ashgate.

138 Dixon-Woods, M., *et al*. (2011), *supr*a note 136. Paton, P. (2008), *supr*a note 135. Rees, V. (2013). *Transforming regulation and governance in the public interest.* Halifax: Nova Scotia Barristers' Society.

139 Rhode, D. L. & Woolley, A. (2012) Comparative perspectives on lawyer regulation: An agenda for reform in the United States and Canada. *Fordham Law Review*, 80, 2761-2790. p. 2774. Adams, T. L. (2016), *supra* note 43. p 1. Rees, V. (2013), *supra* note 138.

140 Adams, T. L. (2006), *supra* note 43. p. 3.

accountability to the public and to put a limit on the monopoly which some occupational groups might have acquired.[141] This was the birth of a hybrid model of self-regulation that essentially combines professionalist-independent assumptions regarding professional services with external or co-regulation from the consumerist-competitive model.[142] The emphasis of a hybrid model of self-regulation has shifted from a focus on protection of the profession to that of protecting the public.[143] Also encompassed in this model is the provision of a more transparent regulatory system, which is not only accessible to public, but also is capable of providing greater choices of services to the public.[144] Some countries, for example Canada, have introduced professional self-regulating systems, which no longer give professions an exclusive scope of practice, but an overlapping scope of practice whereby different professions may carry out similar activities.[145] This approach is seen as giving public members flexibility in determining the nature of services they are looking for and from whom.[146]

Furthermore, the consumerist-competitive mode, which started in the 1970s in England and Australia, is derived from the core values of the public interest theory.[147] This theory is at variance with the professionalism and professional independence model and is characterised by multiple and competing occupations, co-regulation or external regulatory governance, tolerance of non-professionals influencing professional service providers, and a dual regulatory system focusing on individual service providers and enterprises in which they work.[148] This theory is clearly distinguishable by the fact that, in addition to regulating individual professional, it also regulates enterprises in which an individual works.

141 Randall, E. R. (2005), *supra* note 57. p. 2.
142 Pearce, R.G., *et al* (2014), *supra* note 65. pp. 23-24.
143 Randall, E. R. (2005), *supra* note 57. p. 2.
144 Randall, E. R. (2005), *supra* note 57. p. 2.
145 Ontario. (1991). Regulated Health Professions Act. Toronto: Queen's Printer.
146 Randall, E. R. (2005), *supra* note 57. p. 2.
147 Also known as firm-based regulation.
148 Pearce, R.G., *eta* al (2014), *supra* note 65. p. 18.

The regulatory changes advocated by the critics of the professional self-regulation have been justified on the grounds that it is necessary to serve the public interest.[149] However, there seems to be no common definition of the concept 'public interest' especially in the context of professional regulation. Saks[150] connects public interest with the wider social principles such as justice, general welfare and freedom; studies of regulatory changes, especially in the UK, equate public interest to public safety.[151] On the other hand, studies of the public interest in the sphere of law link the concept to access to justice.[152] These divergent views on what constitutes public interest prompted scholars such as Adams[153] to suggest that it is not so much the self-regulating professions' inability to serve the public interest that has ignited the desire for regulatory change, but the changing conceptualisation of the phrase public interest.

The ambiguity of the concept public interest is problematic. The British physicist and mathematician William Thomson Kelvin, cited by Tunbridge, indicated that what is not defined cannot be measured, what is not measured cannot be improved and what is not improved is always degraded.[154] To avoid ambiguity, this study specifically focuses on patient safety. The focus is not public interest as justification for regulating healthcare professions.

The Institute of Medicine in the USA defines patient safety as the prevention of harm to patients and considers patient safety as part and parcel of the delivery of quality health care.[155] In this

149 Adams, T. L. (2016), *supra* note 43. p. 1.

150 Saks, M. (1995) The changing response of the medical profession to alternative medicine in Britain: A case of altruism or self-interest? In Johnson, T Larkin, G & Saks, M (Eds) *Health professions and the state in Europe,* (pp. 103-115). London: Routledge. p. 60.

151 Dixon-Woods, M., *et al*. (2011), *supr*a note 136. Kuhlmann, E. & Saks, M. (2008), *supr*a note 135.

152 Paton, P. (2008), *supra* note 135.

153 For example, when professions' interests and public interests were deemed compatible, professional self-regulation made the perfect choice. Where public interest is linked to human rights as was the case in Canada, professional regulation was altered to bring about more accountability. Where the definition of public interest moves away from service quality towards open competition and cost reduction, professional self-regulation is likely to decline. See Adams, T. L. (2016), *supra* note 43. p. 12.

154 Tunbridge, P. (1992). "Lord Kelvin: His influence on Electrical Measurements and Units". London: Peter Peregrines Ltd. pp. 17-19.

155 Aspden, P., *et al.* (2004). *Patient safety: achieving a new standard for care*. Washington, DC: The National Academies Press ISBN: 030909776.

context, quality healthcare is defined by Mitchell[156] as the all-encompassing sunshade under which patient safety resides. The WHO defines patient safety as "a framework of organised activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur."[157] This definition is much broader and therefore was adopted for this study.

The problem of preventable adverse events in healthcare is not new. Studies in the early 1950s reported on the prevalence of such events, but the subject remained abandoned for sometimes.[158] A body of evidence started to emerge in the early 1990s with the publication of a study on similar events by the Harvard Medical Practice in 1991.[159] This was followed by similar studies in Australia,[160] the UK,[161] and the USA;[162] particularly the report *To err is human: building a safer health system* by the Institute of Medicine. This report estimates that preventable adverse events[163] caused between 44 000 and 98 000 deaths annually in hospitals

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156 Mitchell, P. H. (2008). "Defining patient safety and quality care". In Hughes, R.G. (Ed.). *Patient safety and quality: an evidence-based handbook for nurses*. 2008 April. Chap1. Available from https://www.ncbl.nlm.nih.gov/books/NBK281/.

157 See par. 1.1 and WHO. (2021). *supra* note 16. p. 6.

158 This was the case because patient safety was not initially recognised a key element of quality of health care and any incident that resulted in patient harm was always blamed on malpractice of an individual practitioner than on the system of care. See WHO (2006). *World Alliance for Patient Safety: Forward Programme 2006-2007*. Geneva: World Health Organisation. p. 1. The second reason was that adverse events were regarded as "inevitable complications of care" which requires no special attention. WHO. (2021), *supra* note 16. p. 6.

159 The Harvard study found that 4% of patients suffer some kind of harm in hospitals in that 70% of the adverse events resulted in short lived disability, but 14% of the incidents led to death. See WHO.(2006), *supra* note 158. p. 1.

160 The study regarding the Quality in Australian Health Care released in 1995 found an adverse- event rate of 16.6% among hospital patients. See WHO (2002), Resolution WHA55:18 on Quality of care: Patient Safety. Geneva: World Health Organisation. p. 1.

161 The UK Department of Health in its 2000 report titled "*An Organisation with a Memory"*, established that adverse events occur in around 10% of the hospital admission or about 850 000 adverse events a year. See Department of Health. 2000. *An Organisation with a Memory.* UK, London*:* NHS. p. 5.

162 The US study did not only stimulate the research and discussion about patient safety but has also personalised the discussion of patient safety by recalling previous celebrity patients such as Libby Zion and Betsy Lehman who had died from medical errors. See Stelfox, H., *et al*. (2006). *The 'To Err is Human' report and the patient safety literature*. QualSaf Health Care. (pp. 174 & 177). 15 (3): 174-8 [PubMed].

163 An adverse is an injury caused by medical management rather than the underlying condition or ailment of the patient. An adverse which can be attributed to error of planning or execution of treatment regimen is a preventable adverse event. A negligent adverse event is therefore a subset of preventable adverse

in the USA, which was more than car accidents, breast cancer or AIDS.[164] The report assisted in bringing the subject of patient safety to the top of policy agendas and public debates worldwide.[165] This led to the adoption in May 2002 of the WHO resolution WHA55:18, which calls upon member states to pay closer attention to the problem of patient safety, and to establish and strengthen systems necessary for improving patient safety and quality care.[166] This was followed by the creation of the World Alliance for Patient Safety in May 2004 by the 57th World Health Assembly to facilitate the development of patient safety policy and practice in all member states and to act as a major force for improvement globally.[167] Today more countries have taken a serious look at the problems threatening patient safety.[168]

events that satisfy the criteria used in determining negligence i.e. whether the healthcare professional failed to maintain the standard of care reasonably expected of an average healthcare professional qualified to take care of a patient in question. See p. 28 of the Institute of Medicine. (2000). *To Err is Human: Building a safer Health System*. Washington, DC: The National Academies Press. Available at https:// doi.org/10.17226/9728. (Date of use: 10. September 2019). The test for medical negligence was enunciated in the case of *Mitchel v Dixon 1914 AD 519* where Innes ACJ indicated. p. 525: "A medical practitioner is not expected to bring to bear upon the case entrusted to him the highest possible degree of professional skills and care, he is bound to employ reasonable skill and care; and he is liable for the consequences if he does not''. See also the discussion by Carstens & Pearmain. (2007), *supra* note 6. p. 621 indicating that what is required is not the highest possible degree of professional care and skills, but reasonable knowledge, ability, experience, care, skill, and diligence.

164 Institute of Medicine (2000), s*upra* note 163. p. 26. This report provided the first estimates of the burden of patient harm and drew parallels with other high-risk industries such as aviation. WHO. (2021), *supra* note 16. p. 8.

165 WHO (2021), *supra* note 16. p. 1.

166 In WHA55.18 resolution the Director General of WHO was also directed to develop global standards and guidelines for quality care and patient safety, to promote formulation of evidence-based policies and standards to improve patient care with emphasis on safe clinical practice, support member states to promote a culture of safety and to encourage research into patient safety. See Institute of Medicine (2000), *supra* note 163. p. 6.

167 Under the World Alliance for Patient Safety various programmes were initiated which includes, the Patients for Patient Safety programme led by individuals who had suffered harm from health care; the Taxonomy for Patient Safety for ensuring consistency in the norms and terminology use for patient safety work and the International Classification for Patient Safety; the Patient Safety Research initiative to establish priorities for patient safety connected research; the Reporting and Learning Best Practice Guidelines to assist in the design and development of current and new incident reporting; the Patient Safety Curriculum Guides to help in patient safety education and training at educational institution especially in dentistry, medicine, midwifery nursing and pharmacy; and the African Partnerships for Patient Safety for establishing reliable hospital to hospital patient safety partnership. See WHO (2021), *supra* note 16. p. 11.

168 These are such a Canada, Denmark, the Netherlands, and Sweden. WHO (2021), *supra* note 16. p. 1.

Studies on the global burden of unsafe patient care indicate that an average of one in 10 patients is exposed to an adverse event while getting hospital care in high-income countries.[169] For the low- and middle-income countries the estimate is that up to one in four patients is injured, with 134 million adverse events taking place each year due to unsafe care in hospitals adding to about 2.4 million deaths.[170] According to the WHO, about 60% of fatalities in low- and middle-income countries that are associated with healthcare are due to unsafe and poor-quality care.[171]

On the African continent, the understanding of the burden of unsafe patient care is hampered by inadequate contemporary data. Kolgi-Kamu *et al* in a study that looks at the prevalence of hospital-acquired infections reports a high infection rates in countries such as Mali 18.9%, Tanzania 14.8% and Algeria 9.8% in terms of patients who had surgery.[172] Tapko *et al* also indicated that in 2004, 7% of the African countries did not test donated blood for HIV, 22% did not test donated blood for hepatitis B, and 51% did not test blood for hepatitis C.[173] There is currently a dearth of research on the burden of unsafe patient care in Namibia and this study aimed at narrowing this gap.

Before the publication of the report *To err is human: building a safer health system b*y the US Institute of Medicine in 1999, which scopes the subject of safety and harm in health care and provided the first estimates of the burden of patient harm,[174] the major focus of patient safety

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169 Slawomirski, L.; Auraaen, A.; & Klazinga, N. (2017). The economics of patient safety: Strengthening a value- based approach to reducing patient harm at national level. Paris: Organisation for Economic Cooperation and Development. https://doi.org/10.17875a9858cd-en. (Date of use: 10 March 2019).

170 National Academies of Sciences, Engineering, and Medicine. (2018). Crossing the global quality chasm: Improving health care worldwide. Washington (DC): The National Academies Press. https://www.nap.edu/catalog/25152/crossing-the-global-quality-chasm-improving-health-care-worldwide.

171 WHO, (2021), *supra* note 16. p. 8.

172 Koigi-Kamau, R., Kabare, L.W., & Wanyoike, G. K. (2005) Incidents of wound infections rate after caesarean section delivery in a district hospital Central Kenya. *East African Medical Journal*, 82 (7) 357-361.

173 Tapko, J. B., Sam, O., & Diarra-Nama, A.J. (2007). Status of blood safety in the WHO African region: Report of the 2004 Survey. Brazzaville: WHO Regional Office for Africa.

174 Institute of Medicine. (2000) *supra* note 162 and WHO (2021), *supra* note 16. p. 8.

was on blaming individual practitioners for malpractice.[175] Accordingly, as Downie *et al*[176] pointed out that the approach of dealing with patient safety issues has equally taken a person-centred approach that focuses on assigning blame and responsibility to the individuals believed to have caused harm to a patient. Legal instruments used to address patient safety issues were also aimed at individuals in a form of compliance or control mode of regulation.[177] These legal instruments created a framework for individual accountability, and, as such, individuals were often held accountable for their actions and omissions.[178]

A good example of person-centred approach to patient safety is the responsive regulation model suggested by Braithwaite and Drahos in the field of economics as applied to regulation of healthcare professions by Healy.[179] This model recommends that regulators must respond to issues of context, conduct and culture of those being regulated.[180] The model can be presented in a form of a pyramid, which suggests that regulators should start with soft strategies at the bottom of the pyramid instead of opting for hard enforcement of rules, regulations and standards at the top of the pyramid.[181] The important feature of the model is the ability of the regulators to escalate their responses upwards if necessary, from soft intervention to hard interventions.[182] Regulators are normally known for being punitive in their approach; this model advocates an approach building on the strengths of those being regulated and not just targeting their weaknesses.[183] However, those being regulated must also understand that a

175 Kapp, M..B. (1997). Medical Error Versus Malpractice. *1DePaul Journal of Health Care Law*. volume 1 issue 4: 751-772. https://via.library.depaul.edu/jhcl/vol1/iss4/4.

176 Downie, J. *et al*, (2006), *Patient safety law: from silos to systems*. Canada, Ottawa: Health Policy Research Programme. p. 3.

177 Downie, J. *et al*, (2006), *supra* note 176. p. 3.

178 Downie, J. *et al*, (2006), *supra* note 176. p. 3.

179 Healy, J. Brathwaite, J. (2006) "Designing safer health care through responsive regulation". *Medical Journal*. 184: 556-559.

180 Brathwaite, J., & Drahos, P. (2000). Global business regulation. Cambridge: Cambridge University Press.

181 Healy, J. (2013).*supra* note 33. p. 3.

182 Healy, J. (2013), *supra* note 33. p. 4.

183 Healy, J. (2013), *supra* note 33. p. 4.

polite demand may be followed by a caution and, in cases of persistent non-compliance, a reprimand may ensue.[184]

As indicated by Downie *et al*,[185] critics claim that a person-centred approach detaches unsafe acts from their context and does not always recognise the complexities of system failures. The approach is also seen as being characterised by the naming and shaming of individuals. It is described as hindering open discussion of unsafe practices thus resulting in failure to learn from mistakes and to avoid them in the future.

In its amplification of the system-centred approach to risks in healthcare, the WHO indicates that "adverse events are caused by human error embedded in a complex amalgam of actions and interactions processes, team relationships communications, human behaviour, technology, organisational culture, rules and policies as well as the nature of the operating environment."[186] This shift in thinking about patient safety therefore suggests that when an adverse event occurs, it is not always due to mistakes by an individual practitioner; the system under which he/she is operating may have facilitated human error or aggravated its effect when it happened.

Unlike in the case of the person-centred approach, the thinking about patient safety in the system-centred approach suggests that when an adverse event occurs it is not always due to mistakes by an individual practitioner; the system under which he/she is operating in may have facilitated human error or aggravated its effect when it happened.

Proponents of a systems-centred approach suggest that the foundation of patient safety improvement initiatives should focus on organisations and systems and not on individual practitioners.[187] In this respect, they argue that patient care is provided in an environment

184 Healy, J. (2013), *supra* note 33. p. 4.
185 Downie, J. *et al*, (2006), *supra* note 176. p. n3.
186 WHO, (2021), *supra* note 16. p. 7.
187 Institute of Medicine, (2000), *supra* note 163. p. 56.

characterised by complex interacting factors such as diseases, practitioners, policies, procedures, technology, and resources; when these complex factors interact, medical errors and harm to patients may occur.[188]

Reason[189] named the organisational factors compromising patient safety as the "blunt end" and those associated with healthcare practitioners as the "sharp end." He opined that it is the organisational factors that represent most medical errors.[190] To prevent such errors, it is therefore the organisation in which people work that needs to be adapted to the strengths and weaknesses of individual practitioners to ameliorate the effects of whatever human errors that occur.[191] Similarly, the Institute of Medicine suggests that the healthcare system should be the one to be held accountable and redesigned to mitigate the effect of human factors.[192]

Perrow[193] and Reason[194] call upon regulatory bodies to change their minds and recognise the impact of systemic factors on individual healthcare practitioners when disciplinary actions are being taken against them.[195] They further argue that, without considering the nature and the effects of system factors, action taken against an individual healthcare practitioner would be biased, and the latent factors in the system will patiently wait for an appropriate time to once again cause problems to patient safety.[196]

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188 Reason, J. (1990). *Human error*. New York : Cambridge University Press.

189 Reason, J. (1997). *Managing the risks of organisational accidents*. Aldershot, UK; Ashgate.

190 Reason, J. (1997), *supra* note 189. p. 4.

191 Reason, J. (1997), *supra* note 189. p. 4.

192 Institute of Medicine. (2001). *Crossing the quality chasm: Anew Health System for the 21 Century*. Washington Press. Available from https://doi.org/10.17226/10027 (Date of use: 10 August 2019).

193 Perrow's accident theory believes that accidents are inevitable in certain systems and regarded as normal in complex and highly technological industries. Healthcare systems are classified as one of such systems and therefore prone to accidents. See Institute of Medicine (2000) *supra* note 163. p. 57 and Perrow, C. (1984). *National Accidents*. New York: Basic Books.

194 Reason suggested that complex and tightly coupled systems such as healthcare services as classified by Cook and Woods can spring nasty surprises. See Institute of Medicine, (2000), *supra* note 163. p. 58.

195 Institute of Medicine, (2000), *supra* note 163. p. 56.

196 Institute of Medicine, (2000), *supra* note 163. p. 56

The analytical framework, suggested by Kish-Gepart, and extended by Muzilo *et al,*[197] appears to have taken a more balanced view with respect to postulating that the problems in healthcare services emanate from three levels. The first is related to an individual health practitioner whose performance may be affected by shortage of staff or pure incompetence. Such practitioners are labelled as 'bad apples'. The second is at the organisational setting characterised by poor organisational culture and labelled as 'bad barrels'.[198] The third is related to the overall health system with bad policies and procedures on patient safety and labelled as 'bad cellars'.[199]

It is evident that the analytical framework adopts a systems-centred approach to patient safety, and the responsible regulation model adopts a person-centred approach to patient safety.[200] The analytical framework, and the responsible regulation mode, both recognised the important role individuals, systems, and organisational factors play in compromising patient safety.[201] However, their prescripts on improving patient safety remain entrenched in their distinctive approaches.[202]

It is clear from the discussions above that the thinking about patient safety has shifted towards recognising the role individuals, systems, and organisational factors play in compromising patient safety. What is also clear from the discourse is that the regulatory focus for healthcare professions remains generally person-centred. While such a narrow approach may be regarded

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197 Muzilo, D., *et al* (2006). Bad apples, bad barrels, and bad cellars. In Palmer, D., Smith-Crowe, K., & Greenwoods, R. (Eds.). *Organisational wrongdoing.* (pp. 141–175). Cambridge University.

198 Muzilo, D., *et al* (2006), *supra* note 197. p. 147.

199 Muzilo, D., *et al* (2006), *supra* note 197. p. 147.

200 The regulatory model emphasised that health professionals are experts in the workings of the health services and can find solution to patient safety problems when motivated to do so. They are important regulatory actors and not objects of regulatory actions. See Healy, J. (2013), *supra* note 33. p. 5.

201 The regulatory model recognises the strengthening of both the regulation of healthcare professionals and organisations in order to ensure better and safer health care for patients. In this manner, the model recognises the involvement of multiple regulators and strategies in the regulation of patient safety. See Healy, J. (2013), *supra* note 33. p. 2.

202 Although responsive regulation model emphasised the importance of co-regulation and other strategies towards the middle and the base of the pyramid, the model warns against reliance on a top-down approach which is likely to kill local innovation and commitment of individual commitments.

as appropriate, it may not be sufficient in contributing to the improvement of patient safety. Regulation of healthcare professions ought to move beyond individuals to include the place of work where patient care is being rendered and socialisation of new members of the profession is taking place. This view is premised on an understanding that even a well-qualified healthcare practitioner may be rendered incompetent within a poorly regulated work environment and defective systems.

If the thinking about patient safety has changed to align with the systemic approach, the regulation of healthcare professions can too. The reform for the regulatory framework of healthcare professions in Namibia should seek to support both the person-centred and system-centred approaches. This dissertation argues that such an integrated approach may be significant to the improvement of patient safety.

Health service delivery can broadly be accommodated under the law of obligations: either the law of contract or the law of delict.[203] When medical negligence is suspected, a patient or his or her relatives may opt to institute a civil claim to recover damages[204] and / or may file a criminal charge against the healthcare professional. These may be in addition to lodging a complaint with the Councils for unprofessional conduct. The outcome of the unprofessional

[203] Whether health service is delivered in the public or private facility, in the normal course of events the relationship between the patient and a healthcare professional is a contractual one, but a breach of duty of care and negligence may underline both contract and delict. If there is no contract between parties, the relationship is governed by the law of delict. See Carstens, P.A., & Pearmain, D. (2007), *supra* note 6. pp. 283- 284.

[204] The claim for medical negligence can be rooted on contract or delict depending on the nature of the damages that is sought to be recovered. Since non-patrimonial damages cannot be recovered in contract, delictual claims are normally instituted to recover non-patrimonial damages. See Coetzee, L.C., & Carstens, P. (2013). Medical malpractice and Compensation in South Africa. In Oliphant, K., & Wright, K.W. (Eds.). *Tort and Insurance Law* V 32 (Water and Gruyter Berlin) 397- 437. p. 405. At page 406 Coetzee and Carstens discussed the principle of vicarious liability of the State in cases where negligence happened in a State health facility, for example. See also Pienaar, L. (2016). "Investigating the Reasons behind the increase of medical negligence claims". PELJ/PER. p. 4.

conduct may result in the suspension of a healthcare professional from practice or removal of his or her name from the register at the Council.[205]

A medical negligence, or simply an allegation of such, could result in far reaching consequences against a healthcare practitioner.[206] It is therefore necessary that healthcare professionals, in providing care to patients, should adhere to the ethical principles of patient autonomy,[207] non-maleficence,[208] beneficence[209] and justice.[210]

1.9 Research methodology

Research methods can be broadly divided into two categories: quantitative and qualitative.[211] Quantitative research uses numerical and non-descriptive data and is based on measurement of quantity.[212] Qualitative research, on the other hand, uses non-numerical and descriptive data, and it applies reasoning and use of words.[213] In fact, when one evaluates how the law is helping to improve patient safety, one is engaged in qualitative enquiry. Hence, this study evaluates

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205 If healthcare professional is found guilty of unprofessional conduct the Council can impose on him or her one or more of these penalties, a reprimand, or a caution; suspension for a specified period from practising acts pertaining to his or her profession; removal of the name of the healthcare professional from the register or payment of a fine. See S 42 of the Social Work and Psychology Act 6 of 2004; S 41 of the Allied Health Professions Act 7 of 2004; S 42 of the Nursing Act 8 of 2004; S 50 of the Pharmacy Act 9 of 2004 and s 42 of the Medical and Dental Act 10 of 2004.

206 The negative emotional effect of medical negligence claims on a healthcare professional was indicated by Moore, W., & Slabbert, M. N. (2013). "Medical Information Therapy and Medical Malpractice in South Africa". *SAJBL*. p. 60.

207 According to Beauchamp, T. L., & Childress, J. F. (1994) "*Principles of Biomedical Ethics"* Oxford University Press, the principle of autonomy recognises the duty of healthcare professionals to respect the freedom of patients to make decisions for themselves. pp. 67 -113.

208 The principle of non-maleficence recognises the duty of healthcare professionals not to harm their patients. Beauchamp, T. L & Childress, J. F. (1994), *supra* note 207. pp. 120 -184.

209 The principle of beneficence recognises the duty of healthcare professionals to do good for their patients. Beauchamp, T. L & Childress, J.F. (1994), *supra* note 207. pp. 194-249.

210 The principle of justice recognises the duty of healthcare professionals to treat their patients equally and fairly. Beauchamp, T. L & Childress, J.F. (1994), *supra* note 207. pp. 256-302.

211 Kothari, C. R., & Grag, G. (2015). *Research Methodology : Methods and Techniques.* (3rd ed). New Delhi: New Age International (P) Limited, Publishers. p. 3.

212 Kothari, C. R., & Grag, G. (2015), *supra* note 211. p. 3.

213 Collis, J., & Hussey, R. (2003). *Business research: a practical guide for undergraduate and postgraduate students.* Palgrave Macmillan, Hound mills, Basingstoke, Hampshire.

and describes how the laws regulating healthcare professionals help in improving patient safety in Namibia.

This study also quantitatively determines the number of medical malpractice complaints reported to the regulatory authorities for healthcare professions in Namibia as well as the quantity and value of medical malpractice claims against the State between 2014 and 2019. This analysis enables the researcher to determine the burden of patient safety problems in Namibia. From the review of secondary sources, the researcher is able to compare the Namibian regulatory framework for healthcare professions to that of South Africa and the UK with a view to identify similarities and differences in dealing with patient safety problems and proposed a legal framework for improving patient safety Namibia. This is therefore an exploratory descriptive study. It also employs the mixed methods approach in balancing the quantitative and qualitative data aspects pertinent to this study.

1.9.1 Research as exploratory descriptive

This exploratory descriptive study utilises two research approaches. As an exploratory study, it focuses on studying a relatively unstudied area in Namibia by evaluating the appropriateness of the Namibian regulatory framework for healthcare professions to contribute to the improvement of patient safety. According to Kothari and Garg[214] an exploratory approach is a method of discovering ideas and insights, which is flexible enough to provide opportunity for considering different aspects of the problem under study.

This research also utilises a descriptive approach, which is best suited when there is limited existing information available on the topic. This selected approach aligns with that of Bickman, Rog and Hendrick who state that the descriptive approach is used where a researcher is

214 Kothari, C R and Grag, G (2015), *supra* note 211. p. 22.

attempting to answer "what is" or "what was" questions.[215] This research seeks to answer the following questions: (1) what the number of medical malpractice complaints in Namibia is between 2014 and 2019; and (2) what the number and value of medical litigation against the State are between 2014 and 2019. While a descriptive approach has its limitations, in that it cannot, as Bowling[216] says, be used to identify a causal link between variable, it does, however, play an important role in highlighting a phenomenon of interest that is unknown.[217]

1.9.2 Methods of data collection

Data for this study were collected through the narrative review of literature relevant to regulation of healthcare professions and patient safety. This includes books, government reports on medical litigation, Health Professions Councils of Namibia's annual reports on fitness to practice, legislation, rules, regulations, policies, directives, standards, protocols, academic publications from members of disciplines, including law and health sciences as well as court documents related to the objectives of this study. The review of existing documents assists to gain an understanding of the history and the philosophy behind healthcare profession regulations and patient safety.

When one tries to improve a legal system, it is important to look beyond the borders of a country and to enquire to what extent a legal evolution in one's country finds parallel developments in other jurisdictions.[218] In this study, the researcher drew comparison from South Africa and the UK. While fully aware that interpreting rules and solutions from other

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215 See Bickmann, Rog and Hendrick (1998) as cited in Bickmann, L., & Rog, D.J. (1998). *Handbook of applied Social Science Research Methods.* London: Sage Publications. p. 15.

216 Bowling, A. (2002). *Research methods in health, investigating health and health services.* Philadelphia: Open University Press. p. 195.

217 This view was supported by Steinberg, D. M. (2004). *The Social Work Student's handbook.* New York: The Haworth Social Work Practice Press at p. 48, who indicated that descriptive research helps to correct on perceptions, which are too often inaccurate if only because we rarely have the choice to see a picture in total.

218 Van Hoecke, M. (2015). *Methodology of Comparative Legal Research.* DOI:10.5553/REM/.000010. Retrieved from http:www.researchgate.net. (Date of use 28 June 2020). p. 3.

countries may not work because of a difference in context, these countries are preferred because, like in the case of Namibia, they are common law jurisdictions; they have studies examining the incidence of unsafe acts in hospitals, and, in all, patient safety was identified as a policy priority within the management of their health systems. A document review is also chosen by the researcher as a data collecting method for the comparative study.

1.9.3 Data analysis

Before analysis, the quantitative data generated from this study are classified into two classes: categorical[219] and quantifiable.[220] The researcher uses descriptive statistics to describe the basic features of the study and inferential statistics to draw conclusions beyond the data.[221] Unlike quantitative data analysis, where statistical tools are well understood, in qualitative analysis there are no hard and fast rules on how data should be analysed.[222] For the data generated from documentary review, a secondary data analysis was used.[223] In keeping with a mixed design of this study, regular key themes of qualitative data are identified and quantitatively analysed in terms of the number of times they occur.

1.9.4 Ethical considerations

Research ethics refers to the norms and standards that guide the moral choices about an individual's behaviour and the relationships with other in a research process.[224] It is important

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219 Categorical data cannot be quantified numerically but are either placed into sets or categories as nominal or ranked in some way as ordinal data. See Gray, E. D. (2009). *Doing Research in Real World.* (2nd ed). London: Sage Publications Ltd. p. 450.

220 Quantifiable data can be measured numerically, and they are more precise than categorical data. Gray, E. D. (2009), *supra* note 219. p. 450.

221 Gray, E. D. (2009), *supra* note 219. p. 458 distinguished descriptive statistics from inferential statistics in that they attempt to show what the data is by using graphical analysis, while inferential statistic tries to draw conclusions beyond the data.

222 Gray, E. D. (2009), *supra* note 219. p. 495.

223 This will be done keeping in mind the warning issued by Gray, E. D. (2009), *supra* note 219. p. 498, that secondary data analysis can only be valid if limited to methodological exploration and any attempts to establish new analytical themes from such data will be inappropriate.

224 Cooper, D. R., & Schindler, P. S. (2003). Business Research Methods.(8th Ed). New Delhi: McGraw Hill. https://brainnass.com/file/217875/Bussines_Research_methods-Chapter05.pdf (Date of use: 29 June 2020).

that a researcher adheres to the standard and norms of research ethics to protect respondents and institutions from harm or adverse effects emanating from research undertakings.[225] In this study, data collection does not involve human subjects and the study has no negative impact on human, animal and plant life. The researcher adheres to the University of Namibia's research ethics policy.

1.10 Structure of the dissertation

To achieve the research objectives of this dissertation, the chapters are organised as follows.

Chapter one: Introduction

This is an introductory chapter in which the background of the study, statement of the problem, objectives of the study, significant of the study, limitation and delimitation of the study, theoretical framework of the study, literature review, research methodology, the outline of the study and terminology are presented.

Chapter two: Historical context of health professions regulations in Namibia

In this chapter, the historical background of health professions regulation in Namibia is traced. The focus is on how the legal framework has changed overtime and the governance architecture it has created. Factors that informed the past legislative reforms are discussed and justification of the current arrangement is also covered.

Chapter three: Medical malpractice incidents and claims in Namibia

In this chapter, efforts are made to construct a synopsis of the number of medical malpractice incidents and the value of medico-legal claims against the State. The aim of such analysis is not necessarily to create a causal link between specific adverse events and medico-legal claims, but merely to establish the prevalence of such events in the country and their cost to taxpayers.

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225 Cooper and Schindler(2003), *supra* note 224.

The information presented in this chapter assists in determining the burden of patient safety problems in Namibia and supports the proposal for regulatory reform.

Chapter four: Regulatory framework for healthcare professions in Namibia

In this chapter, a comprehensive evaluation is provided of the laws regulating healthcare professions and how such laws enable the regulatory bodies to contribute to the improvement of patient safety.

Chapter five: Regulation of healthcare professions in South Africa and the United Kingdom: a comparative analysis

The regulatory framework for healthcare professions in South Africa and the UK are analysed in this chapter. These countries were selected as they have studies examining the incidence of unsafe acts in hospitals, and, in all, patient safety was identified as a policy priority within the management of health systems. In addition, the UK together with Germany pioneered the global patient safety movement and hosted the first summit on patient safety in London in March 2016. South Africa is equally an obvious choice of comparison, not only because Namibia and South Africa are neighbouring countries, but also because of the legal history that Namibia shares with South Africa and the Namibian regulatory framework for healthcare professions largely resembles the historical South African regulatory framework.

Chapter six: Consolidation and discussion of study findings

In this chapter the researcher consolidates and discusses the findings of this study on the (i) historical context of health professions regulation in Namibia as presented in chapter two (ii) the situational analysis of medical malpractice incidents and claims in Namibia discussed in chapter three; (iii) evaluation of the Namibian regulatory framework for health care professions presented in chapter four; (iv) the comparative analysis of the South African, and the UK

regulatory systems discussed in chapter five as well as lessons learned from the South African and the UK jurisdictions.

Chapter seven: Conclusion and recommendations

A summary of the main conclusions and recommendations are presented in this chapter. A legal framework for improving patient safety is also included.

1.11 Terminology

In this dissertation, these concepts have the following meaning.

Self-regulation refers to the regulatory process whereby the regulatory body establishes and enforces the rules and standards relating to the conduct of the professionals.[226]

Health refers to a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.[227]

Healthcare refers to services received by an individual or communities to promote, maintain, monitor, or restore health. [228]

Safety is the reduction of risk of unnecessary harm to an acceptable minimum.[229]

Patient safety is a framework of organised activities that creates cultures, processes, procedures, behaviours, technologies, and environments in healthcare that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur.[230]

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226 Barbou Des Place, S. (2006), *supra* note 65. p. 6.

227 WHO. (1947) Preamble to the Constitution of the World Health Organisation as adopted by the International Health Conference, New York, 19 -22 June 1946; signed on 22 July 1946 by the representatives of 61 States(Official Records of the World Health Organisations, no.20, p.100) and entered into force on 7 April 1948. Available at www.who.int/en/.

228 WHO. (2009*). Conceptual Framework for the International Classification for Patient Safety*. Version 1.1 Final Report January 2009. Geneva: World Health Organisations. p. 15.

229 WHO (2009*), supra* note 228. p. 15.

230 WHO. (2021), *supra* note 16. p. 6.

An *incident* can be a reportable circumstance, near miss, no harm incident or harmful incident (adverse event).[231]

A *patient safety incident* is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.[232]

Adverse event is an incident that results in harm to a patient.[233]

231 Department of Health, South Africa (2017). *National policy for patient safety incident reporting and learning in the public sector of South Africa.* Pretoria: Department of Health. p. 10.

232 WHO. (2009), *supra* note 228. pp. 15-16.

233 Department of Health, South Africa (2017), *supra* note 231. p. 10.

CHAPTER TWO

HISTORICAL CONTEXT OF HEALTH PROFESSIONS REGULATION IN NAMIBIA

2.1 Introduction

The regulation of healthcare professions in Namibia cannot be fully understood without an appreciation of the historical development of the Namibian laws. The history of the Namibian laws in general is intertwined with political history and development of the country,[234] as are the health-related laws. The history of the Roman-Dutch law in both Namibia and South Africa is covered in this chapter. So too is the introduction of health profession regulation in South Africa and how such a system found its way into Namibia. The hallmarks of statutory development of health professions regulation in Namibia before and after independence are also discussed in this chapter.

2.2 Introduction of Roman-Dutch law in the Cape of Good Hope

On 5 April 1652, a surgeon and Dutch navigator Johann Antentonzoon 'Jan' van Riebeek arrived in South Africa in Cape Town, the Dutch Cape Colony of the Dutch East Indian Company.[235] This did not only mark the formal takeover of the Cape of Good Hope by the Dutch Republic, but also the introduction of Roman-Dutch law to South Africa effective from 7 April 1652.[236] The Cape was later annexed by the British in 1795 and remained under English

234 Amoo, S. K (2008). An introduction to Namibian law: Materials and Cases. Windhoek: Macmillan Education Publishers (Pty) Ltd. p. 60.

235 Searle, C. (1958). *The history of the development of Nursing in South Africa 1652–1960: A socio-historical survey*. Cape Town: Gothic Printing Company Ltd. p. 23.

236 Amoo, S.K (2008), *supra* note 216. p. 234.

rule until 1910 when the Union of South Africa was created.[237] Although the British government did not formally replace the Roman-Dutch law with English law in South Africa, the English legal literature became the reference material in legal proceedings and the Privy Council became the final court of appeals in the Cape.[238]

2.3 Introduction of Roman-Dutch law in Namibia

From 1884 to 1915, German South West Africa (now Namibia) was under the colonial administration of Germany.[239] At the end of the First World War, Namibia was placed under the League of Nations mandate system as "C" mandate which, although Great Britain accepted to exercise under the supervision of the League of Nations, delegated such responsibility to the Union of South Africa.[240] This marked the occupation of South West Africa (hereafter Namibia) by South African troops in 1915 and the extension of the South African legal system to Namibia.[241] The Roman-Dutch law, which was already part of the South African common law at the time, was formally introduced to Namibia by Proclamation 21 of 1919.[242] The English common law, introduced into the Cape of Good Hope subsequent to the English colonial administration of the Cape, was equally made applicable to Namibia by Proclamation 21 of 1919.[243] With regard to common law that was developed through court decisions in South Africa, such common law was made binding on Namibian courts by the Supreme Court Act No 59 of 1959 which made the High court of South West Africa (SWA) a division of the

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237 Britannica, T. Editors of Encyclopaedia (2009, July 31). Cape Colony. Encyclopaedia Britannica. https://www.britannica.com/place/Cape-Colony. (Date of use: 6 July 2021).

238 Amoo, S. K (2008), *supra* note 234. p. 61.

239 Amoo, S. K. (2008), *supra* note 234. p. 60

240 Zongwe indicated that Article 2 of the mandate agreement gave the mandatory all the powers of administration and legislation over the mandated territory. This had authorised the Union of South Africa to apply its laws to Namibia. Zongwe, D. P. (2020). *Update: Researching Namibian Law and the Namibia Legal System.* p. 4. Available at https://www.nyulawglobal.org/globalex/Namibia1.html. (Date of use: 06 July 2021).

241 Amoo, S. K (2008), *supra* note 234. p. 60.

242 Proclamation 21 of 1919 (SWA Gazette, No 25 of 1919) provided that the Roman-Dutch law was to be applied in Namibia (SWA) 'as existing and applied in the Province of the Cape of Good Hope".

243 Zongwe, D. P. (2020), *supra* note 240. p 4.

Supreme Court of South Africa.[244] The Proclamation 21 of 1919 remained the reference source for common law in Namibia until the promulgation of the Namibian Constitution in 1990.[245]

2.4 Development of health professions regulation in South Africa

During the seventeenth and eighteenth centuries, medical practitioners were drawn from a wide variety of occupations; not all of them were holders of formal qualifications.[246] Those with no formal education simply gained experience in medical practice and they could practice medicine after taking an oath.[247] Towards the end of the eighteenth century, more university-educated medical practitioners settled in the Cape and eventually played an important role in reforming medical practice and subsequently statutory control of medical practice in the Cape.[248] This development in medicine also paved a way for other healthcare professions such as nursing, midwifery, and pharmacy.[249]

In 1807, a Supreme Medical Committee in the Cape was established through which the state started to control the medical profession.[250] The Supreme Medical Committee was later replaced by the Colonial Medical Committee in 1830 when the provisions of Proclamation of 24 April 1807 were repealed by Ordinance No 82 of 1830. The Colonial Medical Committee remained in place until the passing of the Medical and Pharmacy Act No 34 of 1891.[251] This

244 Amoo, S. K. (2008), *supra* note 234. p. 60.

245 Article 66 (1) of the Namibian Constitution stipulates that the common law of Namibia in force on the date of independence shall remain valid to the extent to which such common law does not conflict with the same Constitution.

246 Searle, C. (1958), *supra* note 235. p. 65.

247 Searle, C. (1958), *supra* note 235. p. 65.

248 Burrows, E. H. I (1958) A history of medicine in South Africa up to the end of 19th century. Cape Town: Balkema. p. 45.

249 Searle, C. (1958), *supra* note 235. p. 66.

250 The Supreme Medical Committee was established by a Proclamation of 24 April 1807 and empowered control matters concerning medical education and training, examinations, certifications, licencing, practice standards and ethical control of medical practices in the interest of the public. Searle, C. (1958) *supra* note 235. p. 66.

251 This Act made provisions for the control of several categories of healthcare professions namely, physicians, surgeons, accoucheurs, chemists, druggists, apothecaries, dentists, midwives, and trained nurses. See Searle, C. (1958), *supra* note 235. p. 66.

Act was extended to native territories by Proclamation No 28 of 1892.[252] When the four colonies, namely, Transvaal, Orange River, Cape, and Natal, were merged into a Union in 1910, the medical profession also made several presentations for a consolidation of law to replace the provisions relating to the control of medical professions.[253]

This led to the enactment of the Medical, Dental and Pharmacy Act of 1928, which was later repealed by the Health Professions Act 56 of 1974. Nursing and midwifery started being regulated separately from other healthcare professions after the enactment of the Nursing Act 45 of 1944, which was later repealed by the Nursing Act 69 of 1957 and then the Nursing Act 50 of 1978. Other healthcare professions also became separately regulated under various professions specific Acts such as Chiropractors Act 6 of 1971, Homeopaths, Naturopaths, Osteopaths and Herbalist Act 52 of 1974, Pharmacy Act 53 of 1974, and the National Welfare Act 79 of 1965. Registration of healthcare professions in South Africa started voluntarily but later changed to be compulsory.[254]

2.5 Transfer of the South African health related laws to Namibia

On 19 August 1977, the President of the Republic of South Africa established the office of Administrator-General for the territory of SWA by Proclamation No 180 of 1977. The Administrator-General was also given wide legislative powers under Proclamation 181 of 1977.[255] True to such legislative powers, on 25 November 1977 the Administrator-General issued an Executive Powers (Health) Transfer Proclamation, AG 14 of 1977 which transferred

252 Searle, C. (1958), *supra* note 235. p. 103.
253 Searle, C. (1958), *supra* note 235. p. 230.
254 Searle, C. (1958), *supra* note 235. p. 233.
255 This Proclamation was issued under section 38 of the South West Africa Constitution Act 39 of 1968 and empowers the Administrator-General to make laws by proclamation in the official gazette of the territory and for that territory and in any such law to repeal or amend any legal provision, including any Act of Parliament in so far as it relates to or applies in South West Africa or is connected with the administration thereof or the administration of any matter by any authority therein. The executive powers were equally transferred to the Administrator-General through the Executive Power Transfer (General Provisions) Proclamation, AG 7 of 1977, which came into force on 15 November 1977.

all health-related matters pertaining to SWA from the Minister of Health of the Republic of South Africa to the Administrator-General. This Proclamation came into force on 1 December 1977. On that date, all South African health-related laws became applicable to Namibia and all powers related to health matters were vested in the Administrator-General. It also meant that any part of the health-related laws to get repealed in South Africa after this date would not be applicable to Namibia. At the independence of Namibia in 1990, and by virtue of Executive Powers (Health) Transfer Proclamation, AG 14 of 1977, the following South African Acts relating to the regulation of healthcare professionals were therefore applicable to Namibia: Health Professions Act 56 of 1974; Nursing Act 50 of 1978; Chiropractors Act 6 of 1971; Homeopaths, Naturopaths, Osteopaths Health Services Professions Act 56 of 1974; Pharmacy Act 53 of 1974; and National Welfare Act 79 of 1965.

It is worth noting that despite these Acts having been made applicable to Namibia, and, with the exception of the National Welfare Board of South West Africa established for the registration and control of social workers, the other regulatory authorities were all situated in South Africa with the result that all members of such professions in Namibia had to register with their respective regulators in South Africa and were controlled and disciplined by such regulators.[256] This situation continued to exist after Namibia's independence as time was needed to draft new legislation to establish regulatory bodies in Namibia.[257] That process is discussed later in this chapter.

It is further interesting to note that, probably in anticipation of the imminent independence of Namibia in 1990, the Administrator-General in 1989 issued the Health Services Professions Proclamation AG 70 of 1989 in terms of which certain persons could be authorised to practise

256 HPCNA. (2013). *Explanatory Memorandum on the statutory arrangement of Health Professions in Namibia: past, present, and future*. (unpublished report. Windhoek: HPCNA). p. 1.

257 HPCNA.(2013), *supra* note 256. p. 1.

certain health professions in Namibia. The understanding is that this Proclamation mainly applied to Namibian nationals who were trained as healthcare professionals in various countries while in exile and who returned to Namibia shortly before and after the country's independence in 1990.[258]

2.6 Procedures to be followed with regard to drafting of legislations in Namibia

Given the independence of Namibia in 1990, it was impractical to have any health profession in an independent county controlled by a regulator in another country. As indicated in 2.5 above, the situation continued for a few years after independence because time was needed to draft new legislation to establish home grown regulatory bodies in Namibia.

On 26 January 1993, the Office of the Prime Minister of the Republic of Namibia issued an administrative directive to government ministers and public servants on procedures to be followed when proposing new legislations.[259] These directives are summarised as follows.

(a) Consultation with the Attorney-General

The ministry contemplating to enact a new legislation or amend the existing one must first consult the Attorney-General to ensure that the measures to be affected by the proposed legislation are compatible with the provisions of the Namibian Constitution and to determine whether such measures could not be effected administratively or through other means.[260]

(b) Preparation of a cabinet memorandum on legislation

258 HPCNA.(2013), *supra* note 256. p. 1.
259 Government Notice No 16 *Government Gazette* No 593 of 05 February 1993 (Hereinafter referred to as "GN 16/1993 (GG 593)").
260 GN 16/1993 (GG 593). para. 4.

After having consulted with the Attorney-General, if the originating ministry is satisfied as to the need of new or amending the legislation, it must prepare and submit a memorandum to cabinet stating the problem giving rise to legislation coupled with a broader policy statement on how to solve the problem.[261]

(c) Forwarding the memorandum to the cabinet committee on legislation

Once the cabinet has given approval in principle to the proposed legislation, the originating ministry should submit six copies of the memorandum to the cabinet committee on legislation (hereinafter referred to as CCL).[262]

(d) CCL meeting on the memorandum

On receipt of the memorandum, the secretary of the CCL will arrange for a meeting of CCL and invite the sponsoring minister to attend the meeting along with any of his/ her officials he/she deems necessary. The minister may also choose to delegate the responsibility of attending the meeting to his/her deputy minister or executive director with other officials.[263]

(e) CCL certificate

Once CCL is satisfied that the matter can be approved by cabinet, the secretary of the CCL will provide the sponsoring ministry with a certificate to that effect.[264]

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261 This memorandum must be comprehensive as possible and should clearly state the problem and the background, refer to any existing legislation in that regard, and point out where and what the existing legislation is found wanting. The memorandum should also refer to any consultations held with other Ministries or stakeholders, especially the Treasury and Public Service Commission and outline their responses. A layman's draft or comprehensive policy directive should accompany the memorandum.

262 GN 16/1993 (GG 593). para 4.

263 At this meeting, CCL do consider whether further legal advice is necessary, whether more consultations with other Ministries and stakeholders should take place or some aspects still need Cabinet consideration and should be highlighted as such. See GN 16/ 1993 (GG 593). para. 4.

264 GN 16/1993 (GG 593). para. 4.

(f) Submission to the cabinet for approval of the drafting of the Bill

Having received the CCL certificate, the sponsoring ministry must submit the whole matter to the cabinet in accordance with what has been decided at the CCL meeting. In this memorandum, the sponsoring ministry must specifically request the cabinet to grant approval in principle for the drafting of the Bill.[265]

(g) Drafting of the Bill

Once the cabinet has granted approval in principle for the drafting of the Bill, the secretary to cabinet must confirm this approval in writing to the sponsoring ministry and the ministry of justice. The sponsoring ministry must confirm the receipt of the approval to the executive director for justice within seven days of the cabinet decision. This confirmation must be accompanied by documents such as the memorandum to cabinet, cabinet resolutions, the layman's draft, and detailed drafting instructions. The name and rank of a contact person in the sponsoring ministry should also be indicated and such person should be readily available for consultation by legal drafters and should preferably be no lower in rank than the deputy director and not higher than the deputy executive director.[266]

(h) Sponsoring ministry's response to the Bill

Once the legal drafters have produced the Bill, it is submitted to the sponsoring ministry for review. The ministry's response may either confirm that the Bill meets its requirements, or it may make comments if it wishes, including amendments, and convey them to the legal drafters. The sponsoring ministry may during this stage discuss the aspects of the Bill with the legal

265 GN 16/1993 (GG 593).
266 GN 16/1993 (GG 593).

drafters. A final response is however necessary to enable the ministry of justice to prepare the final draft.[267]

(i) Certification by the Attorney-General

Once the sponsoring ministry is happy with the draft Bill, it will be submitted to the secretary of the CCL for its consideration. The secretary will invite the sponsoring ministry to attend the meeting of CCL. At this stage, it might once again be necessary for legal drafters to effect amendments required by CCL and such amendments may even be considered again during a further meeting of CCL. Once the CCL is satisfied, its secretary will submit the Bill to the Attorney-General for certification.[268]

(j) Arrangement for the introduction of the Bill at the National Assembly

The Attorney-General will, after his/her certification of the Bill, forward it to the secretary of the National Assembly for printing and further arrangement regarding its introduction. At the same time, the sponsoring ministry must prepare the second reading speech.[269]

2.7 Promulgation of the 1993 Acts

During the sixth session of the first Parliament of the newly independent Republic of Namibia the then Minister of Health and Social Services, the late Dr Nicky Iyambo, in 1993 tabled the following Bills: the Social Workers Professions Bill, the National Welfare Amendment Bill, the Medical and Dental Professions Bill, the Pharmacy Professions Bill, the Nursing Professions Bill, the Allied Health Services Professions Bill, and the Council of Health and

267 GN 16/1993 (GG 593).
268 GN 16/1993 (GG 593).
269 GN 16/1993 (GG 593).

Social Services Bill.[270] With the exception of the National Welfare Amendment Bill[271] and the Council of Health and Social Services Bill,[272] the others, as highlighted during the debate in Parliament, were to provide, among others, for the establishment and constitution of professional boards, to define powers, duties and functions of such boards, provide for the registration of healthcare professionals, prescribe the required training and qualifications leading to registration and prohibit the practising of healthcare professions without being registered.[273] The overall aim, as indicated by Parliament, was two-fold for such Bills: the protection of the public against malpractice; and to regulate and protect various health professions and health workers engaged in such professions.[274]

During the parliamentary debate, the Minister of Health and Social Services (hereafter the Minister) emphasised that the professional boards would function independently. He would have no powers to interfere with the activities of such boards unless in accordance with the law. It was also emphasised that the boards would play a watchdog role and if a healthcare practitioner acted unprofessionally, the relevant board would inquire into the matter and if found guilty such practitioner may be suspended, prohibited from practising, or removed from the register.[275]

The Bills were reconsidered by the National Assembly after the inputs of the National Council and passed into law during the seventh session of Parliament.[276] The following Acts

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270 Government of the Republic of Namibia (1993).*Debates of the National Assembly, Sixth Session, First Parliament, 11 May – 9 June 1993 Volume 30*. Windhoek: Government Printers. p. 15.

271 This bill aimed at amending the South African National Welfare Act 78 of 1965 which created the National Welfare Board of South West Africa and to establish the National Welfare Board of Namibia providing for the registration and control of Social Workers. See Government of the Republic of Namibia (1993), volume 30 *supra* note 270. p. 8.

272 This bill was to create an umbrella body to coordinate the activities of the professional boards. See Government of the Republic of Namibia (1993), volume 30 *supra* note 270. p. 31.

273 Government of the Republic of Namibia (1993), volume 30 *supra* note 270. p. 8.

274 Government of the Republic of Namibia (1993), volume 30 *supra* note 270. p. 15.

275 Government of the Republic of Namibia (1993),volume 30 *supra* note 270. pp. 17 & 74

276 See Government of the Republic of Namibia (1993).*Debates of the National Assembly, Seventh Session, First Parliament, 03–25 November 1993 Volume 35*. Windhoek: Government Printers.

(hereinafter referred to as the 1993 Acts) were subsequently promulgated: the Allied Health Services Professions Act 20 of 1993;[277] the Medical and Dental Professions Act 21 of 1993;[278] the Social and Social Auxiliary Workers' Professions Act 22 of 1993;[279] the Pharmacy Professions Act 23 of 1993;[280] the Council for Health and Social Services Professions Act 29 of 1993; and the Nursing Act 30 of 1993.[281]

2.8 Salient provisions of the 1993 Acts

It is imperative whilst discussing the salient provisions of the 1993 Acts to have their long title in mind. It states the following: to provide for the establishment of the professional boards; to determine the powers, duties, and functions of such boards; to regulate the registration and enrolment of the members of the relevant professions; to specify the education, training and qualifications of persons practising such professions; to prohibit the practising of any of such professions without being registered, and to provide for matters incidental thereto.

(a) The Council for Health and Social Services Professions

The Council for Health and Social Services Professions Act[282] established the Council for Health and Social Services Professions, a juristic person[283] with objects to assist in the promotion of health and social welfare of the Namibian population; to act as a coordinating body for the professions in respect of which the professional boards were established; to

277 The Act has repealed the following South African Acts, the Chiropractors Act 6 of 1971; the Homeopaths, Naturopaths, Osteopaths and Herbalist Act 52 of 1974; Health Professions Act 56 of 1974; and Health Services Professions Proclamation AG 70 of 1989.

278 The Act has repealed the Health Professions Act 56 of 1974; and the Health Services Professions Proclamation AG 70 of 1989.

279 The Act has repealed the National Welfare Act 79 of 1965.

280 The Act has repealed the Pharmacy Act 53 of 1974 and Health Services Professions Proclamation AG 70 of 1989.

281 The Act has repealed the Nursing Act 50 of 1978 and Health Services Professions Proclamation AG 70 of 1989.

282 Act 29 of 1993.

283 S 2 of Act 29 of 1993.

promote the standards of tuition and training of and the rendering of professional services by registered healthcare professionals; to assist the professional boards in the performance of their duties and functions; to advise the Minister on matters falling within the scope of its constituting Act or any matter referred to it by the Minister; and to communicate to the Minister any matter of public interest that comes to the attention of the Council in the execution of its duties and functions.[284]

The Council is made up of members appointed by the professional boards and the Minister for a five-year term.[285] The Council serves as the appeal body for matters emanating from the professional boards[286] and it also keeps registers of persons registered by the professional boards.[287] The Council is chaired by a president[288] and administered by a registrar designated by the Minister.[289]

(b) The professional boards

Under the Allied Health Services Professions Act 20 of 1993, ten professional boards were established: Dental Technology Board; Health Inspectors Board; Homeopathic Board; Medical Technology Board; Occupational Therapy Board; Optometric Board; Radiography Board; Physiotherapy Board; Joint Complementary Health Professions Board; and Joint Allied Health Professions Board.[290]

284 S 3 of Act 29 of 1993.
285 S 5 of Act 29 of 1993.
286 S 14 of Act 29 of 1993.
287 S 15 of Act 29 of 1993.
288 S 9 of Act 29 of 1993.
289 S 13 of Act 29 of 1993.
290 S 2 of the Allied Health Services Professions Act 20 of 1993.(Hereinafter referred to as "Act 20 of 1993").

Under the Medical and Dental Professions Act 21 of 1993 two professional boards, the Medical Board, and the Dental Board, were established.[291] Under the Nursing Act 30 of 1993, the Nursing Board was established.[292] The Pharmacy Professions Act 23 of 1993 established the Pharmacy Board.[293] Under the Social and Social Auxiliary Workers' Professions Act 22 of 1993, the Social and Social Auxiliary Workers' Board was established.[294]

The wording of the 1993 Acts is significantly similar in many respects. The Allied Health Services Professions Act 20 of 1993 is used as a reference source for the below discussion regarding the objects, the powers, and other selected provisions of such Acts. The objectives of the professional boards were to assist in the promotion of health and social welfare of the Namibian population; to exercise authority in matters of training and practice of healthcare professions; to promote liaison in the field of training in and out of the country; to advise the Minister on any matter relating to healthcare professions; and to communicate to the Minister any matter of public interest that comes to the attention of the professional boards in the execution of their duties and functions.[295]

Most of the objects of the professional boards significantly resemble the objects of the Council for Health and Social Services Professions. The professional boards, however, had some wider powers: to register health practitioners; to remove and restore the names of health practitioners to the register; to appoint examiners and moderators of examinations; to charge prescribed fees; to grant certificates of registration; to approve educational institutions; to prescribe conditions relating to education and training; to recognise qualifications; and to consider any matter

291 S 2 of Act 20 of 1993.
292 S 2 of Act 20 of 1993.
293 S 2 of Act 20 of 1993.
294 S 2 of Act 20 of 1993.
295 S 3 of Act 20 of 1993.

affecting the professions and make representation or take actions necessary or expedient to achieve the objects of the Act.[296]

Unlike in the case of the members of the Council, who were nominated by professional boards and the Minister, members of the professional boards were elected by their peers to serve for a period of three years.[297] A professional board was chaired by a president and not a chairperson like in the case of the Council.[298] A professional board was empowered to establish a disciplinary committee, education committee and an ad hoc committee whose decisions had no force or effect until confirmed by the professional board.[299]

A professional board was also tasked with a responsibility to inquire into complaints, charge or allegation of improper conduct and to hold professional conduct inquiries into such matters as well as to impose sanctions against those found guilty.[300] A professional board could restrict or suspend from practice any healthcare practitioner who in the opinion of the board and upon the findings of the board was incapable, unfit or incompetent to continue providing healthcare services.[301] The decisions of a professional board can be appealed to the Council.[302]

Unlike the Council, which was administered by a registrar seconded by the Minister, the affairs of a professional board were administered by a secretary who was also a member of the professional board.[303] The 1993 Acts provided for transitional sections until the professional

296 S 4 of Act 20 of 1993.
297 S 5 of Act 20 of 1993.
298 S 8 of Act 20 of 1993.
299 S 10 of Act 20 of 1993.
300 S 28 of Act 20 of 1993.
301 S 36 of Act 20 of 1993.
302 S 49 of Act 20 of 1993.
303 S 8 of Act 20 of 1993.

boards were established and using the Allied Health Services Professions Act as a point of reference, it was stated Section 48 (4) (1) (a) that

> The Minister shall, from time to time, until a board has been established under this Act in respect of any allied health services professions, establish and keep or cause to be established and kept registers in which shall, subject to the provisions of subsection (4). Be entered the name and particulars of every person who –
>
> (i) within a period of three months after the commencement of this Act, or such longer period as the Minister may on good cause shown allow, submits proof to the satisfaction of the Minister that at said commencement such person was resident in Namibia and practising for gain any such profession in Namibia; or
>
> (ii) submits proof to the satisfaction of the Minister that at such commencement such person was resident in Namibia and was studying in Namibia or elsewhere, in order to qualify him or herself for the practising of any such profession; or
>
> (iii) in the case of any other person, submits proof to the satisfaction of Minister that such person is resident in Namibia and intends practising any such professions in Namibia, or in Namibia or elsewhere, is being trained with a view to qualify him or her for practising (sic) of or has been trained and has passed examinations with a view to qualify him or her for practising any of such profession.
>
> (b) ……..
>
> (c) ……

(d) a person registered under this subsection in respect of the profession concerned may practise such profession in Namibia as if a board were established under this Act and he/she was registered with such board.

The significance of this provision is addressed in the next discussion dealing with the immediate challenges experienced during the implementation of the 1993 Acts.

2.9 Challenges arising from the implementation of the 1993 Acts

The 1993 Acts came into force in 1994 and immediately some difficulties were experienced with their implementation.[304] These challenges are outlined below per each Act.

(i) Allied Health Services Professions Act 20 of 1993

In 1994 it was realised that there were some allied health professions that were not made registrable under this Act, particularly those that were never recognised in Namibia before.[305] Those not registrable were: dental technologists, oral hygienists, medical assistants, clinical officers, rural medical aides, medical instructors, general health assistants, and child health officers.[306] There was also an issue of clinical psychologists who felt misplaced under the Allied Health Services Professions Act.[307] Clarity was also needed as to whom was eligible to vote and stand for election in the first election of members of the professional boards established by this Act.[308] The Act only provided the right to vote to those who were registered in terms of the repealed Acts[309] and a new approach was needed to include everybody. It was

304 Government of the Republic of Namibia (1993). *Debates of the National Assembly, Ninth Session, First Parliament, 28–26 July 1994 and 23 August–6 September 1994 Volume 40*. Windhoek: Government Printers. p. 105.
305 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 147.
306 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 147.
307 Government of the Republic of Namibia (1993), volume 40 s*upra* note 304. P. 148.
308 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 147.
309 S 5 (2) of Act 20 of 1993.

therefore necessary that the Minister exercise the functions of the professional boards to register all eligible healthcare professionals falling under this Act.[310] The National Assembly then passed the Allied Health Services Amendment Act 19 of 1994 which seeks to rectify some of these challenges; more specially to allow all persons registered by the Minister to participate in the first election of the members of the professional boards.[311]

(ii) Medical and Dental Professions Act 21 of 1993

With regards to this Act, it was realised that medical interns could not vote at the election of members of the medical board.[312] It was also noticed that dental technicians and oral hygienists, who were made registrable under this Act, should be registered under the allied health services professions boards.[313] The right to vote was also restricted to those who were registered under the repealed Acts.[314] To deal with this challenge, the Minister had to exercise the functions of the professional boards by registering all eligible healthcare professionals falling under this Act.[315] The National Assembly passed the Medical and Dental Professions Amendment Act 16 of 1994 to deal with the challenges identified; more especially to enable all persons registered by the Minister to participate in the first election of the members of the professional boards.[316]

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310 S 48 of Act 20 of 1993.

311 The long title of the Amendment Act indicates that the Act was to provide for the establishment of the joint professional boards in respects of certain allied health professions; to provide for which persons qualify as members of such professional boards and which persons entitled to vote in the election of such members; to provide that only persons registered under the Allied Health Services Professions Act 20 of 1993 were eligible as candidates for election or entitled to vote in the first election of members of the professional boards; and to empower the Minister to temporarily exercise the powers and perform the functions and duties of the professional boards.

312 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p.144.

313 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p.144.

314 S 5 (2) of the Medical and Dental Professions Act 21 of 1993.

315 S 48 of the Medical and Dental Professions Act 21 of 1993.

316 The Amendment Act removed any reference to and repealed the section relating to dental technicians and oral hygienists. It also provided that medical interns were entitled to vote in the election of members of the Medical board and that only medical practitioners registered in terms of the Medical and Dental Professions Act 21 of 1993 were eligible as candidate for election at the first election of members of the medical board. It further provided that only medical practitioners and medical interns registered in terms of the same Act were entitled to vote at the first election of the medical board. With regards to dentistry,

(iii) Nursing Act 30 of 1993

With regard to nursing professions, it was also difficult to determine who qualified to elect or to be elected as a member of the nursing board.[317] This was not only a problem because the Nursing Act provided the right to vote to those who were registered in terms of the repealed legislation,[318] but also because collecting the names, addresses, qualifications of nurses was difficult as the majority of them were still registered in South Africa.[319] Some nurses had also practised in other countries at the time and were still registered in those countries, while others were not registered at all, but authorised by the Minister under the Health Services Professions Proclamation AG 70 of 1989.[320] There was also a need to allow enrolled nurses and nursing assistants to vote for members of the nursing board.[321] The Nursing Profession Amendment Act 21 of 1994 was passed to address these challenges[322] and the Minister had to perform the function of the board with respect to registration of every eligible practitioner.[323] Once the registration process was completed, all registered practitioners could then participate in the election of members of the nursing board.[324]

only dentists registered in terms of the same Act were eligible as candidates for election at or entitled to vote in, the first election of the member of the dental board. See the long title of Medical and Dental Professions Amendment Act 16 of 1994.

317 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 139.

318 S 5 (2) of the Nursing Act 30 of 1993.

319 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 139.

320 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 140.

321 S 5 (2) of the Nursing Act 30 of 1993.

322 The Amendment Act provided for enrolled nurses, enrolled midwives and nursing assistants to vote in the election of members of the nursing board. It further provided that only registered nurses and registered midwives registered in terms of the Nursing Act 30 of 1993 were eligible as candidates for election at the first election of members of the nursing board and only registered nurses, registered midwives, enrolled nurses, enrolled midwives, and nursing assistants registered or enrolled in terms of the same Act were entitled to vote at such first election. See the preamble of the Nursing Act 30 of 1993.

323 S 53 of the Nursing Profession Amendment Act 21 of 1994.

324 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 140.

(iv) Pharmacy Professions Act 23 of 1993

The first challenge was that this Act excluded some pharmaceutical professions, namely, pharmacist's assistants and pharmaceutical technicians.[325] As was the case of the other 1993 Acts, only those who were registered in terms of the repealed legislation could participate in the election of the members of the professional boards.[326] Not every pharmacy practitioner at the time was registered in terms of the existing law.[327] To provide an equal opportunity for everyone, the Minister was compelled to exercise the powers given to him in terms of the Act[328] to register every eligible pharmacy practitioner on behalf of the professional board yet to be established. The Pharmacy Profession Amendment Act 22 of 1994 was promulgated to address the challenges identified and to allow all practitioners registered by the Minister to be able to participate in the first election of professional board members.[329]

(v) Social and Social Auxiliary Workers' Professions Act 22 of 1993

The social and social auxiliary workers' professions had a rather unique situation whereby the National Welfare Act 79 of 1965, which was still applicable in Namibia, provided that no social worker could be employed in the public service unless he/she was registered with the National Welfare Board.[330] On the other hand, the Social and Social Auxiliary Workers' Professions Act 22 of 1993 provided that the Minister may authorise social workers not registered with the professional board of social workers to be employed by the state.[331] These two legislations

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325 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 149

326 S 5 (2) of the Pharmacy Professions Act 23 of 1993.

327 Government of the Republic of Namibia (1993), volume 40 *supra* note 343. p. 149.

328 S 56 of the Pharmacy Professions Act 23 of 1993.

329 In addition to the pharmacists, the Amendment Act made pharmacists' assistants and pharmaceutical technicians entitled to vote in the election of members of the pharmacy board but only pharmacists registered in terms of the Pharmacy Professions Act 23 of 1993 shall be eligible as candidates at the first election of such members. See the long title of the Pharmacy Profession Amendment Act 22 of 1994.

330 S 38 of the National Welfare Act 79 of 1965.

331 S 39 of the Social and Social Auxiliary Workers' Professions Act 22 of 1993.

needed to be harmonised hence the introduction of the National Welfare Amendment Act 20 of 1994.[332]

As in the case of other healthcare professions, the social and social auxiliary workers' professions also had a challenge in determining who had the right to vote for members of the professional board.[333] The Minister had to exercise the functions of the professional board under section 51 of the Act to register all eligible social and social auxiliary workers.[334] Parliament had to step in by passing the Social and Social Auxiliary Workers' Amendment Act 21 of 1994, which clarified the right to vote and enabled all persons registered by the Minister to participate in the first election of the members of the professional boards.[335]

2.10 Term of office of members of the professional boards

The term of office of the members of the professional boards was first set at three years.[336] This was later extended with an additional year with the promulgation of the following Acts: The Allied Health Services Amendment Act 15 of 1998; the Social and Social Auxiliary Workers' Professions Amendment Act 8 of 1998; the Nursing Professions Amendment Act 10 of 1998; the Pharmacy Professions Amendment Act 7 of 1998; and the Medical and Dental Professions Amendment Act 9 of 1998. Later, the General Law (Health Professions) Amendment Act 21 of 2003 was promulgated and amended specific sections of the 1993 Acts with a purpose to

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332 This Act repealed the repealed section 38 of the National Welfare Act 79 of 1965 requiring that only registered social workers may be appointment as professional welfare officers in the public service.

333 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 136.

334 Government of the Republic of Namibia (1993), volume 40 *supra* note 304. p. 136.

335 The Amendment Act provided that only social workers and social auxiliary workers registered in terms of boards as provided in terms of section 51 of the Social and Social Auxiliary Workers' Professions Act 22 of 1993 shall be eligible as candidates for election at, or entitled to vote in, the first election of members of the Social and Social Auxiliary Workers' board and the Minister shall be empowered to temporarily exercise the powers and perform the functions and duties of the professional

336 Ss 3 of the 1993 Acts.

extend the tenure of office of members of the various professional boards for a period of five years.

2.11 Experience with the professional boards

Eighteen professional boards were established in terms of the 1993 Acts to regulate various healthcare professions. Most of these boards since 1995 started operating. The following challenges were experienced in the administration of the 1993 Acts.

- The professional boards consisted only of elected members of the relevant professions, thereby creating the perception that such boards were established to protect the interest of the healthcare professionals as opposed to their function to protect the public.[337]
- The 1993 Acts did not provide for the appointments of board members by the Minister, and therefore for representation on the professional boards of persons who represent the community, the tertiary educational institutions, the legal profession, or Ministry of Health and Social Services. The latter carries the overall responsibility for health in Namibia and is also the largest single employer of healthcare practitioners.[338]
- There were no provisions in the 1993 Acts for an independently employed registrar and secretariat to conduct the administrative business of the professional boards. Secretaries of the boards were elected members of the boards, and full-time healthcare practitioners with the result all regulatory work and board meetings took place after hours. This generally resulted in ineffective functioning of the boards. [339]
- Apart from the medical, dental, pharmacy and nursing boards, many professional boards had no formal administrative structure to properly keep registers and records

337 Amadhila, L. (2003 July 24): Memorandum on approval in principle for the drafting of the professional Bill para: 4.1.
338 Amadhila, L. (2003 July 24), *supra* note 337. para. 4.2
339 Amadhila, L. (2003 July 24), *supra* note 337. para. 4.3

and only some operated in an office with a typist to assist clients. Practitioners and members of the public had no means of contacting the other professional boards during office hours.[340]

- The professional boards established under the 1993 Acts were too many for a comparatively small number of healthcare practitioners in Namibia; this was cumbersome and not cost effective.[341]
- There was a rapid proliferation of allied and complementary health professions demanding the establishment of new professional boards and this indicated a need for a more streamlined statutory structure to improve regulatory efficiency.[342]
- The Council of Health and Social Services Professions had no executive powers; its function was merely to advise the Minister on matter pertaining to the various categories of health practitioners. It was also a coordinating and appeal body for professional boards.[343]
- Although the 1993 Acts provided for transitional clauses, most outdated South African regulations made under the repealed Acts were only applicable to Namibia if they were made before December 1979. This caused a lot of confusion and delay in decision-making: for example, regarding registrations and determining the scope of practice for healthcare practitioners.[344]
- Due to lack of experience, a proper administrative system and process, most professional boards were unable to set standards for professional practice, control

340 Mafwila, C. K. (2017). *Evaluation of the corporate governance practices and performance of the Health Professions Councils of Namibia* (unpublished MBA thesis, International University of Management). p. 5.

341 Amathila, L. (2003 July 24), *supra* note 337. para. 4.4.

342 Amathila, L. (2003 July 24), *supra* note 337. para. 3.

343 Amathila, L. (2003 July 24), *supra* note 337. para 3.

344 HPCNA. (2016). "Explanatory Memorandum of the statutory arrangement of health professions in Namibia: past, present and future". Windhoek: Health Professions Councils of Namibia. p. 4.

mechanisms over education and training, and investigate complaints of unprofessional conduct.[345]

- The Minister was inundated with questions and complaints regarding the inability of some professional boards to deal with applications for registration.[346]

The Minister at the time was of the view that many professional boards were unable to deliver on their mandates. Hence, on 15 November 1996, the Minister requested the Council for Health and Social Services Professions to revisit the legal framework governing the professional boards and propose a new structure aimed at doing away with the fragmentation of such boards.[347] The Minister particularly expressed her concern regarding the large number of professional boards serving the health professions for a relatively small population and that an amalgamated structure would serve the purpose better.[348]

2.12 Promulgation of the 2004 Acts

In January 1997 the Minister appointed a task group to investigate the possibility of restructuring of certain professional boards. This group was assisted by Dr M Adibo, a consultant from the WHO.[349] The group consulted extensively and eventually proposed for the repeal of the 1993 Acts, the amalgamation of the eighteen professional boards into five councils under the new Acts; these proposals met the Minister's approval in principle.[350]

The following draft Bills were then put together and submitted to cabinet on 24 July 2003.[351]

345 HPCNA. (2016), *supra* note 344. p. 4.
346 Mafwila, C. K. (2017), *supra* note 340. p. 6.
347 Mafwila, C. K. (2017), *supra* note 340. p. 5.
348 HPCNA. (2016), *supra* note 344. p. 5.
349 HPCNA. (2016), *supra* note 344. p. 5.
350 Mafwila, C. K. (2017), *supra* note 339.
351 Amathila, L. (2003 July 24), *supra* note 337. para. 1.

- The Medical and Dental Professions Bill of 2003[352]
- The Pharmacy Professions Bill of 2003[353]
- The Nursing Professions Bill of 2003.[354]
- The Allied Health Professions Bill of 2003.[355]
- The Social Work and Psychology Professions Bill of 2003.[356]
- Council for Health and Social Services Profession Repeal Bill of 2003.[357]

Informed by the respective challenges experienced by the professional boards and the directive of the Minister, these Bills were passed into law in July 2004[358] introducing the following notable changes.[359]

- The Council for Health and Social Services Profession and eighteen professional boards established in terms of the 1993 Acts disappeared and five Councils were created.[360]

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352 This bill provides for the establishment and constitution of a professional Council for the medical and dental professions, to determine the powers, duties and functions of such Council, to regulate the registration of persons practising medicine and dentistry, to specify the education and training and qualifications of medical and dental practitioners and to prohibit the practising of medicine and dentistry without being registered.

353 The bill provides for the establishment and constitution of a professional Council for pharmacy practitioners to determine the powers, duties, and functions of the Pharmacy Council, to regulate the registration of persons practising Pharmacy, to specify the education and training and qualifications of pharmacy practitioners and to prohibit the practising pharmacy without registration.

354 This bill seeks to establish a professional regulatory authority for nursing, midwifery and accoucheury professions, to determine the powers, duties, and functions of such an authority, to regulate the registration of persons practising nursing, midwifery and accoucheury, to specify the education and training and qualifications of these professions and to prohibit the practising such professions in the absence of registration.

355 The bill provides for the creation of a professional Council for allied health care professions, to determine the powers and functions of such a Council, to regulate the registration of persons practising the allied health care professions, to specify the education and qualifications for allied health care practitioners and to limit the practising of such professions without being registered.

356 The constitution of the Council to be known as the Social Work and Psychology Council was provided for in this bill. The duties and functions of this authority were also determined.

357 This bill aimed at repealing the Council for Health and Social Services Professions Act No 29 of 1993 and to provide for the transfer of moneys standing to that Council's credit.

358 Social Work and Psychology Act, 6 of 2004; Allied Health Professions Act, 7 of 2004; Nursing Act, 8 of 2004; Pharmacy Act, 9 of 2004; and Medical and Dental Act, 10 of 2004, (Hereinafter referred to as "the 2004 Acts").

359 The wordings of the 2004 Acts are similar and for discussion of the changes introduced by these Acts reference is conveniently made to the Allied Health Professions Act, 7 of 2004 (Hereinafter referred to as "Act 7 of 2004").

360 Amathila, L. (2003 July 24), *supra* note 337. para. 5.1.

- In respect of the allied health and complementary health professions, professional committees were established under the Allied Health Professions Council and the members of these committees were to be elected by members of the related professions.[361]
- The medical assistants and clinical officers' board established in terms of the Allied Health Services Professions Act 20 of 1993 was removed and, together with that of the ophthalmic assistants, these professions can now register under the Medical and Dental Council. These professionals have the rights to elect medical and dental practitioners as Council members.[362]
- Compared to the 1993 Acts, where the professional boards consisted of elected members of the professions only, the 2004 Acts provided for members of the Councils to be appointed by the Minister from amongst professionals employed by the Ministry of Health and Social Services, professionals designated by tertiary educational institutions, members of the public appointed by the Minister, as well as including a legal practitioner. Related professionals were still to be elected by their peers to serve on the Councils.[363]
- The disciplinary committees established under the 1993 Acts were replaced by professional conduct committees.[364]
- Having the Council for Health and Social Services Profession abolished as an appeal body, an appeal committee was established.[365]

361 S 13 of Act, 7 of 2004.
362 S 17 of the Medical and Dental Act, 10 of 2004.
363 S 7 of Act 7 of 2004.
364 S 12 (2) of Act 7 of 2004.
365 S 52 of Act 7 of 2004.

- More categories of allied and complementary health professionals were introduced,[366] and the Minister has the power to declare more such professions as registrable from time to time.[367]
- The requirements and the procedures relating to registration with the Council were more clearly defined; provisions for evaluation by the Council of persons who apply for registration were included.[368]
- The 2004 Acts also provide for the inspection of the practices of registered person by the Councils.[369]
- The 2004 Acts also provide for the investigation and assessment of impaired registered persons, and for continuing professional development.[370]
- The social work and psychology professions were grouped together to fall under one Council.[371]
- A pharmacy practice may also be owned by a close corporation, and not only by a pharmacist or by a company. Like in case of a company, a close corporation must comply with certain requirements set out in the Pharmacy Act.[372]
- The powers of the professional boards to set tariff of fees in the 1993 Acts have been removed.[373]
- The 2004 Acts made provisions for the Councils to appoint jointly a registrar, assistant registrar, and staff to execute the business of the Councils. For this to happen, a provision was made for the appointment of a joint council committee. The Councils have to enter into a written agreement to provide for the efficient joint conducting of

366 S 18 of Act 7 of 2004.
367 Ss 60 of Act 7 of 2004.
368 Ss 19 & 21 of Act 7 of 2004.
369 S 51 of Act 7 of 2004.
370 Ss 33 & 47 of Act 7 of 2004.
371 S 17 of the Social Work and Psychology Act, 6 of 2004.
372 S 36 of the Pharmacy Act, 9 of 2004.
373 Amathila, L. (2003 July 24), *supra* note 337. para. 5.12.

the office of the Registrar.[374] This was built into the system to ensure proper coordination and cost-effective use of resources and standards that should lead to excellence.[375]

- Members of the joint secretarial are remunerated from the funds of the Councils.[376] In addition, the Minister may, in consultation with the minister of finance, and subject to such conditions as the Minister may determine, grant to the Councils out of the moneys appropriated by Parliament such financial assistance, as he/she may deem necessary.[377]
- Provision was made for the appointment of an Interim Council with members appointed by the Minister.[378]
- The term of office for Council members was fixed at five years, but members are eligible for re-appointment, re-election or re-designation.[379]

The 2004 consolidated 82 identified health, allied and complementary health professions in five Councils, as opposed to eighteen professional boards.[380] These Councils became the professional authority structure of these professions, and are tasked to perform their duties in an accountable fashion that effectively protects the public interest.[381]

2.13 Establishment of the Interim Councils

The 2004 Acts provided for the Minister to establish by notice in the Gazette, an Interim Council.[382] The Interim Council may exercise the powers and perform duties and functions of the Council and to act for or on behalf of the Council and in its name, place and stead, as if it

374 S 15 of Act 7 of 2004.
375 HPCNA. (2016). *supra* note 344. p. 6.
376 S 15 (4) of Act 7 of 2004.
377 S 14 (2) of Act 7 of 2004.
378 S 59 of Act 7 of 2004.
379 S 7 (12) of Act 7 of 2004.
380 Amathila, L. (2003 July 24), *supra* note 336. para. 7.
381 Amathila, L. (2003 July 24), *supra* note 336. para. 7.
382 S 59 of Act 7 of 2004.

were the Council until such time the Council has been constituted.[383] Accordingly, the Minister established four Interim Councils on 4 October 2004 to act for and on behalf of the Councils until such Councils were duly constituted.[384] The first important tasks of the Interim Councils were to take over all the registers from the former professional boards, to set up administrative structures and processes, to compile guidelines for assessing applicants for registration, and drafting of new regulations to create legal parameters for professional conduct, education and practice.[385] All the members of an Interim Council were appointed by the Minister.[386] The Interim Councils were in place until the establishment of the substantive Councils.

2.14 Establishment of the Councils

Finalising the registers of practitioners to prepare for the voters' roll took long as there were no electronic registers at that time.[387] Elections were conducted strictly according to the requirements of the election regulations.[388] For unknown reasons, the nominations received by some of the professions were extremely disappointing forcing the Minister to step in and appoint additional members of the Council in order to comply with the number to establish a

383 S 59 (6) of Act 7 of 2004.

384 Government *Gazette* of the Republic of Namibia No. 3293 of 04 October 2004. These Councils were the Interim Allied Health Professions Council; the Interim Social Work and Psychology Council; the Interim Pharmacy Council; the Interim Medical and Dental Council; and the Interim Nursing Council.

385 HPCNA.(2013), *supra* note 256. p. 7.

386 Section 63 of the Nursing Act, 8 of 2004 for example, provides that the Minister may appoint as members of the Interim Nursing Council, the Head of Nursing Services in the Ministry of Health who must be registered as a nurse and as a midwife or an accoucheur; not less than one person who is registered as a nurse and as a midwife or an accoucheur and who has experience in primary health care matter; one legal practitioner having not less than ten year experience in the practising of law; and not less than one person who is not a registered person. The Head of the Nursing Department of the University of Namibia is an *ex officio* member of the Council.

387 HPCNA. (2013), s*upra* note 256. p. 7.

388 The regulations relating to the first election of members of the Social Work and Psychology Council are contained in GN 142/2006 (GG 3694) and GN 26/2007 (GG 3795). The regulations relating to the first election of members of the Nursing Council are contained in GN 145/2006 (GG 3694), GN 23/2007 (GG 3795) and GN 171/2007 (GG 3861).The regulations relating to the first election of members of the Allied Health Professions Council are contained in GN 143/2006 (GG 3694), GN 27/2007 (GG 3795) and GN 172/2007 (GG 3861). The regulations relating to the first election of members of the Medical and Dental Council are contained in GN 142/2006 (GG 3694) and GN 25/2007 (GG 3795).The regulations relating to the first election of members of the Pharmacy Council are contained in GN 144/2006 (GG 3693) , GN 24/2007 (GG 3795) and GN 170/2007 (GG 3861).

Council.[389] The five Councils were established on 26 September 2007 and their members were published in the Government Gazette on 10 March 2008.[390]

Experience gained during the Interim Councils served as a roadmap to take the new Councils forward.[391] The composition of members who served on the Councils was approximately 50% more than those who served on the Interim Councils.[392] These Councils managed to put in place strategic planning systems; complete electronic registers of all practitioners, students, interns, accredited educational institutions and training facilities; establish a joint legal department to deal with all offences reported to the Councils by institutions and public members for investigation; and a joint administrative structure providing for policies and guidelines in finance and human resources.[393] The term of office of these Councils was extended eight times;[394] firstly because the election regulations were not in place when the term of office of members of the Councils came to an end, and secondly because holding elections

389 This was the case with respect to the Medical and Dental Council and the Social Work and Psychology Council for which not enough candidates were nominated to stand for elections and the few nominees were regarded as dully elected.

390 The first Medical and Dental Council was announced in GN 59 /2008 (GG 4008); the first Nursing Council was announced in GN 60/2008 (GG 4008); the first Allied Health Professions Council was announced in GN 61/2008 (GG 4008); the first Social Work and Psychology Council was announced in GN 62/2008 (GG 4008); and the first Pharmacy Council was announced in GN 270/2008 (GG 4166).

391 HPCNA. (2013), s*upra* note 256. p. 7.

392 HPCNA. (2013), s*upra* note 256. p. 7.

393 HPCNA. (2013), s*upra* note 256. p. 7.

394 The term of certain members of the Social Work and Psychology Council were extended by GN 223/2012 (GG 5023), GN 68/2013 (GG 5060), GN 255/2013 (GG5303), GN 31/2014 (GG 5425), GN 150/2014 (GG 5559), GN 193/ 2015 (GG 5818), GN 220/2016 (GG 6125) and GN 59/2017 (GG 6263).The term of certain members of the Nursing Council were extended by GN 221/2012 (GG 5023), GN 71/2013 (GG 5060), GN 259 /2013 (GG5303), GN 30/2014 (GG 5425), GN 15/2014 (GG 5559), GN 191/ 2015 (GG 5818), GN 222/2016 (GG 6125) and GN 57/2017 (GG 6263).The term of certain members of the Allied Health Professions Council were extended by GN 224/2012 (GG 5023), GN 69/2013 (GG 5060), GN 258/2013 (GG5303), GN 32/2014 (GG 5425), GN 154/2014 (GG 5559) , GN 192/ 2015 (GG 5818), GN 221/ 2016 (GG 6125) and GN 60 /2017 (GG 6263).The term of certain members of the Pharmacy Council were extended by GN 224/2012 (GG 5023), GN 69/2013 (GG 5060), GN 258/2013 (GG5303), GN 28/2014 (GG 5425), GN 153/2014 (GG 5559) , GN 190/ 2015 (GG 5818), GN 223/ 2016 (GG 6125) and GN 56 /2017 (GG 6263).The term of certain members of the Medical and Dental Council were extended by GN 222/2012 (GG 5023), GN 70/2013 (GG 5060), GN 258/2013 (GG5303), GN 29/2014 (GG 5425), GN 151/2014 (GG 5559) , GN 189/ 2015 (GG 5818), GN 224/ 2016 (GG 6125) and GN 58 /2017 (GG 6263).

every five years was found to be expensive.[395] This led to the amendments of the 2004 Acts to enable the Minister to appoint all the members of the Councils as opposed to holding of elections.[396] It is however important to note that when the extended term of the previous members of the Councils ended on 31 March 2018, the Amendment Acts had not yet been passed by Parliament resulting into a vacuum for a period of six months until the current Councils took office on 04 October 2018.[397]

2.15 The Health Professions Bill

Like with the former professional boards established by the 1993 Acts, lessons learnt during the former phases of administering the Councils in terms of the 2004 Acts served as motivation to streamline the functioning of the Councils.[398] It remains a challenge to administer these five juristic bodies with each governed by its separate legislation while sharing the secretariat and funding from treasury.[399] Some of these Councils are financially sound as they have many healthcare practitioners on the register, while others with fewer practitioners on the register are unable to finance their operations, meaningfully contribute to the acquisition of joint assets and to the operational cost of the joint secretariat. Such Councils, more than others, are heavily dependent on the annual government grant.[400]

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395 HPCNA.(2017). *Briefing Notes on the Drafting of the Health Professions Bill*. Windhoek: Health Professions Councils of Namibia. p. 2.

396 See the Allied Health Professions Amendment Act 8 of 2018; the Medical and Dental Amendment Act 9 of 2018; the Nursing Amendment Act 10 of 2018; the Pharmacy Amendment Act 11 of 2018; and the Social Work and Psychology Amendment Act 12 of 2018.

397 The appointment of the current members of the Nursing Council was announced in GN 299/2018 (GG 6770),the appointment of the current members of the Social Work and Psychology Council was announced in GN 298/2018 (GG 6770),the appointment of the current members of the Allied Health Professions Council was announced in GN 301/2018 (GG 6770),the appointment of the current members of the Pharmacy Council was announced in GN 300 /2018 (GG 6770), and the appointment of the current members of the Medical and Dental Council was announced in GN 297/2018 (GG 6770).

398 HPCNA. (2013), s*upra* note 256. p. 8.

399 HPCNA. (2016), s*upra* note 344. p. 9.

400 HPCNA. (2013), s*upra* note 256. p. 7.

To address some of these challenges, in October 2013 the then Minister of Health Dr Richard N Kamwi directed the Councils to explore a new legal framework aimed at creating a unitary regulatory authority under a single Act while retaining the powers of self-regulating in the hands of health professionals.[401] Consultations were carried out in 2014 and the model of having one statutory authority under one legislation was found ideal.[402] The first draft Health Professions Council of Namibia Bill (hereinafter referred to as the Bill) was produced in 2016 and it proposed the establishment of one statutory body to be known as the Health Professions Council of Namibia and on which all regulatory powers and function will be vested.[403] Its powers and functions will however be executed through the assistance of professional boards under the Council.[404]

It has been proposed that the current five Councils are to be turned into five professional boards, and with the powers to the Minister to create more professional boards from time to time should it be necessary.[405] The draft Bill also proposes a licensing regime of health practitioners in addition to the current registration.[406] The Council is also empowered to suspend the license when the fitness to practice of a practitioner is in question.[407] The other innovation proposed in the Bill is the introduction of a public service category of registration aimed at making scarce skills to the underserved rural areas of the country.[408] Proposals also aimed at fast tracking the investigation of complaints relating to unprofessional conduct[409] and at least to engage the

401 HPCNA. (2016), *supra* note 344. p. 9.
402 HPCNA. (2013), s*upra* note 256. p. 3.
403 Clause 3 of the Bill indicates "there is established a juristic person to be known as the Health Professions Council of Namibia". See also clause 4 of the Bill on the powers and functions of the Council.
404 Clause 84 of the Bill provides that the Council may delegate some of its powers and functions to a board.
405 Clause 13 of the Bill establishes the Allied Health Professions Board, the Medical and Dental Board, the Nursing Board, the Pharmacy Board and the Social Work and Psychology Board. The Minister may also abolish, amend the constitution of a professional board, or establish one or more professional boards.
406 Clause 43 of the Bill.
407 Clause 45 of the Bill.
408 Clause 41 of the Bill.
409 Clause 63 of the Bill provides that if a registered person is served with a notice of inquiry, the registered person may submit to the Council a written admission of guilt to the charge of unprofessional conduct specified in the notice. The admission of guilt must set out in full the facts supporting the charge of

complainants in cases where a disciplinary action against a registered person is unwarranted.[410] The Council will be empowered to suspend a license of a registered person in respect of whom a complaint of unprofessional conduct is made, or, the Council on its own accord to instruct the preliminary investigation committee to investigate, pending the outcome of the investigation.[411] Failure to comply with continuing professional development (CPD) may be the reason for suspension or cancellation of a practice license and removal of a name of a registered person from the register.[412]

This Bill was approved in principle by Cabinet on 5 April 2016,[413] then by the CCL on 19 May 2016,[414] and certified by the Attorney-General in 2017. The Bill was submitted to Parliament for tabling but had to be withdrawn[415] because some stakeholders raised concerns about its contents and wanted to suggest more changes before tabling.[416] Further consultations on the contents of the Bill were held,[417] and in September 2021 the latest version of the Bill was

unprofessional conduct that the registered person admits of being guilty and may include arguments in mitigation of penalty. The Council may accept, on good cause shown, an admission of guilt.

410 Clause 61 of the Bill provides that if the Council finds a registered person not guilty of unprofessional conduct and the person who lodged the complaint with the Council resulting in the investigation so request, the Registrar in concurrence with the Council may appoint a registered person of not less than ten years experienced person in his or her profession and who may not be a member of the Council or professional board, to explain to the complainant the grounds for the findings of the Council and to reply to the best of his or her ability to any questions by the complainant relating to the matter.

411 See clause 59 of the Bill. There is no doubt this provision can only be invoked in cases where continued practice by a registered person while the investigation is being carried out against him or her will endanger the safety of patients or that of the practitioner him or herself.

412 See Clauses 45 & 49 of the Bill.

413 Cabinet Decision No. 5th / 05.04.16/013.

414 Minutes of the meeting of the CCL (19 May 2016). Ministry of Justice of the Republic of Namibia.

415 The request for the withdrawal of the Bill from Parliament was made by the Minister of Health in a letter to the Speaker in August 2018.

416 The most extensive comments on the Bill were submitted to the Minister of Health by the Pharmaceutical Society of Namibia on 29 October 2018.

417 Minutes of the consultative meeting held at the Ministry of Health Headquarters in Windhoek on 25 June 2018 indicates that 42 healthcare professionals attended the meeting. The following professional bodies were represented: Psychology Association of Namibia, Namibia Dental Association, Namibia Emergency Care Practitioners Association, Namibia Speech, Language and Hearing Association, Namibia Nurses Union, Namibia Association of Medical Laboratory Science, Dental Therapy Association, Dental Technology Association of Namibia, Medical Association of Namibia, Namibia Optometrist Association. Pharmaceutical Association of Namibia, Namibia Nursing Association, Independent Midwives Association of Namibia, Namibia Society of Physiotherapist, Biokinetics Association of Namibia, Dietetic Association, and Namibia Association of Occupational Therapists.

recommended by the Minister to the Attorney-General for certification before tabling in Parliament hopefully during its first session in 2022.

2.16 Assessment of the transformation of health professions regulation in Namibia

The development of health professions regulation in South Africa laid a foundation for the Namibian regulatory framework for healthcare professions and, at independence in 1990, the country had inherited the South African health-related laws as made applicable to the then SWA.[418] For a few years after independence, healthcare professions in Namibia continued to be controlled by relevant regulatory bodies in South Africa. This situation was found to be unacceptable both politically and administratively. A desire for a home-grown dispensation immediately kick-started the development of healthcare professions regulation in Namibia which culminated into the promulgation of the 1993 Acts.[419] The overall aim of the 1993 Acts, as indicated by Parliament during the debate, was to protect the public against medical malpractice.[420] This pronouncement by Parliament clearly reflects public protection as justification for professional regulation[421] Furthermore, the 1993 Acts empowered the regulatory authorities to set professional standards for education, training and practice, recognise professional qualifications, register healthcare practitioners, inquire into complaints, charge or allegation of improper conduct and to impose sanctions against those found guilty.[422] This approach mirrors the features of the professional self-regulation model, namely, the sharing of the ethos and standard of professional behaviour, the transmission of ethical standards for education and practice to members of the profession and the control over

418 Para. 4.4.
419 Para. 4.7.
420 Para. 4.4.
421 Para. 2.2.
422 Para. 4.8.

behaviour and conduct of healthcare practitioners who are found incapable of providing safe patient care.[423]

However, the legal framework introduced by the 1993 Acts was highly fragmented and excluded some healthcare professions that ought to be regulated.[424] Furthermore, members of the regulatory authorities were all healthcare professionals creating suspicions that such bodies were established to protect the interest of healthcare practitioners as opposed to public protection. The regulatory framework did not create an effective administrative structure and subsequently the mandate of the regulatory bodies were poorly executed.[425] These shortcomings led to the enactment of the 2004 Acts, which are still in force in Namibia, and are evaluated in chapter four.[426]

2.17 Summary

In this chapter the historical background of health professions regulation in Namibia was traced. The focus was on how the legal framework has changed overtime and the governance structures it has created. Factors that informed the past legislative reforms were discussed. Justification of the current arrangement was also covered. Medical malpractice incidents and claims in Namibia are analysed in the next chapter.

423 Para. 1.7.
424 Para. 4.9.
425 Para. 4.9.
426 Para. 4.12.

CHAPTER THREE

MEDICAL MALPRACTICE INCIDENTS AND CLAIMS IN NAMIBIA

3.1 Introduction

Patients become psychologically vulnerable when diagnosed with an ailment and have to undergo treatment.[427] The reality of facing an illness may result in severe anxiety or post-traumatic symptoms.[428] This is the case even when a proper diagnosis has been made and the results of the treatment plan are predictable.[429] The emotional distress becomes more intense when all does not go well.[430] Patients may also suffer physical injuries that may affect their daily activities, social life, and family relationship.[431] Some physical injuries may result in permanent harm with long term emotional effects.[432] The severity of both physical and emotional injuries may be exacerbated by the way in which an adverse event is subsequently managed.[433] If no proper clarification on what happened is given to a patient, this may distress a patient even further.[434] Some adverse events result in additional surgeries, prolonged hospitalisation, chronic pain, physical disfigurement, huge hospital bills and depression.[435]

The effects of an adverse event are not limited to an injured patient as their family also is likely to suffer financially and emotionally especially if the injured person was a breadwinner or a dependent.[436] Family and friends may equally endure severe emotional pain and long-term

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427 Carstens, P., & Pearmain, D. (2007), *supra* note 6. p. 489.

428 Tedstone, J..E., & Tarrier, N. (2003).“Post -traumatic stress disorder following medical illness and treatment. *Clinical Psychology Review*, 23 (3): 4009 - 448. p. 409.

429 Vincent, C. (2003) “Understanding and responding to adverse events” *New England J of Medicine* 1054.

430 Gallagher, T.H., Waterman, A.D., Ebers, A.G., Fraser, V.J., & Levinson, W. (2003)“Patients’ physicians’ attitudes regarding the disclosure of medical errors” *JAMA* 1005.

431 Vincent, C., Phillips, A., & Young, M. (1994) “Why do people sue doctors? A study of patients and relatives taking legal action” *Lancet*. 1609.

432 Vincent, C. (2003), *supra* note 429. p. 1054.

433 Vincent, C. (2003), *supra* note 429. p. 1054.

434 Gallagher, T.H., *et al* (2003), *supra* note 430. p. 1005.

435 Vincent, C.(2003), *supra* note 429. p. 1054.

436 Vincent, C. (2003), *supra* note 429. p. 1054.

sadness in the case of a patient's subsequent demise.[437] Incidences of adverse events normally cast doubts on the competency of healthcare practitioners to provide care and safety to patients.

The legal consequences of medical negligence may be a civil action in which damages could be claimed for negligent or intentional wrongs. Such an action underlines a connection between medical malpractice claims and the adverse events due to medical negligence.[438] The focus of chapter is on medical malpractice complaints against healthcare practitioners that were reported by members of the public to the regulatory bodies in Namibia as well as the data on medical malpractice claims against the State in Namibia between 2014 and 2019.

3.2 Disciplinary action and onus of proof

The legal consequences of medical negligence may be: a civil action in which damages could be claimed for negligent or intentional wrongs; a criminal prosecution in cases where there is gross misconduct causing intentional harm or delict; or a disciplinary action by the professional regulator.[439] Once reported to the regulator, patient complaints are investigated to establish whether an injury to the patient was caused by an act or omission on the part of a healthcare professional which may warrant a disciplinary inquiry before a disciplinary committee of the regulator, on account of unprofessional conduct, which can include acts and omissions regarded as medical negligence.[440] The objective of a disciplinary inquiry differs from that of a civil claim, in that the focus is not on compensation for damages suffered by the patient, but rather on upholding the standards of the profession and protecting the interest of the public.[441]

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437 Vincent, C., & Coulter, A. (2002). 'Patient safety: what about the patient" *Quality and Safety in Healthcare 78*.

438 Oosthuizen, W. T., & Carstens, P. A. (2015A). "Medical Malpractice: The extent, consequences and causes of the problem". *THRHR.* 2015 (78), 270: 269- 284. p. 283.

439 Patel, B. (2008)."Medical negligence and *res ipsa loquitur* in South Africa". *SAJBA.* Vol 1.(2), 57: 57-60.

440 Carstens, P., & Pearmain, D. (2007), *supra* note 6. p. 855.

441 Oosthuizen, W. T., & Carstens, P. A. (2015A), *supra* note 438.

It is the accepted principles of our law that the onus of proof of civil liability on the part of a health practitioner rests with the patient and is based on a preponderance of probabilities. In criminal matters, the burden of proof rests with the State, and the guilt of the health practitioner must be proven beyond reasonable doubt.[442] In disciplinary proceedings before a disciplinary committee of the regulator, the pro forma complainant must prove the charges of unprofessional conduct against the healthcare practitioner on a preponderance of probabilities.[443]

3.3 Medical malpractice complaints in 2014/15[444]

During the 2014/2015 financial year, the five Councils received a combined number of 48 complaints from the public against registered healthcare practitioners. These cases (n=48) are broken down per Council as follows. Medical and Dental Council: n=25; Nursing Council: n=8; Social Work and Psychology: n=7; Allied Health Professions Council: n=4; and the Pharmacy Council: n=4.[445]

The nature of complaints against medical practitioners involves negligence and unprofessional conduct.[446] Poor general nursing care of patients accounted for 50% of the complaints reported against nurses and midwives: 38% of such complaints related to the mishandling of newborn babies or lack of care resulting in still births, and 12% related to theft.[447]

Compared to the 2013/ 2014 financial year, complaints received against medical and dental practitioners in 2014/2015 were 5% less; complaints against nurses and midwives were 6% less, and complaints against social workers and psychologists were 10% more compared to the

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442 Claassen, N. J. B. & Verschoor, T. (1992). *Medical Negligence in South Africa*. Pretoria: DIGMA. p. 615.

443 Carstens, P., Pearmain, D. & (2007), *supra* note 6. p. 856.

444 The financial year of each Council runs from the 01 April to the 31 March the following year. See, for example s 13 (7) of the Medical and Dental Act, 2004 which states that " the financial year of the Council ends on the last day of March in each year."

445 HPCNA Annual Report 2014/15 (2015) p. 19.

446 HPCNA Annual Report 2014/15 (2015) p. 20.

447 HPCNA Annual Report 2014/15 (2015) pp. 20-21.

previous year.[448] The Medical and Dental Council received the highest number of complains during the 2014/2015 financial year, and the Pharmacy Council and the Allied Health Professions Council received less complaints compared to other Councils. These complaints mainly related to conducting business without registration and practising outside the scope of practice.[449] These cases are reflected in Figure 1 below.

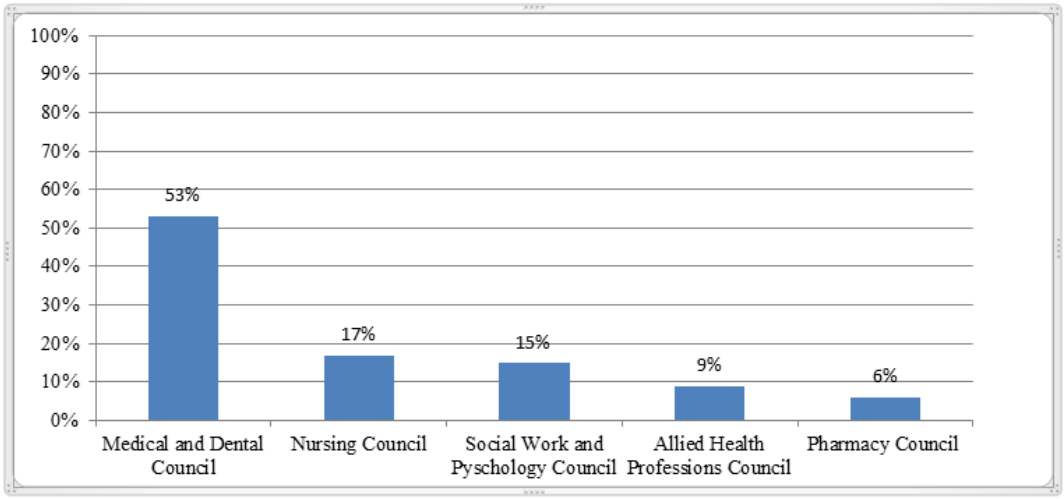


Figure 1: Cases reported per Council during 2014/2015. *Source: HPCNA Annual Report 2014/2015.*

During the 2014/ 2015 financial year the preliminary investigation committee (PIC) of the Medical and Dental Council investigated 84 (n=84) cases against medical practitioners, and out of these cases 18 cases were recommended to the Council for closing as there were no evidence of professional misconduct against the 18 practitioners. Thirty-four (n=34) cases were recommended to the Council for professional conduct inquiry as there was sufficient evidence

448 According to HPCNA 2013/14 Annual Report the complaints received per Council were, Medical and Dental Council received = 37, Nursing Council =15, Social Work and Psychology = 3, Allied Health Professions Council = 3, and Pharmacy Council = 6.

449 HPCNA Annual Report 2014/15 (2015). p. 21.

of professional misconduct. The remainder (n=32) needed to be investigated further by the end of the 2014/2015 financial year. Only five (n=5) cases against dentists were investigated during the same period.[450]

During the same period, the PIC of the Nursing Council investigated 52 (n=52) cases. In view of insufficient evidence of professional misconduct 14 (n=14) cases were recommended to the Council for closing. Four cases (n=4) were recommended to the Council for professional conduct inquiry, and the remainder (n= 34) were still under investigation.[451]

With regard to the Allied Health Professions Council, its PIC investigated eight (n=8) cases. Three (n=3) cases were recommended to the Council for closing due to lack of evidence of professional misconduct against the practitioners. Four (n=4) cases were recommended to the Council for professional conduct inquiries, and one (n=1) case was still under investigation by the end of the financial year.[452]

For the Social Work and Psychology Council, seven (n=7) cases were investigated by its PIC during the 2014/15 financial year. By the end of that period one (n=1) case was recommended for closing due to lack of evidence of professional misconduct against the practitioner; one (n=1) case was recommended to the Council for professional conduct inquiry because there was evidence of professional misconduct against the practitioner; and the remainder (n=5) needed to be investigated further.[453]

The Pharmacy Council dealt with 21 (n=21) cases over the same period. Out of these four (n=4) cases were closed due to lack of evidence of professional misconduct against the respective practitioners; two (n=2) cases were recommended to the Council for professional conduct

450 HPCNA Annual Report 2014/15 (2015). p. 22.
451 HPCNA Annual Report 2014/15 (2015). p. 22.
452 HPCNA Annual Report 2014/15 (2015). p. 22.
453 HPCNA Annual Report 2014/15 (2015). p. 23.

inquiry as there were there were evidence of professional misconduct against the two practitioners; and the remainder (n=15) needed to be investigated further.[454]

Challenges facing the management of fitness to practice complaints included the reluctance of healthcare practitioners under investigation to respond to the respective Councils' request for information, lack of local medical experts who were willing to assist the Councils in providing expert opinions,[455] delays in releasing medical records from the hospitals and health facilities, especially those owned by the State, and lack of financial resources for professional conduct inquiries.[456]

3.4 Medical malpractice complaints in 2015/16

During the 2015/2016 financial year, the five Councils received a combined number of 46 (n=46) new complaints from the public against registered healthcare practitioners. These cases are broken down per Council as follows. Medical and Dental Council: n=31; Nursing Council: n=5; Social Work and Psychology Council: n=1; Allied Health Professions Council: n=6; and the Pharmacy Council: n=3.[457]

Compared to the 2014/ 2015 reported cases, the Medical and Dental Council in 2016/2017 received 14% more complaints against medical practitioners. The nature of these complaints involved negligence, unprofessional conduct, and inappropriate billing. The Nursing Council received 15% less complaints compared to the previous year. A total of 50% of cases against nurses and midwives related to general nursing care, and the other 50% related to lack of care resulting in still births. The Social Worker and Psychology Council received 15% more complaints compared to the previous year; and the Allied Health Professions Council received

454 HPCNA Annual Report 2014/15 (2015). p. 23.

455 As a result, Councils rely on South African health professionals for expert opinion which on average takes about three months to obtain and subsequently delaying the finalisation of cases. See HPCNA Annual Report 2014/15 (2015). p. 26.

456 HPCNA Annual Report 2014/15 (2015). p 24.

457 HPCNA Annual Report 2015/16. P. 13.

4% more complaints compared to the previous year. It is worth noting that an increase in the number of complaints registered by the Allied Health Professions Council was against emergency care practitioners. There was no change with regards to the number of complaints received by the Pharmacy Council in comparison with the previous year.[458] The cases reported to the Councils during 2015/2016 are reflected in Figure 2 below.

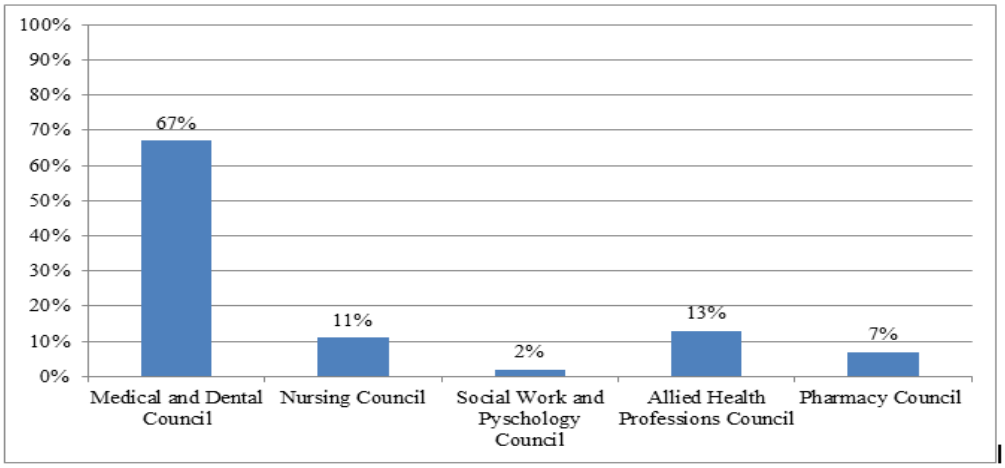


Figure 2: Cases reported per Council during 2015/2016. *Source: HPCNA Annual Report 2015/16.*

During the 2015/16 financial year, the PIC of the Medical and Dental Council investigated 53 (n=53) cases against medical practitioners, and 11 (n=11) of these cases were recommended to the Council for closing as there was no evidence of professional misconduct against the respective practitioners. Seven (n=7) cases were recommended for professional conduct inquiry; and the balance (n=35) cases were to be investigated further.[459] Five (n=5) dental cases were investigated over the same period, and two (n=2) of the cases were recommended to the

458 HPCNA Annual Report 2015/16. P. 14.
459 HPCNA Annual Report 2015/16. p. 15.

Council for closing as there was no evidence of professional misconduct against the respective practitioners; and the remainder (n=3) were pending further investigation.[460]

The PIC for the Nursing Council investigated 24 (n=24) cases during 2015/16, and four (n=4) of these cases were recommended to the Council for closing as there was no evidence of professional misconduct against the respective practitioners. A similar number (n=4) of cases was recommended to the Council for professional conduct inquiry; and the remainder (n=16) were to be investigated further.[461]

With regards to the Allied Health Professions Council, its PIC investigated seven (n=7) cases during 2015/16, and three (n=3) of these complaints were recommended to the Council for closing as there was no evidence of professional misconduct against the respective practitioners. One (n=1) case was referred to professional conduct inquiry, and the remainder (n=3) were to be investigated further.[462]

The PIC of the Social Work and Psychology Council investigated five (n=5) cases during 2015/16, and three (n=3) of these complaints were recommended to the Council for closing as there was no evidence of professional misconduct against the respective practitioners. One (n=1) case was recommended to the Council for professional conduct inquiry, and one (n=1) was to be investigated further.[463]

Over the same period, the PIC of the Pharmacy Council handled seven (n=7) cases. One (n=1) case was recommended to the Council for closing as there was no evidence of professional misconduct against the respective practitioner. Two (n=2) cases were recommended for

460 HPCNA Annual Report 2015/16. p. 16.
461 HPCNA Annual Report 2015/16. p. 15.
462 HPCNA Annual Report 2015/16. p. 15.
463 HPCNA Annual Report 2015/16. p. 15.

professional conduct inquiry; the remainder (n=4) were still under investigation on 31 March 2016.[464]

During 2015/16 the Nursing Council found a nurse guilty of unprofessional conduct and negligence and suspended her from practising the profession of nursing for a period of two years, of which one year was suspended for a period of two years without committing the same transgressions and the payment of a fine in the amount of N$ 25 000.00. The Allied Health Professions Council found a medical technologist guilty of unprofessional conduct and negligence and suspended him from practising his profession for a period of one year and a fine of N$ 30 000. The Pharmacy Council found a pharmacist guilty of operating a pharmacy practice without the practice having been registered with the Council and fined him an amount of N$ 70 000.00.[465]

3.5 Medical malpractice complaints in 2016/17

During the 2016/2017 financial year, the five Councils received 110 (n=110) new complaints from the public against registered healthcare practitioners. These are broken down per Council as follows. Medical and Dental Council: n= 86; Nursing Council: n=16; Social Work and Psychology Council: n=3; Allied Health Professions Council: n=3: and Pharmacy Council: n=2.[466]

Compared to the 2016/17 report, the Medical and Dental Council received 13% more complaints against medical practitioners. The nature of complaints involved negligence, unprofessional conduct, inappropriate billing, and improper relationship with patients. The Nursing Council received 4% more complaints compared to the previous year. Almost two-thirds (60%) of the cases reported against nurses and midwives related to general attitudes

464 HPCNA Annual Report 2015/16. p. 16.
465 HPCNA Annual Report 2015/16. pp.17 – 18.
466 HPCNA Annual Report 2016/17. p.15.

towards patients, 20% to lack of proper nursing care, and 20% to lack of care resulting in still births. There was no change in the number of complaints received by the Social Worker and Psychology Council compared to the previous year. The Allied Health Professions Council received 11% less complaints compared to the previous year; and the Pharmacy Council received 5% less in comparison to the previous year.[467]

During the 2016/17 financial year, the PIC of the Medical and Dental Council investigated 153 (n=153) cases against medical practitioners. Just over 20% (n=36) of cases were recommended to Council for closing as there was no evidence of professional misconduct against the relevant practitioners. Seventeen of all the cases (n=17/n=153) were recommended to Council for professional conduct inquiry; and the remainder (n=100) of cases were to be investigated further. There were eight (n=8) dental cases investigated over the same period: the majority (n=7) were recommended to the Council for closing as there was no evidence of professional misconduct against the relevant practitioners; and the remaining case (n=1) needed further investigation.[468]

The PIC for the Nursing Council investigated 34 (n=34) cases during 2016/17. Less than a third (n=10) of these cases were recommended to the Council for closing as there were no evidence of professional misconduct against the relevant practitioners. Five (n=5) cases were recommended to the Council for professional conduct inquiry; and the remainder (n=19) of cases were to be investigated further.[469]

Regarding the Allied Health Professions Council, its PIC investigated 10 (n=10) cases during 2016/17, and half (n=5) of these complaints were recommended to the Council for closing as there was no evidence of professional misconduct against the relevant practitioners. One (n=1)

467 HPCNA Annual Report 2016/17. p.16.
468 HPCNA Annual Report 2016/17. p.17.
469 HPCNA Annual Report 2016/17. p. 17.

case was recommended to the Council for professional conduct inquiry; and the remainder (n=4) of cases were to be investigated further.[470]

The PIC of the Social Work and Psychology Council investigated four (n=4) cases, and half (n=2) of them were recommended to the Council for closing as there was no evidence of professional misconduct against the respective practitioners. One (n=1) case was recommended to the Council for professional conduct inquiry; and the remaining case (n=1) was to be investigated further.[471]

Over the same period, the PIC of the Pharmacy Council handled eight (n=8) cases. One (n=1) case was recommended to the Council for closing as there was no evidence of professional misconduct against the relevant practitioner. One (n=1) case was recommended for professional conduct inquiry, and as of 31 March 2016 there were six (n=6) still under investigation.[472]

During 2016/17 the Nursing Council found three (n=3) nurses and midwives guilty of failure to provide proper care to an expectant mother resulting in still birth. These nurses and midwives were fined N$ 15 000.00, N$ 10 000.00, and N$ 5 000, respectively. The Council also found other nurses and midwives (n=8) of failure to observe and report findings on a mother who underwent a caesarean section that resulted in her death. These practitioners were fined an amount ranging from N$ 10 000.00 to N$ 25 000.00.[473]

The Social Work and Psychology Council found a social worker guilty of improper handling of a family involved in the suspected case of sexual abuse. The social worker was suspended from practising her profession for a period of six years and a fine of N$ 70 000.00. The

470 HPCNA Annual Report 2016/17. p. 18.
471 HPCNA Annual Report 2016/17. p. 18.
472 HPCNA Annual Report 2016/17. p. 18.
473 HPCNA Annual Report 2016/17. p. 19.

suspension and a fine were appealed by the practitioner before the appeal committee of the Council resulting in a reduction of her fine to N$ 40 000.00 to be paid within a period of 30 days and the suspension period reduced to four years, of which two years were suspended on condition that she is not found guilty of practising outside of her scope of practice. If the practitioner should however fail to pay the fine within the set timeframe, one of the suspended two years should actually become effective.[474]

The Pharmacy Council found a pharmacist guilty of dispensing scheduled medicine without a prescription issued by a medical practitioner. The pharmacist was suspended from practice for a period of 12 months, which period was suspended in order for the accused person to pass within a period of 12 months, an examination to be set by the Council and to pay a fine N$ 60 000.00.[475]

The Medical and Dental Council found a medical practitioner guilty of failure to provide proper care to an expectant mother resulting in still birth. The medical practitioner was ordered to pay a fine of N$ 70 000.00 and his practice was to be subjected to an inspection by the Council on the general standard of provision of healthcare. Another medical practitioner was found guilty of employing another medical practitioner for his private practice while such a practitioner was restricted to work under supervision in the public sector. This medical practitioner was ordered to pay a fine of N$ 100 000.00.[476]

3.6 Medical malpractice complaints in 2017/18

During the 2017/2018 financial year, the Councils received 71 (n=71) new complaints from the public against registered healthcare practitioners. These cases are broken down per Council as follows. Medical and Dental Council: n=46; Nursing Council: n=8; Social Work and

474 HPCNA Annual Report 2016/17. pp. 20-21.
475 HPCNA Annual Report 2016/17. pp. 20-21
476 HPCNA Annual Report 2016/17. pp. 20-21

Psychology Council: n=1; Allied Health Professions Council: n=9; and the Pharmacy Council: n=7.[477] The monthly record of these complains is indicated in Table 1.

Table 1: Monthly record of number of complaints reported to Councils

Month	Medical & Dental Council	Nursing Council	Social Work & Psychology Council	Allied Health Professions Council	Pharmacy Council	TOTAL
April 2017	3	1	0	1	1	6
May 2017	5	1	0	1	1	8
June 2017	6	1	0	2	0	9
July 2017	6	2	0	0	2	10
August 2017	6	0	0	2	0	8
September 2017	1	0	0	1	1	3
October 2017	3	1	0	1	0	5
November 2017	9	0	1	0	0	10
December 2017	0	0	0	0	1	1
January 2018	1	1	0	0	0	2
February 2018	4	1	0	1	0	6
March 2018	2	0	0	0	1	3
TOTAL	**46**	**8**	**1**	**9**	**7**	**71**

Source: HPCNA Annual Report 2017/18.

Compared to the 2017/18 report, the Medical and Dental Council received 19% less complaints against medical practitioners. The nature of complaints remained negligence, unprofessional conduct, inappropriate billing, and improper relationship with patients. The Nursing Council received 27% more complaints compared to the previous year. The breakdown of the complaints is as follows: 70% were of the cases reported against nurses related to lack of proper general care of patients; 5% related to improper attitudes towards patients; and 25% of

477 HPCNA Annual Report 2017/18. p. 20.

complaints related to lack of care resulting in still births. The Social Worker and Psychology Council received 50% more complaints than the previous year. These complaints mainly related to practising outside the scope of practice. The Allied Health Professions Council received 84% more complaints compared to the previous year. A breakdown of these complaints indicates that 80% related to practitioners practising outside their scope of practice, and 20% related to practising without registration with the Council. The Pharmacy Council received 90% more complaints in comparison with the previous year; 45% related to overcharging for services rendered to clients, and 55% related to inappropriate advertising and touting.[478] The percentages of cases reported per Council during 2017/18 are indicated Figure 3 below.

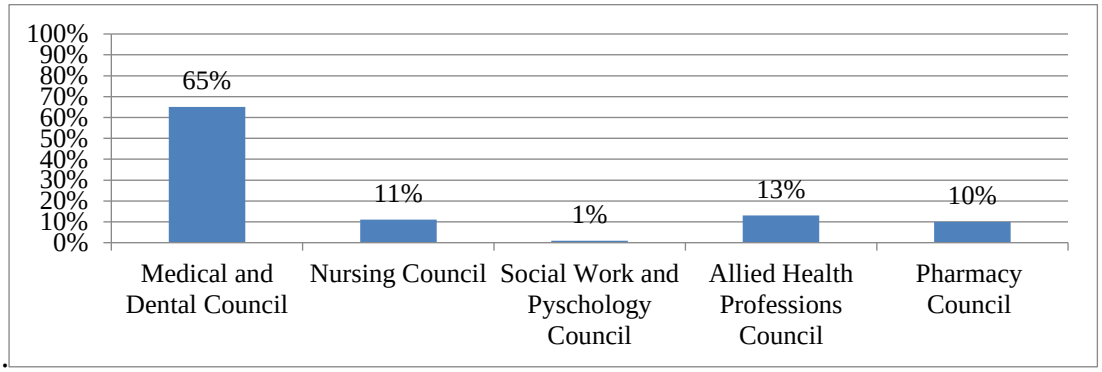


Figure 3: Cases reported per Council during 2017/18. *Source: HPCNA Annual Report 2017/18.*

The cases investigated by the various Councils during 2017/18 are indicated in Table 2 below.

Table 2: Status of cases investigated in 2017/18

Councils	**Investigated cases**	**Cases closed**	**Cases for further investigation**	**Cases for professional conduct**
Medical and Dental	88	24	48	16

478 HPCNA Annual Report 2017/18. p. 21.

Nursing Council	11	5	5	1
Pharmacy Council	5	0	5	0
Social Work and Psychology	9	4	2	3
Allied Health Professions	0	0	0	0
Total	113	33	60	20

Source: HPCNA Annual Report 2017/18.

It is interesting to note that the number of cases pending professional conduct inquiries in all the Councils, except social work and psychology, increased significantly. This was attributed to lack of funds to have such cases finalised.[479]

Figure 4 presents a comparison of the data for 2017/18 and 2016/17.

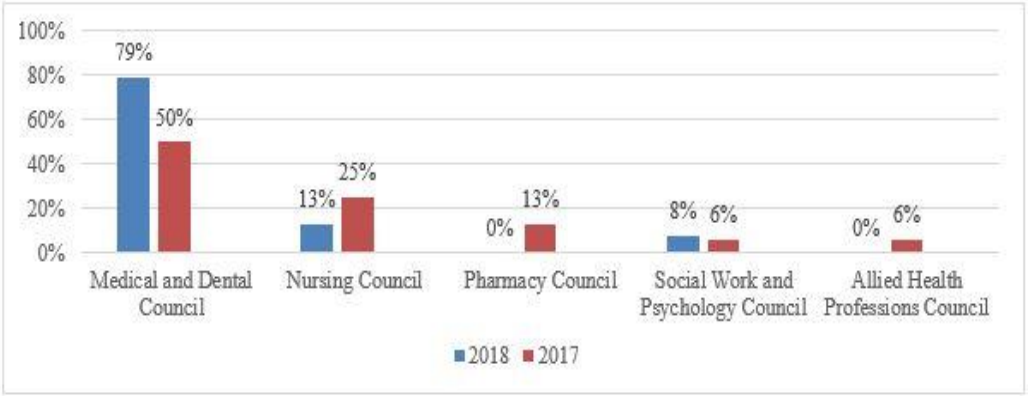


Figure 4: Cases pending professional conduct inquiry in 2017/18 compared to 2016/17. *Source: HPCNA Annual Report 2017/18.*

479 HPCNA Annual Report 2017/18. p. 24.

During 2017/18 six nurses appeared before the disciplinary committee of the Nursing Council on charges ranging from failure to provide required care to advocate for patients' rights. During these inquiries, the nurses charged with unprofessional conduct expressed that they were mostly overworked and experienced a high level of pressure in their working environment due to shortage of staff especially in the public sector amidst a high number of patients needing care.[480]

3.7 Medical malpractice complaints in 2018/19

During the 2018/2019 financial year, the Councils received 48 (n=48) new complaints from the public against registered healthcare practitioners. These cases are broken down per Council as follows. Medical and Dental Council: n=31; Nursing Council: n=6; Social Work and Psychology Council: n=2; Allied Health Professions Council: n=5: and Pharmacy Council: n=4.[481]

The Medical and Dental Council received 25% more complaints against medical practitioners during this period. Obstetrics and gynaecology related complaints dominated the nature of complaints received by this Council, followed by surgery and dentistry. While the total number of complaints received by the five Councils was low during this period, out of all the complaints 90% were against medical practitioners. The indicators point at the practice of obstetrics and gynaecology as the main source of complaints, the majority being against general medical practitioners. Complaints against dentists remained relatively low.[482]

The Nursing Council received 6% less complaints compared to the previous year. Complaints related to the provision of general nursing care as was dominant in previous years, followed by complaints relating to improper attitudes towards patients. It is worth noting that complaints

480 HPCNA Annual Report 2017/18. p. 21.
481 HPCNA Annual Report 2018/19. p. 20.
482 HPCNA Annual Report 2018/19. p. 21.

relating to lack of care that resulted in still births declined significantly. Complaints against nurses generally decreased, but the imbalance of patient-nurse ratio in public health facilities, as recorded in most responses to complaints by nurses, continues to contribute to lack of attention given to state patients resulting in complaints.[483]

The Social Worker and Psychology Council received a similar number of complaints as in the previous year. These complaints again related to practising outside the scope of practice by social workers, psychologists, and psychological counsellors. The Allied Health Professions Council received 10% less complaints compared to the previous year. These complaints were related dental therapists practising as dentists, practising outside of scope of practice, and rendering professional services without being registered. There seemed to be a trend of dental laboratories employing unregistered persons to perform professional functions. The Pharmacy Council received a similar number of complaints as in the previous year. Complaints related to unethical behaviour and fraud.[484]

The overall demographic representation of complaints in terms of the regions in Namibia was that the Khomas region was the dominant one, followed by the respective regions of Erongo, Otjozondjupa and Kavango East and West, Oshana and Ohangwena.[485] The reported cases per Council are presented Figure 5 below.

483 HPCNA Annual Report 2018/19. p. 21.
484 HPCNA Annual Report 2018/19. p. 21.
485 HPCNA Annual Report 2018/19. p. 21.

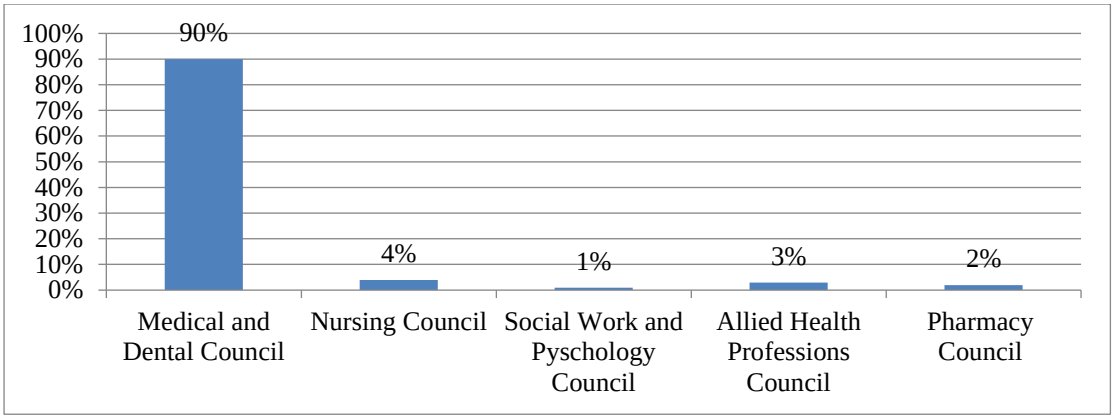
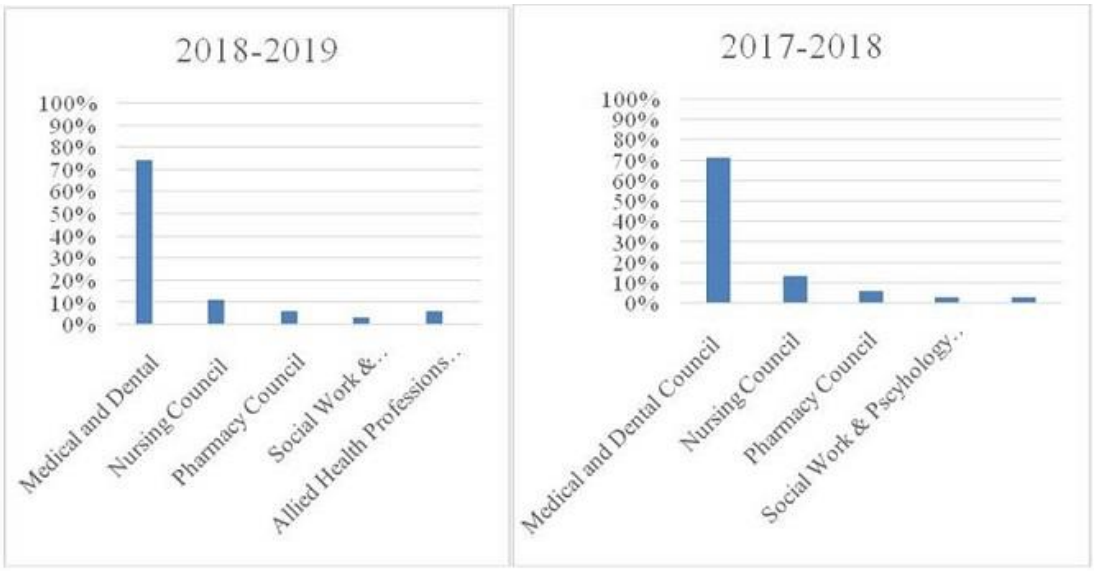


Figure 5: Reported cases per Council in 2018/19. *Source: HPCNA Annual Report 2018/19.*

A comparison of the pending cases on 31 March 2019, to those in the previous year, shows that the Medical and Dental Council had an increase of 3%; delays in obtaining expert opinions and medical records played a major role in the increased number of pending cases.[486] A high request for expert opinion was attributed to complicated services that medical practitioners provide and issues surrounding a complaint that may not fairly be investigated without the involvement of an expert. The delays in obtaining patient hospital records from various hospitals and health facilities across the country also contributed to the number of pending cases.[487] Figure 6 presents a comparison of 2018/19 pending cases to those in 2017/18.

[486] HPCNA Annual Report 2018/19. p. 24.
[487] HPCNA Annual Report 2018/19. pp. 24-25.



Source: HPCNA Annual Report 2018/19.

Figure 6: Pending cases per Council in 2018/19 compared to 2017/18. *Source: HPCNA Annual Report 2018/19.*

Due to limited funds, each Council was only allowed to hold one professional conduct inquiry during this period.[488] This decision resulted in more pending cases to the professional conduct inquires as indicated in the Figure 7 below.

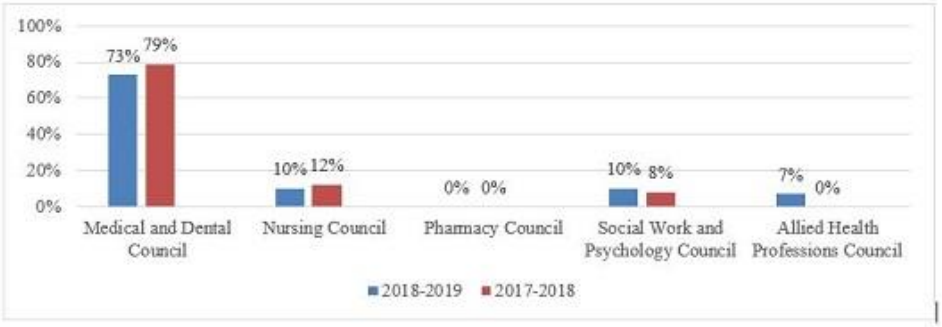


Figure 7: Cases pending the professional conduct inquiries in 2018/19. *Source: HPCNA Annual Report 2018/19.*

488 HPCNA Annual Report 2018/19. p. 26.

3.8 Funds of the Councils and expenses related to medical malpractice

The funds of each Council consist of the following.

(a) All annual fees, application fees, examination fees, registration fees, fees relating to investigations and any other fees payable to the Council.

(b) Donations or grants made for the benefit of the Council.

(c) Interests derived from investments made in terms of the provisions of the Act.

(d) Any fine paid to the Council in terms of the provisions of the Acts.

(e) Financial assistance, which the Minister may grant, subject to such conditions as he/ she may determine and in consultation with the minister responsible for finance, to the Council from the moneys appropriated by Parliament for such purpose, to exercises its powers and perform its duties and functions.[489]

Although the Councils are allowed to generate income from their activities as indicated above, but as provided for in the constituting Acts, government financial assistance remains the main source of funding to the Councils since their establishment in 2004, as such funds constitute 70% of their annual income.[490] The funding profile of the Councils by government is indicated in Table 3.

Table 3: Funding profile of the Councils by government

FINANCIAL YEARS	**BUDGET IN N$**	**GRANT IN N$**	**DEFICIT IN N$**
2004 // 2005	2,696,704.00	1,000,000.00	1,696,704.00

[489] S 13 of the Social Work and Psychology Act 6 of 2004; S 14 of Act 7 of 2004; S 13 of the Nursing Act 8 of 2004; S 13 of the Pharmacy Act 9 of 2004 & S 13 of the Medical and Dental Act 10 of 2004.

[490] HPCNA Funding Proposal 2020.

2005 // 2006	6,403,441.00	1,600,000.00	4,803,441.00
2006 // 2007	9,897,355.00	4,500,000.00	5,397,355.00
2007 // 2008	12,177,349.00	5,000,000.00	7,177,349.00
2008 // 2009	13,400,000.00	9,900,000.00	3,500,000.00
2009 // 2010	10,981,840.00	9,900,000.00	1,081,840.00
2010 // 2011	17,236,299.00	9,900,000.00	7,336,299.00
2011 // 2012	19,604,929.00	9,900,000.00	9,704,929.00
2012 // 2013	16,155,003.00	9,900,000.00	6,255,003.00
2013 // 2014	14,259,929.00	8,000,000.00	6,259,929.00
2014 // 2015	24,774,813.00	10,600,000.00	14,174,813.00
2015//2016	43 603 142.00	20,000,000.00	23,603,142.00
2016//2017	43 603 142.00	20, 000,000.00	23,603,142.00
2017//2018	43 603 142.00	20, 000,000.00	23,603,142.00
2018//2019	43 603 142.00	20, 000,000.00	23,603,142.00
2019//2020	43 603 142.00	20, 000,000.00	23,603,142.00
TOTALS	365,603,372.00	180,200,000.00	185,403,372.00

Source: HPCNA Funding Proposal 2020.

Although the amount of money given to the Councils by government increased over 16 years, it is clear from Table 3 that such increments have not been constant. It is also evident that the government grant constitutes 70% of the Councils annual income. Without such financial

assistance they would not be able carry out their statutory mandates. The annual reports of the Councils clearly indicate that persistent budget shortfalls render them to unable to promptly deal with medical malpractice cases as indicated below.

- By the end of the 2014/15 financial year, a total of 14 (n=14) cases were pending professional conduct inquiries, and in the same year only the Medical and Dental Council held a professional conduct enquiry. The other Councils deferred their professional conduct inquiries to the following year due to lack of funds.[491]
- Although during the 2015/16 financial year the Nursing Council, the Allied Health Professions Council, the Social Work and Psychology Council, and the Pharmacy Council managed to hold at least one professional conduct inquiry each. Such inquiries were tightly scheduled within the limited funds available. Cases pending professional conduct inquiries by the end of that financial year remained 14.[492]
- For the financial year 2016/17 the Nursing Council, the Medical and Dental Council, the Social Work and Psychology Council, and the Pharmacy Council only managed to have one professional conduct inquiry each.[493]
- During the 2017/18 financial year, only the Medical and Dental Council, the Pharmacy Council, and the Nursing Council were able to hold one professional conduct inquiry each.[494]
- By the end of the 2018/19 financial year, Councils collectively had a backlog of 29 (n=29) cases cleared for professional conduct enquiries; with some dating back from as far as 2009.[495]

491 HPCNA Annual Report 2015/16. pp. 24-27.
492 HPCNA Annual Report 2016/17. pp. 17-20.
493 HPCNA Annual Report 2018/19. pp. 25, 27 & 29.
494 HPCNA Annual Report 2017/18. pp. 19-20.
495 HPCNA Annual Report 2014/15. p. 26.

The estimated cost for one professional conduct inquiry over a period of five (5) days is N$450 000.00. There is also a possibility of an appeal following each inquiry and the cost thereof in all likelihood equals that of an inquiry. The Councils had planned to conduct 25 professional conduct inquiries and 10 appeals during the 2020/2021 financial year at a cost of N$15 750 000.00. However, with the current financial resources available to the Councils annually, they can only manage at least five cases per year due to insufficient funds.[496]

It is also worth noting that due to lack of internal capacity, and the complicated nature of most of the medical malpractice complaints reported to the Councils, medical and legal opinions are most often sought from external experts. Such opinions can only be obtained at a fee payable by the Councils to such experts. The cost for a legal opinion on average is N$35 000.00 per case, and that of a medical opinion is about N$ 8 500.00 per case. The Councils on average receive 50 medical malpractice complaints per year. They request on an average 25 legal opinions and 30 medical opinions per year. The costs for 25 legal opinions and 30 medical opinions per year is about N$1 139 000.00.[497]

3.9 Medical malpractice and medical negligence

Medical malpractice is a broad term, which encompasses professional negligence and other intentional or negligent acts, such as the breach of confidentiality and fiduciary practitioner-patient relationships.[498] Healy[499] indicated that the concept 'medical negligence' was coined by Sir William Blackstone in 1768 when he wrote about how trust is broken between a patient and health practitioner, resulting in harm to the patient.[500] In a medical context, negligence is

496 HPCNA Funding Proposal 2020.
497 PCNA Funding Proposal 2020.
498 Carstens, P. & Pearmain, D. (2007), *supra* note 6. p. 599.
499 Healy, J. (1999) *Medical Negligence and Common Law Perspectives. London* : Sweet & Maxwell.
500 McQuoid Mason, D. (2007) "Professional Negligence and Medical malpractice Bioethics and Health Law Lecture notes, 13 April 2007. p. 3.

a form of culpable inattentiveness with a risk of harming a patient. Herring[501] identified three characteristics for medical negligence, namely:

- the healthcare practitioner being taken to task owed the patient a duty of care, which is a reasonable standard of care required by law;
- the healthcare practitioner has breached the duty of care, where the required action should be that he/she acted in accordance with a practice accepted as proper and reasonable, and
- the breach of duty of care caused the patient loss, where proving negligence is inadequate to apportion blame, but the patient has subsequently suffered loss or injury.

Medical malpractice may also be exemplified by an omission or inaccurate diagnosis of a health condition from which the patient suffers and the administration of treatment to a patient without the proper and reasonable standard of skill, care and competence required from a healthcare practitioner.[502]

The following case is a distinctive example of healthcare practitioners' failure to measure up to the required standard of care and skill that resulted in damage for the patient and can be classified as medical malpractice and negligence.

3.9.1 Foreign object in the body of a patient: The case of Y[503]

The instance of a foreign object being left in a patient's body after the completion of a surgical operation is considered as a typical example of medical negligence.[504] In the case of Y, a pair of surgical scissors was discovered in the patient's body after two consecutive abdominal

501 Herring, J. (2006). *Medical Law and Ethics*. New York: Oxford University Press.

502 Claassen & Verschoor (1992), *supra* note 442. p. 31.

503 This is a fictitious name used to protect the true identity of the deceased patient.

504 Claassen & Verschoor (1992), *supra* note 442. p. 40.

operations in hospital K.[505] Each operation was carried out by a different team of doctors and nurses. After the two operations, Y suffered from excruciating abdominal pain. On one of Y's frequent visits to a local clinic a nurse suspected that something was amiss. Patient Y was then referred to hospital K for further investigation. A plain-film abdominal radiograph (X-ray) was done, and a foreign body was visualised in Y's abdomen. An urgent surgical operation was performed to remove the foreign body which was a pair of surgical scissors. Y died some months later. A post-mortem was not done.

The case was reported to the Medical and Dental Council of Namibia by Y's family member for an investigation. Part of the problem with this case was that the available evidence made it impossible to infer at which of the two operations the instrument was left in the body of Y. Although, in the opinion of one of the two medical experts consulted during the investigation, it was more likely that the surgical instrument was left in the body of Y at the first operation, this could not be stated with certainty.[506] While it was clear that one of these teams was responsible, and there was at least negligence by one of them, the Council had no strong evidence to implicate who the real culprit was. The case was subsequently closed with some advice to the family of Y to explore a civil claim against the State. There is no evidence that the family successfully pursue this option.

Barlow, as quoted by Claassen and Verschoor,[507] formulated the following rules, which, if complied with will prevent the leaving behind of foreign objects in a patient's body on completion of a surgical operation.

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505 This is a fictitious name used to protect the true identity of a State Hospital.

506 It is worth noting that the records in the operating room indicated that all instruments used at both operations were accounted for and the department where used instruments are re-sterilised had no mechanism in place to detect a missing instrument from a surgical pack.

507 Claassen & Verschoor (1992), *supra* note 442. pp. 41– 42.

- It is the duty of the medical practitioner to search the body of the patient and see that any instrument he/she used has been removed therefrom.
- Where a certain instrument is missing, he/she must not presume that it has been removed but must ascertain the true position.
- Where several instruments are used, the surgeon may rely on the count of the assisting nurse, provided it is clearly understood that this does not exempt him or her from his or her duty of making an adequate search of the body of the patient.

This case suggests firstly that the Barlow rules were not applied by one of the surgeons who operated on Y, and secondly that hospital K had no other mechanism of detecting a missing instrument instead of relying on the diligence of its surgical teams. The case also exposed the missing link between the professional conduct regime by a regulatory authority and the civil liability system under which medical malpractice claims could have been pursued. Furthermore, justice could have prevailed in this case if Namibia had a no-fault system for payment of compensation without the need to institute medical malpractice claims and proving causality as an element of delict.

Like in the case of Y, the victims of medical malpractice are more often than not disadvantaged to institute medical malpractice claims against the defendants because such accidents happen when victims are unconscious or anaesthetised. The position of such victims is even more compounded by the complexity of medical practice and the unavailability or willingness of medical experts to assist them in establishing a *prima facie* case against the defendants. To aid such victims in their quest for justice, the researcher finds it appropriate to explore the application of the common law doctrine of *res ipsa loquitor* to medical malpractice cases.

3.9.2 Application of *res ipsa loquitur* to medical malpractice

Accidents may occur in situations where the evidence of the alleged negligence on the part of the defendant is not readily available to the plaintiff. The doctrine of *res ipsa loquitur* is the expedient label to describe a situation where, apart from the plaintiff's failure to establish the precise cause of the accident, the evidence of the accident by itself is sufficient to justify the conclusion that the defendant was probably negligent and in the absence of a plausible explanation by the defendant to the contrary, such negligence caused harm to the plaintiff.[508]

The doctrine of *res ipsa loquitur* literally means "the facts speak for themselves" or "the case speaks for itself" and its effect is that an inference of negligence can be made if an accident occurs in a manner that would have not been the case had there been no negligence on the part of a defendant, but there is no direct evidence of negligence.[509]

Claassen and Verschoor could have not been clearer in explaining the doctrine of *res ipsa loquitur* that -

> The maxim is based on the fundamental principle that the mere evidence of the detrimental occurrence and the fact that it was caused by an object under the exclusive control of the defendant, constitute a *prima facie* factual presumption that the defendant had been negligent. The very occurrence of the detrimental incident speaks for itself because it is more consistent with negligent on the defendant's part than with another cause. The damage or *injuria* must be of such kind that it would normally not have taken place in the absence of negligence. This does not necessarily imply that the onus has shifted from the plaintiff to the defendant, but if the defendant does not succeed to

508 Van den Heever, P, & Lawrence, N. (2015). "Inference of Negligence - is it the time to jettison the maxim res ipsa loquitur?" *DE Rubus.* July 2015. p. 32.

509 Carstens, P. A., & Pearmain, D. (2007), *supra* note 6. p. 567.

give an acceptable explanation for the incident, the court may find that he was negligent.[510]

Considering Claassen and Verschoor's exposition of the maxim, it would then mean that the doctrine of *res ipsa loquitur* can be invoked only when: (1) a patient suffers an injury that is not an expected complication of medical care; (2) the injury does not normally occur unless someone has been negligent; and (3) the defendant was responsible for the patient's well-being at the time of the injury. For clarity, assume that a portable X-ray (bedside radiography) is ordered in an intensive care unit on a young, otherwise healthy patient recovering from appendicitis. After the radiographer has left, it is found that the patient has a dislocated shoulder. This is not an expected complication of an X ray; there are no explanations for the injury other than mishandling or failing to restrain the patient properly, and the radiographer was responsible for the patient's well-being at the time the injury occurred.

The application of the doctrine of *res ipsa loquitur* to medical malpractice cases differs across jurisdictions. For example, in the United States of America (USA) it is normally assumed that a surgeon was negligent where it appears after an operation that a foreign object was left behind in a patient's body and the court would not require expert evidence to prove that the surgeon was negligent.[511] The only requirements that must be met to enable a plaintiff to rely on the doctrine of *res ipsa loquitur* are:

- The incident must be of a kind which ordinarily does not occur in the absence of someone's negligence;
- The incident must be caused by an agency or instrumentality within the exclusive control of the defendant, and

510 Claassen, N.J.B., & Verschoor, T. (1992), *supra* note 442. p. 27.
511 Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 41.

- The incident must have been due to any voluntary action or contribution on the part of the defendant.[512]

The successful application of the doctrine of *res ipsa loquitur* in the USA was bolstered by the following approaches adopted in that jurisdiction:

- The permissible inference approach in which the jury is allowed to draw inference from the plaintiff's case without other evidence that the defendant was negligent. This approach certainly lessens the burden of proof on the shoulders of the plaintiff.
- The presumption approach and the advantage to be drawn from this approach for the plaintiff is that the successful invocation of the doctrine of *res ipsa loquitur* is regarded as having created a presumption and the jury is not only allowed to infer negligence against the defendant but in the absence of exculpate evidence by the defendant the court would require the jury to do so.

The shifting of the burden of proof approach which provides the greatest relief to the plaintiff in medical malpractice cases. This literally means that the defendant is required to prove on the preponderance of the evidence that the injury was not caused by his or her negligence.[513]

In *Salgo v Leland Standard Jr Uni Bd of Trustees* as quoted by Van den Heever, the court welcomed the application of the doctrine of *res ipsa loquitur* to medical negligence by stating that –

> The application of the doctrine of *res ipsa loquitur* in malpractice cases is a development of comparatively recent years. Before that time, the facts that medicine is not an exact science, that the human body is not susceptible to precise understanding, that the care given of a medical man is the degree of learning and skill common in his

512 Van den Heever, P. (2002). *The application of the Doctrine of Res Ipsa Loquitur to Medical Negligence Actions: A Comparative Survey*. Unpublished Thesis. University of Pretoria. P. 173.

513 Van den Heever, P. (2002), *supra* note 512. p. 183.

> professional locality, and that even with the greatest of care untoward results do occur in surgical and medical procedures, were considered paramount in determining whether the medical man in given circumstance had been negligent. But gradually the courts awoke to the so-called conspiracy of silence.[514]

The strategic value of the application of the doctrine of *res ipsa loquitur* to medical malpractice claims in the USA from which Namibia can draw important lessons is that there is no need for an expert to testify as to the proper standard of care; the court is allowed to draw inference from the plaintiff's case without other evidence that the defendant was negligent; the court can infer negligence against the defendant in the absence of exculpatory evidence; and the burden of proof can actually shift for the defendant to prove that the injury was not caused by his or her negligence.

The application of the doctrine of *res ipsa loquitur* to medical malpractice cases under the South African law and by extension the law of Namibia,[515] is different from that of the USA. The South African position on *res ipsa loquitur* was set in the case of *Van Wyk v Lewis*[516] in which an appendectomy and gallbladder drainage was performed by a surgeon. Because of sepsis, the surgical area had to be packed with swabs. There was some urgency for the patient to be removed from the operating table, and the surgeon proceeded to close the wound once he was satisfied, and the theatre nurse confirmed that all swabs were accounted for. Some months later, the patient pulled out a cloth like the size of a swab with the tape still attached. In this case, the court did not apply the doctrine of *res ipsa loquitur* since the judge felt that the surgeon could not be held liable as it was the duty of the theatre nurse to ensure that the swab count was done correctly. The court felt that in determining negligence, all circumstances need to be

514 Van den Heever, P. (2002), *supra* note 512. p. 188.
515 Para 2. 3.
516 1924 AD 438.

considered. In rejecting the doctrine of *res ipsa loquitur*, Judge A J Wessels stated: "The mere fact that a swab was left in a patient is not conclusive of negligence." It would therefore mean that the doctrine cannot be invoked to aid an injured patient in proving his or her case and subsequently providing a protective amour for healthcare practitioners or State facing medical malpractice claims.[517]

After referring to *Van Wyk v Lewis*, Brand JA, in *Butherezi v Ndaba* pointed out that the doctrine of *res ipsa loquitur* could hardly, if at all, find relevance to a medical malpractice case reasoning that the reluctance of the South African courts to apply the doctrine in such cases was because adverse events do happen during surgical procedures and medical treatment due to accidents; to hold a healthcare practitioner negligent in such cases would be to "impermissibly reason backwards from the effect to the cause."[518]

In South African law there is only one inquiry in a medical negligence claim, namely, whether the plaintiff, having regard to all the evidence in the case, has discharged the onus of proving on a balance of probabilities, the negligence averred against the defendant.[519]

In what may be regarded as an effort to completely neutralise the relevance of the doctrine of *res ipsa loquitur* a South African court in *Goliath v MEC for Health, Eastern Cape*[520] concluded that in every case, including where the doctrine of *res ipsa loquitur* is applicable, the inquiry at the end of the matter is whether the plaintiff has discharged the burden of proof in connection with the claim of negligence. The court opined that the time may be ripe for the South African courts to discard the doctrine from the legal vocabulary.[521]

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517 Strauss, S. A. (1984). *Doctor, Patient, and the Law: A Selection of Practical Issues.*2nd Ed. Pretoria: JL van Schaik. p. 244.

518 *Butherezi v Ndaba 2013 (5) SA 347 (SCA),* para 9.

519 *Butherezi v Ndaba* 2013, *supra* 518, para 11.

520 *Goliath v MEC for Health, Eastern Cape 2015 (2) SA 97 (SCA).*

521 Van den Heever & Lawrence (2015), *supra* 508. p.33.

According to Van den Heever and Lawrence, the court in *Goliath v MEC for Health, Eastern Cape* case provided legitimacy for the preposition that a plaintiff in a medical negligence case is free to allege that the facts, as known to him or her at the time of pleadings, give rise in themselves to a *prima facie* case of negligence. Such allegation may or may not be sustained at the end of the case but has an effect at the pleading stage of forcing the defendant to produce evidence sufficient to displace the inference that precaution was not taken or run a risk of a judgment be given in favour of the plaintiff.[522]

To ensure that the court draws the correct inference from the proven fact the following basic rules of judgment were postulated in *R v De Blom*[523]

- the inference must be compatible with all proved facts;
- the evidenced facts should be of such that they eliminate every other sensible inferences which can be drawn, and
- if other inference can be drawn there should be uncertainty whether the inference sought to be drawn is correct.

The application of the doctrine of *res ipsa loquitur* could have been of great value and assistance to the case of Y. Firstly, leaving a pair of surgical scissors in his body was not an expected complication of surgery. Secondly, there could be no plausible explanation as to why a pair of surgical scissors was left in Y's body than the failure of the surgeon to account for the instruments used during surgery. Lastly, the surgeon was responsible for Y's wellbeing during the occurrence and in full control of the instrument used during surgery. The challenge in this case however is the uncertainty as to which surgery resulted in a pair of surgical scissors being left in the deceased's body.

522 Van den Heever & Lawrence (2015), *supra* 508. p.33.
523 *R v De Blom 1939 AD 188 202 -203.*

While the purpose of the doctrine of *res ipsa loquitur* is to alleviate a victim's burden of proof in cases where direct proof is not available, the South African case law clearly indicates that the courts are reluctant to apply the doctrine to medical malpractice cases and, in occasions where attempts were made to have it applied, the doctrine did not succeed in shifting the burden of proof from the plaintiff to the defendant as it would be the case under the USA law.

In Namibia, the doctrine of *res ipsa loquitur* has been successfully applied in delict. For example, in *Taapopi v Jason*[524] the court held that the presumption of negligence on the application of the doctrine operated against the defendant.[525] However, Namibia is likely to follow the South African approach in medical malpractice cases.

Claiming for compensation from the State is also not a walk in the park for injured patients. The process is littered with several challenges and may include litigation cost, burden of proof, expert witness, and obtaining compensation from the State as discussed below.

3.9.3 Litigation cost

In an adversarial system, such as that of Namibia, litigation can be a costly exercise; medical malpractice claims often take years to be resolved. Only a few injured patients can afford litigation.[526]

3.9.4 Burden of proof

In civil cases, the onus of proof rests with the patient. In order to succeed with a medical malpractice claim, liability against a practitioner or State must be established on a

524 *Taapopi v Jason* (HC-MD-CIV-ACT-DEL2018/04431) [2020] NAHCMD 321 (30 July 2020).

525 In this case a disengaged itself from a motor vehicle driven by the first defendant on a public road and crashed into a motor vehicle driven by the plaintiff. The driver of the vehicle and the owner of the motor vehicle (defendants) failed to satisfactorily explain their conduct and to displace the presumption that they were negligent. The found the defendants negligent on the application of the *res ipsa loquitur* rule.

526 Oosthuizen, W. T., & Carstens, P. A. (2015A), *supra* note 438. p. 414.

preponderance of probability.[527] To compound matters it is inherently in the nature of medicine that tragic outcomes are often inevitable; healthcare practitioners cannot guarantee successful treatment outcomes and, consequently, cannot simply be held accountable for every adverse event or unsuccessful medical intervention.[528] The fact that a patient was injured is not necessarily an indication of sub-standard care.[529]

3.9.4 Expert witnesses

Medical treatment and interventions can be extremely complex; it can be complicated to establish that harm to a patient was a direct consequence of sub-standard medical care.[530] To overcome this hurdle, expert medical evidence is generally required to prove the case and obtain compensation.[531] Suitable expert witnesses may be in short supply or simply reluctant to testify because the process is time-consuming as it may involve examining patients, compiling reports, consulting with lawyers, studying literatures, and providing testimony during the trial proceedings.[532] The process may also turn out to be financially detrimental to an expert witness who may be self-employed, and the patient may not be able to afford paying such a witness a reasonable fee.[533] The nature of adversarial system, and its inherent rigorous cross-examination, may deter suitable expert witnesses from giving evidence in a malpractice proceeding.[534] It is also difficult to find expert medical witnesses who are willing to testify against fellow members of their profession.[535]

527 Claassen, N. J. B., & Verschoor, T. (1992) *supra* note 442. p. 26.
528 Oosthuizen, W. T., & Carstens, P. A . (2015A), *supra* note 438. p. 414.
529 Oosthuizen, W. T., & Carstens, P. A. (2015A), *supra* note 438. p. 414.
530 Oosthuizen, W. T., & Carstens, P. A. (2015A), *supra* note 438. p. 850.
531 *Michael v Linksfield Park Clinic (Pty) Ltd* 2001 3 SA 1188 (SCA).
532 Strauss, S. A. (1984), *supra* note 517. p. 433.
533 Strauss, S. A. (1984), *supra* note 517. p. 433.
534 Oosthuizen, W. T., & Carstens, P. A. (2015A), *supra* note 438. p. 388.
535 Oosthuizen, W. T., & Carstens, P. A. (2015A), *supra* note 438. p. 388.

3.9.6 Obtaining compensation from the State

Section 2 of the Crown Liability Act[536] provides that a delictual claim against the State shall be cognisable by a court if the claim arises out of any wrong committed by any servant of the State acting in his or her capacity and within the scope of his or her authority. The same Act, however, does not allow for the execution or attachment against the State, nor an accessible and simple process to secure effective satisfaction of judgement debts sound in money.[537] An injured patient is therefore likely to encounter difficulties when seeking to recover damages from the State.[538] The researcher is of the view that section 3 of the Crown Liability Act is unfair and may not pass the constitutional muster.

3.10 Public health expenditure in Namibia

The 2011 census estimate of the Namibian population was nearly 2.4 million.[539] The government of Namibia has consistently made the largest contribution to health spending: 56% in the 2015/16 budget, and 63% in the 2016/17 budget.[540] Over the same period, 30% of health spending was covered by the private sector; the remaining 7% represented donor funding.[541] Although the majority of users of public healthcare are indigent, even the affluent sometimes turn to public healthcare when their private medical aid schemes becomes unaffordable or depleted. In the 2015/2016 financial year the total government health expenditure was N$ 15, 180 629 910 which represented 14% of the total general government expenditure.[542] Ninety-six percent (96%) of this spending constituted the current expenditure[543] while the remaining

536 Act 1 of 1910.

537 Section 3 of the Crown Liability provides that "no execution, attachment or like process shall be issued against the defendant or respondent in any such action or proceeding or against any property of the Crown..."

538 *Nyathi v MEC for Department of Health, Gauteng* 2008 5 SA 94 (CC).

539 Namibia Statistics Agency. April 2014. *Namibia Population and Housing Census 2011*.Windhoek. Namibia

540 Ministry of Health and Social Services (MOHSS). August 2018. *Namibia's Health and HIV Financing Landscape from the 2015/16 & 2016/17 Resource Tracking Exercises.* Windhoek, Namibia. p. 06.

541 MOHSS (2018), *supra* note 540. p. 5.

542 MOHSS (2018), *supra* note 540. p. 5.

543 This is expenditure on health goods and services consumed within the financial year.

4% constituted capital expenditure.[544] Namibia's total health expenditure for 2016/2017 was 9% of the country's gross domestic product (GDP). This was lower than the Abuja Declaration target of allocating 15% of the country's budget to the health sector, but together with South Africa, this was the highest for countries classified as upper-middle income in the WHO's Africa region.[545]

According to the statistics released by the World Bank [the latest available], the average spending on healthcare in the world, as a percentage of a country's GDP is 10%.[546] Namibia's total health expenditure for 2016/2017 per gross product was also lower than the world average of 10%. Namibia has allocated more money to the health sector in the past five years. However, except for the financial year ended 31 March 2014, the actual expenditure has always been constantly higher than the authorised expenditure per year as indicated in Table 4 below.

Table 4: Public health expenditure over a period of five years

Financial year	Authorised	Actual expenditure	Personnel expenditure
2013/2014	N$ 5 245 498 000	N$ 5 024 205 459.23	N$ 2 185 476 274.09
2014/2015	N$ 6 066 803 000	N$ 6 072 685 581.24	N$ 2 558 019 958 .15
2015/2016	N$ 6 236 793 000	N$ 6 575 542 503.24	N$ 3 016 296 950.50
2016/2017	N$ 6 955 535 878	N$ 7 237 349 040.73	N$ 3 466 637 967.09
2017/2018	N$ 6 961 898 000	N$7 119 085 364.38	N$ 3 733 117 780.62
Total	**N$ 31 466 527 878**	**N$ 32 028 867 948.06**	**N$ 14 959 548 930.04**

Source: Reports of the Auditor General on the accounts of the Ministry of Health and Social Services for the financial years ending 31 March 2014/2015/2016/2017/2018.

544 This includes goods and services whose benefits are consumed over a period longer than one year.
545 MOHSS (2018), *supra* note 540. p. 9.
546 The World Bank "Health expenditure, total (% of GDP)" *The World Bank* available at http://data.worldbank.org.indicator (Date of use: 31 March 2020).

While the high spending on healthcare is a positive sign for Namibia, it is clear that its public health sector remains underfunded resulting in over expenditure every year. Personnel costs are a significant chunk of the annual allocation, and this further erodes the capacity to deliver the needed healthcare services.

3.11 Contingent liabilities for medical malpractice in Namibia

There has been a raft of delictual claims for damages based on medical negligence instituted in the Namibian courts in recent years, mainly in the public healthcare sector.[547] Media reports abound of medical malpractice claims against the State for damage suffered in public hospitals.[548] The number and value of medical malpractice claims against the State for a period of five years are presented in Table 5 below.

Table 5: Medical malpractice claims against the State over a period of five years

Financial year ending	Number of claims	Amount paid
31/03/2014	5	N$ 1 179 843.98
31/03/2015	5	N$ 218 473.25

547 See for example, *S v Shivute* 1991 (1) SACR 566 (Nm); *Gomachab v Minister of Health and Social Services and Another* (P) I 198/2007 [2001] NAHC 268 (16 September 2011); and *LM and Another v Government of the Republic of Namibia* (I 1603/ 2008 I 3007/ 2008) [2012] NAHC 211 (30 July 2012).

548 Smith, J.M. (2020, March 05) in an article titled "Grieving dad sues for N$ 2.7 Million" in the *Namibian Sun* newspaper at page 3, reported about a father suing the Health Ministry for N$ 2.75 million after his daughter died shortly after giving birth at the Sesfontein health clinic in late 2018. The father alleged that the clinic staff failed to provide the necessary care and services to his daughter when she went into labour resulting into a retained placenta, blood loss and death. The same newspaper also published report regarding a maternal death at the Walvis Bay State Hospital which has cost the taxpayer N$ 650 thousand in a medical negligence. See Smith, J.M (2019, September 26). N$ 650 000 for negligence. *Namibian Sun*, P 01. This was actually the case of *Lopez v Minister of Health and Social Services* (HC – MD -CIV -ACT -DEL- 2017/ 02346) [2019] NAHCMD 367 (24 September 2019), in which a patient died after she delivered a still born baby and the doctor on call failed to properly and timeously assess her condition when the opportunity to do so presented itself. The nursing sister was equally found to have failed to appraise the doctor on call regarding the record -based condition of the patient. Both the medical personnel and the Minister of Health (in his official capacity) were found liable on the basis of their breach of their legal duty towards the patient. The judgement was for the plaintiff in the amount of N$ 651. 042 and the cost of suit. See paragraph 52 of the judgement.

31/03/2016	6	N$ 345 308.49
31/03/2017	10	N$ 2 820 323.60
31/03/2018	2	N$ 1 600 000.00
Total	28	N$ 6 163 949. 32

Source: Reports of the Auditor General on the accounts of the Ministry of Health and Social Services for the financial years ending 31 March 2014 /2015/2016/2017/2018.

As indicated in Table 5, the cumulative number of compensations claims against the State over a period of five years was relatively low. However, this number indicates the amount paid out by the State and excludes unsuccessful claims. Data on unsuccessful compensations could not be found. There is no specific budgetary provision made for compensation claims by the Ministry of Health and Social services. Hence the amount paid in compensation claims means that money has to be diverted from the delivery of care services to settle the claims.[549] This practice of paying compensation claims from the operational budget undermines the delivery of healthcare services. This may lead to more medical malpractice claims against the State due to the ensuing decline in the standard of service delivery.

3.12 Summary

The number of medical malpractice complaints that were reported to the five regulatory authorities in Namibia over a period of five years was determined. It is clear that such cases vary from Council to Council. The Medical and Dental Council recorded the highest number of complaints consistently, followed by the Nursing Council. Complaints were investigated by the PIC of the Councils and were escalated to a professional conduct inquiry committee based on available evidence. Some cases were closed by the Councils due to lack of sufficient

[549] Reports of the Auditor - General on the accounts of the Ministry of Health and Social Services for the Financial Years ending 31 March 2014 /2015/2016/2017/2018.

evidence warranting a disciplinary action while others are yet to be finalised. It is also clear that Councils are financially handicapped to promptly manage medical malpractice complaints.

The number of medical malpractices claims against the State over a period of five years was also discussed. The monetary value of such claims on the State was explored. It is however clear from the discussion in this chapter that claiming damages against the State may not only be expensive to the indigent, but also could be challenging with respect to finding a willing medical expert witness to prove liability or securing effective satisfaction of judgement debts sound in money.

Also discussed in this chapter were the concepts of medical malpractice and medical negligence as well as the application of the doctrine of *res ipsa loquitor* to medical malpractice cases tapping from the USA and the South African experience. The study concludes that application of the doctrine is of great value to medical malpractice claims in the USA and that the South African courts are reluctant to apply it to similar cases. Evaluation of the current regulatory framework for healthcare professions in Namibia is evaluated in the next chapter.

CHAPTER FOUR

REGULATORY FRAMEWORK FOR HEALTHCARE PROFESSIONS IN NAMIBIA

4.1 Introduction

Namibia, after the attainment of independence and sovereignty, adopted a Constitution with an entrenched Bill of Rights[550] and a provision that elevates the Constitution as the supreme law of Namibia.[551] Through such a provision, the historical legal system, which was based on the doctrine of legislative sovereignty, was successfully replaced with that of constitutional supremacy. Equally, the Namibian judiciary was also provided with a constitutional leverage to promote the principles of democracy, constitutionalism, protection of fundamental rights and freedom of individuals as well as the rule of law and justice for all.[552]

Article 95 of the Constitution provides that "the state shall actively promote and maintain the welfare of the people by adopting, inter alia, policies aimed at "e) ensuring that every citizen has a right to fair and reasonable access to public facilities and services in accordance with the law". It is also inspired by Article 8 of the Constitution on respect of human dignity which states in sub-article 2(b) that "no person shall be subjected to torture or cruel, inhuman or degrading treatment or punishment." Although the Namibian Constitution did not make a provision specific to the provision of healthcare, the reality of constitutional supremacy has undoubtedly impacted on the understanding, nature, scope, and application of laws related to health professions regulation and patient safety.

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550 Chapter 3 of the Constitution of the Republic of Namibia (1990).

551 Article 1 (6) of the Constitution of Namibia provides that " This Constitution shall be the Supreme Law of Namibia".

552 Amoo, S. K., & Mapaure, C. In Ruppel, O. C. & Winter, G. (eds). (2011). *Justice from within: Legal Pluralism in Africa and beyond.* Hamburg: Verlag Dr Kovac. p. 481.

Besides the supremacy of the Constitution of the Republic of Namibia and the applicable common law principles discussed in this chapter, the practice of healthcare professions in Namibia is predominantly regulated by relevant statutes, namely, the 2004 Acts as referred to in chapter two.[553] The 2004 Acts are of particular importance as they established the five regulatory bodies for health professions in Namibia. The appropriateness of the legal framework for healthcare professions to improve patient safety is evaluated in this chapter using the three components of the traditional model of professional self-regulation: cultivation of distinctive ethical standards, socialisation of new members, and social control of deviants.

The wording of the 2004 Acts is substantively the same. For the purpose of this chapter, reference is conveniently made to the Medical and Dental Act, 10 of 2004 (hereinafter referred to as "the Act") and to the Medical and Dental Council of Namibia (hereinafter referred to as the Council). However, unique provisions found in the other Acts of 2004 that are relevant to patient safety are also explored.

4.2 The governance architecture of the Council

Section 3 of the Act established the Council as a juristic person.[554] The composition of the Council is specified in section 5 of the Act consisting of persons appointed by the Minister of Health[555] (hereafter referred to as the Minister) and members elected by eligible registered

553 Social Work and Psychology Act, 6 of 2004; Allied Health Professions Act, 7 of 2004; Nursing Act, 8 of 2004; Pharmacy Act, 9 of 2004; and Medical and Dental Act, 10 of 2004.

554 S 13 (1) states that "There is established a Council to be known as the Medical and Dental Council of Namibia". Subsection (2) indicates that the Council is a juristic person who is capable, in its own name, of suing and of being sued, and, subject to the provision of the Act, of performing all such acts as a juristic person may perform lawfully.

555 The persons appointed by the Minister are four of which one is a staff member of the Ministry of Health who is either a medical practitioner or a dentist, and who has expertise and experience in primary healthcare matters to the satisfaction of the Minister; two persons representing the public, of whom one must be a legal practitioner having not less than ten years' experience in practising law and one of them must a person who, in the opinion of the Minister, is suitably qualified, having regards to the functions of the Council to serve as one of its members, but who is not a registered person; and one person who is designated by the Vice-Chancellor of the University of Namibia which person is a medical practitioner or a dentist involved in the education and training of persons who will qualify, on the completion of such education and training for registration in terms of the Act.

persons.[556] The Executive Director of the Ministry of Health is an *ex officio* member of the Council provided that he/she is a registered medical practitioner. If he/she is not a medical practitioner, the Minister must appoint, in the place of the executive director, a medical practitioner who is also a staff member of the Ministry of Health and who the Minister considers as suitable to serve on the Council as such a member. Members of the Council hold office for a period of five years and are eligible for re-appointment or re-election at the expiration of that period. The Minister makes known by notice in the Gazette the names of the members of the first Council and the names of the members of the subsequent Council are similarly made known by the registrar of the Council.[557]

The Council has wider powers under section 6 of the Act, *inter alia*, it may buy, lease, acquire, sell, let or dispose of, or hypothecate or pledge or otherwise deal with any movable or immovable property of the Council or any right over or relating to such immovable property; take up, borrow, lend or invest money; open and operate banking and savings account; make or accept donations; enter into agreement with any person, body, institution or organisation on such terms as the Council and that person or entity may agree upon; obtain information necessary to achieve its objects and perform its functions, including require any registered person in writing to submit to the Council such information as the Council may consider necessary; consider any matter affecting the professions to which the Act applies or take such action in any matter the Council may consider advisable; on application by any person, recognise any qualification held by that person in respect of the professions to which the applies as being equal to any qualification prescribed in terms of the Act; co-opt any person onto any

556 The elected members of the Council are ten of which five are medical practitioners elected by medical practitioners, genetic counsellors, the biomedical engineers, the clinical biochemists, the medical biological scientists, the medical physicists, medical scientists, the clinical officers, the rural medical aids and the ophthalmic assistants. The other five persons are dentists elected by dentist and oral hygienists. For one to stand for election he/she must be a registered person, a Namibian citizen and an ordinarily resident in Namibia.

557 Members of the current Council were announced in GN 297 (GG 6770/ 2018).

of its committees; authorise a person to inspect the professional practice of any registered person and to report to the Council on his or her findings in respect of such inspection; charge the fees determined by it in respect of any inspection it may regard necessary to enable it to consider an application for approval of an educational institution, or for any amendment of a condition imposed on such institution; and to do all such things as it may regard necessary or expedient in order to achieve the objects of the Act.

The Council is expected to generate funds to finance its activities[558] however the Minister may, in consultation with the minister of finance, and subject to such conditions as the Minister may determine, grant to the Councils out of the moneys appropriated by Parliament such financial assistance, as he/she may deem necessary.[559]

In each year, after the closing of the Council's financial year,[560] the Council is expected to submit to the Minister a report on its activities during such financial year, together with a copy of the audited financial statement and the balance sheet in respect of the financial year concerned. The Minister must table these documents in the National Assembly within a period of six months after the date of receiving the report and the audited financial statement from the Council.[561]

4.3 Cultivation of distinctive ethical standards

For purposes of this study, this component refers to the standards by which individuals may enter the profession and by which they may then practise medicine**.**

558 S 13 of the Act indicates that the fund of the Council consists of annual fees, application fees, examination fees, registration fees, fees relating to investigations and any other fees payable to the Council in terms of the Act. Council can also receive donation or grants, interest derived from its investments, imposition of fines or moneys received or made available for the benefit of the Council.

559 S 14 (2) of the Act.

560 According to s 13 (7) the financial year of the Council ends on the last day of March in each year.

561 S 13 (6) (a) & (b) of the Act.

4.3.1 Registration

The Act has created a registration regime for healthcare practitioners in Namibia and only registered persons are allowed to practice medicine.[562] In this context, only registered persons are allowed to perform the following functions for gain:

- the physical or mental examination of persons,
- the diagnosis, treatment, or prevention of physical or mental defects, illness, or deficiency in persons,
- the giving of advice regarding such defects, illnesses, or deficiencies,
- the prescribing or providing of medicine or any artificial denture or other dental appliances in connection with the defects, illnesses, diseases, or deficiencies,
- the prescribing, compounding, or dispensing of a medicine for consumption by human, or
- the rendering of pharmaceutical care.[563]

The Minister, on the recommendation of the Council, is empowered to prescribe by way of regulations the qualifications which entitles the holder to registration under the Act.[564] However, no qualifications obtained from an educational institution or other examining authority situated outside Namibia may be prescribed by the Minister unless such qualification entitles the holder to practice the profession concerned in the country or state in which such educational institution or other examining authority is situated; and the Minister is satisfied that such qualification is of a standard of professional education not lower that the qualification

562 S 17 of the Act provides that no person may practice a within the Republic of Namibia as a medical practitioner, dentist, or any other profession registrable unless he/she is registered in terms of the Act.

563 S 17 (2) of the Act.

564 S 18 (1) of the Act. The minimum qualifications required for registration as medical practitioners are prescribed in GN 277 (GG 6442/ 2017) and the minimum qualifications required for registration as dental practitioners in GN 51 (GG 3595/2006).

prescribed in Namibia in respect of the profession concerned.[565] Any person who wishes to be registered under the Act must submit to the registrar of the Council an application accompanied by the certificate relating to the qualification upon which the applicant relies for registration together with such proof of identity and a letter of good standing if the applicant was registered previously in a country other than Namibia to practice a profession in respect of which registration is applied for.[566]

Registration may only be granted by the Council after having considered the application for registration, the documents and other information submitted and where applicable, the results of any evaluation[567] and on satisfaction that the applicant met the requirements relating to study and qualifications prescribed in respect of the profession concerned; has submitted all required documents in support of his or he application; he/she is a fit and proper person to be so registered.[568] The Council may however refuse the application if it is satisfied that the applicant has not met these requirements.[569]

The Council must establish and keep separate registers in respect of different professions or registered persons as the Council, may determine from time to time, the registration of persons; and students or interns who are completing training or internship relating to a qualification required for registration to practice any such profession.[570] The register must contain personal and professional information of the registered practitioner.[571] The Act also provides for the

565 S 18 (2) of the Act.
566 S 19 of the Act.
567 S 20 (3) of the Act provides that the Council may require an applicant to pass to its satisfaction an evaluation in order to determine whether or not the applicant possesses adequate professional knowledge, skills, and competence in the profession for which registration has been applied for; and is proficient in the official language of Namibia.
568 S 20 (2) of the Act.
569 S 20 (2) (b) of the Act.
570 S 23 of the Act.
571 S 23 (3) of the Act.

removal of names from the register for specific reasons[572] and for the restoration of names to the register provided certain requirements are satisfied.[573]

The purpose of registration and certification is to ensure that all persons practising healthcare professions are not only suitably qualified and but able to safely practice in connection with the diagnosis, treatment, pharmaceutical care, or the prevention of physical or mental defects, illnesses, diseases, or defects in persons. The Act prohibits any person who is not registered from performing these acts and doing so while unregistered is guilty of an offence and, on conviction, liable to a fine not exceeding N$ 20 000 or to imprisonment for a period of time not exceeding five years, or to both such fine and such imprisonment.[574]

It is interesting to note that, while the Act grants powers to the Council to register healthcare practitioners, it also creates a regime under which the Minister may grant written authorisation to any person who complies with the prescribed conditions and requirements, to practise a

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572 In terms of S 24 of the Act, the Council may remove from the register the name of any registered person –

- who failed to notify the registrar of any change of his or her address or correct physical address within a period of three months after the date of a request for such information by the registrar,
- who has requested in writing that his or her name be removed from the register,
- who has failed to pay to the Council on or before 31 March of the year concerned the annual fees determined by the Council and payable by that registered person,
- whose name has been removed from the register, record or roll of any educational institution from which that person received the qualification by virtue of which he/she was registered in terms of the Act,
- who has been found guilty of unprofessional conduct and upon whom the penalties prescribed in s 42 (1)(c) have been imposed, and
- who is declared mentally ill in terms of the Mental Health Act 18 of 1973.

573 The requirements include the submission of the prescribed application of restoration of a name to the register and such prescribed documents and information or as the Council may require; if the name of the person was removed from the register due to none payment of annual fees, proof of payment of the outstanding annual fees concerned; if the name of the person was removed from the register for having been found guilty of unprofessional conduct and upon whom the prescribed penalties have been imposed, proof to the satisfaction of the Council that he/she has complied with all conditions or requirements as may be prescribed or as the Council may require in respect of such application, and the applicant is fit and proper person to be so restored to such register; if the name of the person was removed from the register after having been declared mentally ill, written proof to the satisfaction of the Council of his or her sound mental health that the order of court placing him or her under curatorship has been set aside; and payment of the fees determined by the Council in respect of such application for restoration.

574 S 34 (1) of the Act.

healthcare profession in the employment of the State.[575] It is worth noting that the Minister may only grant authorisation to practise in the employment of the State after consultation with the Council and, once the authorisation has been granted, the Minister must submit to the Council, as soon as practicable, a copy of the written authorisation.[576] Once the practitioner is properly authorised, he/she becomes the subject of the disciplinary powers of the Council as stipulated in Part V of the Act and should he/she contravene or fail to comply with any restrictions or condition in respect of his or her professional activities as specified in certificate of authorisation, he/she is guilty of an offence and on conviction liable to a fine not exceeding N$ 6000 or to imprisonment for a period of time not exceeding 18 months, or to both such fine and such imprisonment.[577]

4.3.2 Ethical standards and codes of professional conduct

Ethics is derived from a Greek word "ethikos" which means character; in this context it refers to a system of moral principles or standards governing the conduct of a member of the medical profession in the exercise of his or her profession.[578] Ethical standards may be shared as informal norms and values of the medical community or formally in a codified manner and carry the force of the law.[579]

In Namibia, the Council is mandated by Parliament to guide registered persons regarding the code of conduct and ethical standards relating to their professions.[580] In this connection, the Council issued rules specifying the acts or omissions by registered persons which constitute

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575 S 62 of the Act. It is worth noting that no regulations have been issued by the Minister in terms of this section prescribing the requirements and conditions to complied with by a person who may apply for authorisation.

576 S 62 (9) of the Act.

577 S 62 (10) & (11) of the Act.

578 Venes, D. (2017). *Taber's Cyclopedic Medical Dictionary*. 23rd Ed. Philadelphia: F.A. Davis Company. p. 853.

579 Gorman, H. E. (2014), *supr*a note 45. p. 494.

580 S 5 of the Act.

unprofessional conduct[581] and in respect of which the Council may conduct inquiries and disciplinary proceedings.[582] These rules, for example, prohibit the canvassing or touting for patients, accepting or receiving fee or commission for referring patients to the other practitioner, practising in partnership with an unregistered person, distribution of false information concerning medicines, divulging confidential information regarding a patient without express consent of the patient or his or parent or guardian and performing professional acts in respect of which the practitioner is inadequately trained or insufficiently experienced.[583] In addition, to avoid healthcare professionals performing activities in respect of which they are inadequately trained or insufficiently experienced, the Minister issues regulations stipulating the acts falling within the scope of practice of a healthcare practitioner.[584]

Furthermore, the Council has issued ethical guidelines for healthcare professionals outlining the following core ethical values and standards for good medical practice.[585]

i. to respect patients as persons, and acknowledge their intrinsic equal worth, dignity, and sense of value;
ii. not to harm or act against the best interest of patients, even when they conflict the health professional's own interest;
iii. to act in the best interest of patients even when there are conflicts with the health professional's own interest;
iv. to recognise that some interests of individuals may be so important that they acquire the status of human rights in the form of either claims of freedom to be respected by all;

581 S 1 of the Act defines " unprofessional conduct" as an improper or dishonourable or unworthy conduct, or conduct which, when regard is had to the profession of the registered person, is improper or disgraceful or dishonourable or unworthy, and includes acts and omissions specified in terms of S 37(1)".
582 S 37 (1) of the Act.
583 Rules relating to improper conduct or misconduct by a medical practitioner. GN 197 (GG 2851/2002).
584 Regulations relating to scope of practice of a medical practitioner. GN 35 (GG 6249/2017).
585 HPCNA (2010). *Ethical Guidelines for Health Professionals*. Windhoek: Health Professions Councils of Namibia. p. 3.

v. to respect patient's right to self-determination or to make their own informed choices, living their lives by their own beliefs, values, and preferences;

vi. to incorporate core ethical values and standards as the foundation for good and upright character and responsible medical practice;

vii. in a professional relationship with patients, to regard the truth and truthfulness as the basis of trust;

viii. in a professional relationship with patients, to treat personal or private information as confidential, unless overriding reasons confer a moral right to disclosure;

ix. to be sensitive to and empathise with individual and their social needs for comfort and support or seek and create opportunities to translate emotions, such as feelings of sympathy or empathy into action;

x. to respect the right of people to have different ethical beliefs as these may arise from deeply held personal, religious, or cultural convictions;

xi. to treat all individuals and groups in an impartial, fair, and just manner, and

xii. to continually strive to attain the highest level of knowledge and skill required within the health professional's area of practice.

4.4 Socialisation of new members

This component refers to the teaching of new members of the medical community how to exercise ethical and practice standards daily. Any disgraceful conduct by a healthcare professional would seemingly signify the failure of one or both of the key institutions of professional socialisation, namely, medical schools where standards of professional conduct

are formally taught, and hospitals and clinics, where healthcare practitioners absorb professional norms and values through informal observation and interaction.[586]

Under section 5 of the Act, the Council is given powers to control and exercise authority in all matters affecting the education and training of persons in or relating to the diagnosis, treatment, pharmaceutical care, or the prevention of physical or mental defects, illnesses, diseases, or defects in persons; and the way practises in connection with the diagnosis, treatment, pharmaceutical care, or the prevention of physical or mental defects, illnesses, diseases, or defects in persons are to be exercised.

With regard to education and training, Council powers are given effect in section 16 of the Act, which, provides that no person or educational institution may offer or provide in Namibia any education, tuition or training having as its object to qualify any person to practice any profession to which the Act applies, or perform any activity directed at the physical examination of any person, or the diagnosis, treatment, pharmaceutical care, or the prevention of any physical defect, illness, disease or deficiency in persons, unless such education, tuition or training has been approved by the Council in writing as being appropriate education, tuition or training for such purposes.[587]

The approval granted to a person or educational institution may be made subject to such conditions and requirements, and may be granted for such period, as the Council may determine at the time of such approval and specify in the certificate of approval.[588] The Council may then appoint in writing, from time to time, a person to investigate whether the prescribed conditions and requirements determined by the Council, in respect of a person or an educational

586 Gorman, H. E. (2014), *supr*a note 45. p. 497.
587 S 16 (1) of the Act.
588 S 16 (6) of the Act.

institution, are being complied with and to report to the Council his or her findings in such form and manner as the Council may determine and inform that person in writing.[589]

The Council may withdraw in writing the approval granted to the person or educational institution, if it is satisfied, after having given the person or educational institution an opportunity to be heard, that the person or such educational institution has failed to comply with any applicable prescribed condition, or condition or requirement determined by the Council and specified in the certificate of approval. Any person or educational institution who contravenes or fails to comply with the provisions of this section is guilty of an offence and on conviction liable to a fine not exceeding N$ 6000 or to imprisonment for a period of time not exceeding 18 months, or to both such fine and such imprisonment.[590]

Section 30 of the Act also provides that every educational institution in Namibia, at which a qualification can be obtained, and which qualification will entitle the holder to registration in terms of the Act, must furnish the Council in writing, at the request of the Council and within a period of 30 days after the receipt of such a request, with full particulars in respect of

- the standard of general education and training required of students for admission to the relevant course or field of study;
- the courses of study, training and examinations required of a student before such qualification may be granted;
- the particulars of examinations conducted and the results thereof in respect of a specific student or of a specific category of students, and

589 S 16 (7) of the Act.
590 S 16 (11) of the Act.

- such other particulars relating to the education and training offered by such educational institution as the Council may from time to time require.[591]

If any educational institution fails or refuses to submit the particulars requested by the Council or it appears to the Council that any provision of the Act or any condition prescribed or determined by or in terms of the Act pertaining to the educational institution is not properly being complied with, and such improper compliance may adversely affect the standard of education, tuition and training in respect of the professional training concerned to be maintained at such educational institution, the Minister may determine, on recommendation of the Council and by notice in the Gazette, that any qualification granted by the educational institution after the date specified in such notice does not entitle any holder thereof to registration in terms of the Act.[592]

The Council may appoint in writing, a person to investigate whether the prescribed conditions, and the conditions and requirements determined by the Council, in respect of an educational institution are being complied with by such an educational institution, and to report to the Council on such investigation within such period of time and in such manner as the Council may determine and specify in such written appointment.[593] Professional ethics has been made part of both basic education curriculum and continuing professional development (CPD).

Besides formal education, the Act also provided a framework CPD.[594] It has become mandatory for all registered healthcare professionals to comply with CPD requirements, which includes the attending or completion or presenting of study courses or refresher courses, or the passing

591 S 30 (1) of the Act.
592 S 30 (2) of the Act. It is important to note that no such action has ever been taken by the Minister against an educational institution.
593 S 30 (6) of the Act.
594 S 32 of the Act and the regulations relating to continuing professional development applicable to registered persons 92 (GG 4482/2010).

of examinations relating to such professional development,[595] and that the registration of a registered person may not be maintained unless that registered person has complied to the satisfaction of the Council, with the prescribed CPD requirements.[596]

Unique from the other 2004 Acts, the Pharmacy Act 9 of 2004 provides for the registration of both the persons to practice the pharmacy profession, the pharmacies and the owners of such pharmacies, the training pharmacies and tutor pharmacists; and for pharmacy practices owned by pharmacists, companies and close corporation conducting business as pharmacists.[597] It is mandatory that every pharmacy, including those conducted by a public company or a close corporation, is managed by a registered pharmacist and is under the continuous personal supervision and control of such a person.[598] It is also required that the name of the pharmacist in charge of a pharmacy is displayed conspicuously at the main entrance of the pharmacy in case a member of the public wishes to speak to him or her.[599] Pharmacists are prohibited to pay any person a commission or reward a person in connection with a prescription which a medical practitioner, dentist or veterinarian has issued and whoever does it is guilty of an offence and on conviction liable to a fine not exceeding N$ 6 000 or to imprisonment for a period of time not exceeding 18 months, or to both such fine and such imprisonment.[600]

Apart from for section 55 of the Act, which allows the Council to authorise any person to investigate or inspect any matter relating to the education and training of a healthcare professional or to inspect the professional practice of a healthcare professional including the premises where such practice is being performed, the Namibian regulatory framework for

595 S 32 (1) of the Act.
596 It should be noted that in terms of S 26 of the Act, all registered persons must maintain their registration by paying the prescribed annual fees to the Council.
597 See Sections 19, 25, 35 & 36 of the Pharmacy Act 9 of 2004.
598 S 39 (1) of the Pharmacy 9 of 2004.
599 S 39 (2) of the Pharmacy 9 of 2004.
600 Ss 59 & 68 of the Pharmacy Act 2004.

healthcare professions does not empower the Council to determine, monitor and enforce standards of professional conduct in healthcare settings where socialisation of healthcare professionals is taking place.[601]

4.5 Social control of deviants

This component refers to enforcement of ethical and practice standards and disciplining those who may violate them. Professional social control can function through a casual engagement method or through formal systems of supervising and chastisement.[602] The Act has given the Council powers to deal firmly, fairly and promptly with a registered person against whom a charge, complaint or allegation of unprofessional conduct has been laid or whose fitness to practise his or her profession is in doubt.[603]

Section 37 provides that the Council can inquire into or deal with any complaint, charge or allegation relating to a registered person and such powers are not limited to the acts and omissions specified in the rules issued by the Council.[604] It is also important to note that the rules issued by the Council must be approved by the Minister in writing and published in the Gazette before they can have force and effect.[605] Using these rules, the Council can investigate and conduct an inquiry into any complaint or charge or allegation of unprofessional conduct against any person registered lodged with the Council.[606]

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601 S 55 provides that "the Council may authorise in writing any person –
to investigate or inspect any matter relating to the education, tuition or training of any person receiving such education, tuition, or training for the purpose of qualifying himself or herself to practise a profession to which this Act applies; to inspect the professional practice of any registered person, including the premises where such practice is being conducted"

602 Gorman, H. E. (2014) *supr*a note 45. p. 499.

603 S 5 of the Act.

604 S 37 (2) of the Act.

605 S 37 (3) of the Act. The rules relating to improper conduct or misconduct by a medical practitioner are published in GN 197 (GG 2851/ 2001) and the rules relating to improper conduct or misconduct by dental practitioner is published in GN 197 (GG 2851/ 2002).

606 S 38 (1) of the Act. The regulations relating to the procedures on lodging of complaints and procedures to be followed at disciplinary inquiry are prescribed in GN 31 (GG 2489/ 2001).

When the Council is in doubt as to whether or not an inquiry should be conducted, it may seek information from any person, including the person against whom the complaint or allegation has been lodged.[607] Any registered person who refuses to comply, or who complies insufficiently, with a lawful instruction of the Council, is guilty of unprofessional conduct, and liable to payment of a fine not exceeding the prescribed amount.[608]

The Council may delegate any of its powers to the preliminary investigations committee (hereafter referred to as the PIC) and appoint the members of such a committee including its chairperson who must determine the procedures to be followed at the meetings of the committee. The president and the vice-president of the Council are however prohibited from serving on the PIC. In addition, the PIC has the power to co-op one or more registered persons to its ranks.[609]

The duty of the PIC is to conduct preliminary investigation into any matter in respect of which the Council is to conduct an inquiry and referred to it by the Council. Once the PIC has carried out an investigation, it must submit a written report to the Council relating to the preliminary investigation conducted, including the findings and recommendations in respect of the matter investigated.[610]

Section 12 (2) of the Act provides that the Council must establish a standing professional conduct committee (hereafter referred to as the PCC) to exercise the disciplinary powers of the Council set out in PART V of the Act. It would therefore mean that the Council may conduct an inquiry by itself or delegate all or any of its powers to conduct an inquiry to the PCC. The membership of the PCC consists of not less than one medical practitioner, one dentist, one legal

607 S 38 (4)(a) of the Act.
608 S 37 (4)(a) of the Act.
609 S 12 (5) (b) (c) (d) of the Act.
610 S 12 (5) (b) (c) (d) of the Act.

practitioner having not less than ten years of experience in the practising of law, and one other person who is not a registered person. A professional conduct inquiry must be open to the public, unless the PCC, and subject to Article12(1) (a) of the Namibian Constitution, otherwise determines.[611]

The penalties that may be imposed on a person who is found guilty of unprofessional conduct at an inquiry or who admits that he/she is guilty of the charge concerned may include a reprimand or caution; suspension from practising or performing acts pertaining to the profession in respect of which that person is registered; removal of the name of that registered person from the register; or payment of a fine.[612] The Council may recover any fine imposed at an inquiry by means of proceedings in a competent court. A finding made or a penalty imposed, by the Council, unless appealed against it, remains effective after the date determined by the Council or PCC.[613] If an appeal is lodged against a penalty for the removal or suspension of a registered person from practice, such penalty remains effective until the appeal has been finally determined.[614]

The Council may postpone, for such period of time and on such condition as it may determine, the imposition of penalty or may impose any penalty, but order its execution to be postponed for a specific period and on such condition as the Council may determine. If at the end of the period of time for which the imposition of a penalty was postponed the Council is satisfied that the person has observed all the relevant conditions relating to such suspension, the Council

611 S 39 (14) of the Act.

612 S 42 (1) of the Act. The maximum fine that the Council or PCC may impose under s 42 (1)(d) are prescribed in GN 155 (GG 5559/ 2014. It is also important to note that s 37 (4) (b) of the Act, provides that any registered person who is found guilty of an offence under the Hospitals and Health Facilities Act 36 of 1994 is equally guilty of unprofessional conduct, and on proof of such conviction in a professional conduct inquiry liable to any one or more of the penalties prescribed in s 42 (1). The Hospitals and Health Facilities Act is discussed in more detail in the next chapter.

613 S 42 (2) of the Act.

614 S 42 (9) of the Act.

must give notice to the registered person that no penalty will be imposed upon him or her. The same should happen if the execution of a penalty has been suspended and the Council is satisfied that the registered person has observed all relevant conditions. The registered person must be notified by that person that such penalty will not be executed. Should the registered person however fail to observe any of the conditions of suspension of imposition or execution of the penalty, the Council must put the suspended penalty into operation by notice to that person, unless if the registered person satisfies the Council that such failure was due to circumstances beyond his or her control.[615]

A registered person who has been suspended from practising the profession in respect of which he/she is registered, or from performing certain acts, or whose name has been removed from the register, is disqualified from practising such profession and his or her registration certificate is regarded to be cancelled until the period of suspension has expired or his or her appeal against such penalty is upheld, or until his or her name has been restored to the register by the Council.[616] A person who practices the profession while on suspension or after his or her name has been removed from the register, is guilty of an offence and on conviction liable to a fine not exceeding N$ 20 000 or to imprisonment for a period of time not exceeding five years, or to both such fine and such imprisonment.[617]

It is important to note that the institution of a professional conduct inquiry against a registered person does not prejudice the right of any person, body, or institution to institute civil proceedings, or the prosecutor-general to institute criminal proceedings, or an employer to take disciplinary action against the registered person arising from or based on the same facts.

615 S 43 (1) & (2) of the Act.
616 S 44 (1) & (2) of the Act.
617 S 44 (3) of the Act.

Similarly, civil or criminal proceedings against a registered person, or the fact that an employer has taken disciplinary action against a registered person, does not prejudice the right of the Council to institute a professional conduct inquiry against that registered person, or from imposing penalties on that person for unprofessional conduct arising from or based on the same facts. [618]

Although any incriminating reply or information obtained, or incriminating evidence directly or indirectly derived from questioning in a professional conduct inquiry is not admissible as evidence against that person in criminal or civil proceedings in a court of law, such incriminating evidence is admissible in criminal proceedings where the registered person who has been dully summoned to appear before the Council or PCC for the purpose of an inquiry is to stands trial for (a) refusing or failing, without sufficient cause, to attend the inquiry; (b) refusing to take the prescribed oath or to make an affirmation when required by the person presiding at such inquiry; (c) leaving the inquiry without the consent of the chairperson of the PCC, whether or not that person has given evidence; (d) refusing to give evidence before the PCC; (e) refusing to answer fully and satisfactorily to the best of his or her knowledge and brief any question lawfully put to him or her; or (f) refusing to produce any document, book, record or a thing which that person has in terms of the summons been required to produce.[619]

To ensure justice, the Act made provision of review and appeal processes. Section 56 of the Act provides that any person who is aggrieved by a finding or a decision made, or a penalty imposed, or the refusal or failure to make a finding or a decision by the Council or by the PCC, may appeal to the appeal committee of the Council against such a finding or a decision made, or such a penalty imposed, or such a failure to make a finding or a decision. In addition, a

618 S 40 (1) & (2) of the Act.
619 Ss 40 (3) & 39 (8) (c) of the Act.

person who is aggrieved by any decision of the appeal committee may appeal to the High Court of Namibia against such a decision.[620] In that case, the appellant must lodge a file of notice of appeal with the registrar of the High Court within a period of 30 days after the date upon which the decision appealed against was made.[621] However, the High Court may allow, on good cause shown, an appeal to be lodged after the expiry of the period of 30 days.[622]

The Act also made special arrangement for suspected unnatural deaths of patients while receiving medical care in that a death of a person whilst under the influence of a general or local anaesthetic or of which the administration of anaesthetic has been a contributory cause, shall not be regarded to be a death from natural causes as contemplated in the Inquests Act[623] or the Births, Marriages and Deaths Registration Act.[624] Such a death should be considered as unnatural, and a formal inquest must be carried out to determine the actual cause of death.[625]

Seeing that healthcare professionals are equally fallible, section 48 of the Act empowers the Council to manage in a prescribed manner, a registered practitioner who has become impaired[626] to such extent that: (a) it would be against the public interest to allow him or her to continue practising the profession for which he/she is registered; (b) he/she is unable to practice the profession with reasonable skills or safety to his or her patients; or (c) he/she has become

620 S 57 (1) of the Act.
621 S 57 (2) of the Act.
622 S 57 (3) of the Act.
623 Act 6 of 1993.
624 Act 81 of 1963.
625 S 52 of the Act.
626 According to s 48 (1)(a) of the Act impairment refers to "a mental or physical condition or the abuse of, or the dependence on, any medicine, scheduled substance, dependence – producing substance, chemical substance or any other substance, which negatively affected the competence, attitude, judgement or performance of any registered person".

unfit to purchase, acquire, keep, use, administer, prescribe, order, supply, or possess any scheduled substance.[627] The Minister responsible for health has issued regulations relating to[628]

- the investigation of the impaired healthcare practitioner and the circumstances under which such investigation may be conducted,
- the assessment of the condition of the impaired healthcare practitioner and the procedure relating to such an assessment,
- the manner in which an inquiry must be conducted in order to make a finding relating to the impaired healthcare practitioner's competence to practice the profession for which he/she is registered,
- the conditions or restrictions which may be imposed on the impaired healthcare practitioner's registration or practice,
- the suspension or removal of the impaired healthcare practitioner from practising his or her profession and the manner in which such order must be executed,
- the rescission of any condition imposed or of an order for the suspension or removal from practising a profession, and
- the appointment of a health assessment committee to conduct investigations, assessments, and inquiries in respect of an impaired healthcare practitioner.

It is important to note that if an impaired healthcare practitioner continues to practice the profession in respect of which he/she is registered or simply performs any act relating to such profession while she or he is suspended or removed from the register in accordance with these regulations or in any manner disregards or act contrary to any condition applicable to him or her in terms of these regulations, the impaired healthcare practitioner is guilty of an offence

627 S 48 (2) of the Act.
628 See GN 299 (GG 5338 / 2013) and S 48 (4) & (5) of the Act.

and on conviction liable to a fine not exceeding N$ 20 000 or to imprisonment for a period of time not exceeding five years, or to both such fine and such imprisonment.[629]

4.6 The liability system

Health service delivery can broadly be accommodated under the law of obligations: either the law of contract or the law of delict.[630] When medical negligence is suspected a patient or his or her relatives may opt to institute a civil claim to recover damages[631] and or may file a criminal charge against the healthcare professional. These may be in addition to lodging a complaint with the Councils for unprofessional conduct. The outcome of the unprofessional conduct may result in the suspension of a healthcare professional from practice or removal of his or her name from the register at the Council.[632] A medical negligence, or simply an allegation of such, could result in far reaching consequences against a healthcare practitioner.[633]As indicated in chapter one, it is necessary that healthcare professionals in providing care to patients should adhere to the ethics principles of patient autonomy, non-maleficence, beneficence and justice.[634]

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629 S 48 (6)of the Act.

630 Whether health service is delivered in the public or private facility, in the normal course of events the relationship between the patient and a healthcare professional is a contractual one, but a breach of duty of care and negligence may underline both contract and delict. If there is no contract between parties, the relationship is governed by the law of delict. See Carstens, P.A., & Pearmain, D. (2007), *supra* note 6. pp. 283- 284.

631 Coetzee, L.C., & Carstens, P. (2013), *supra* note 204. p. 405 and Pienaar, L. (2016), *supra* note 204. p. 4.

632 If healthcare professional is found guilty of unprofessional conduct the Council can impose on him or her one or more of these penalties, a reprimand, or a caution; suspension for a specified period from practising acts pertaining to his or her profession; removal of the name of the healthcare professional from the register or payment of a fine. See S 42 of the Social Work and Psychology Act 6 of 2004; S 41 of the Allied Health Professions Act 7 of 2004; S 42 of the Nursing Act 8 of 2004; S 50 of the Pharmacy Act 9 of 2004 and s 42 of the Medical and Dental Act 10 of 2004.

633 Moore, W., & Slabbert, M. N. (2013), *supra* note 206. p. 60.

634 Para 1.8.

4.6.1 The law of contract[635]

A patient enters in a contractual relationship when consulting a healthcare practitioner in a private practice, and a particular practitioner, and when he/she presents him/herself for medical treatment at a hospital, he/she enters into a contractual relationship with that particular hospital.[636] Liability flows naturally from such a relationship: in the former case, the healthcare practitioner incurs liability for negligent conduct that may occur; in the latter case both the hospital authority and its staff may also incur liability for the negligent conduct of the hospital employee.[637] Contractual agreement between a healthcare practitioner or hospital comes into being by a mere consensus between the parties and no formalities are required.[638] In such cases where no expressed agreement has been reached, the terms of such engagement may be implied from the conduct of the parties depending on the specific circumstances of the case.[639]

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635 A contract may be defined as an agreement arising from either true or quasi-mutual assent, which is or is intended to be enforced by law. The doctrine of quasi-mutual assent was coined in *Smith v Hughes* 1871 LR 6 QB 597 607 an enquiry into the existence of an agreement which always proceed as follows: judging by the external manifestation where the parities of the same mind at the conclusion of contract? If so, there was an agreement. If the answer is no, was the one party reasonably entitled to assume, from the words or actions of the other party, that they were truly of the same mind? If so, there will be deemed to have an agreement, if not, then, and only then one is entitled to say there was no agreement. See Christie, R.H. (2006). *The Law of Contract in South Africa*. 5th Ed. Durban: LexisNexis Butterworths. pp. 2 & 24.

636 Coetzee, L.C.; & Carstens, P. (2011) *"Medical Malpractice and Compensation in South Africa"* 86 Chi.-Kent L. Rev. 1263. Available at: https:// scholarship kentlaw.iit.edu/cklawreview/vol86/iss3/10. p. 1269. The legal relationship between a healthcare practitioner is a consensual one and mostly entered on an *ad hoc* basis. Generally, there is no legal duty on a healthcare practitioner to accept a patient and it is equally true that healthcare practitioners have no general rights to treat any person. A healthcare practitioner's right to treat a patient is based entirely on the patient's consent except in cases where the patient is under a statutory duty to submit him or herself to treatment or examination for purposes of public health or in cases where a patient is brought to a healthcare practitioner in an unconscious or semi-conscious state. See Strauss, S.A (1984), *supra* note 517. p. 3.

637 Strauss, S.A (1984) *supra* note 517. p. 3.

638 Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 115.

639 The implied agreement normally entails that a healthcare practitioner undertakes to examine the patient, to diagnose his or her ailment and to treat the patient with such professional skill, competence, and judgement in the similar manner the average healthcare practitioner in the same branch of the profession and under the same circumstances would do. See Coetzee, L. C.; & Carstens, P. (2011), *supra* note 610. p. 1269.

Written contracts between patients and healthcare providers, or hospitals, are also common especially before an invasive surgical procedure for which an expressed consent is required.[640] Irrespective of whether the agreement is expressly or implicitly provided, a healthcare practitioner only undertakes to act in accordance with the recognised, accepted, customary or usual practices of his or her profession and to treat the patient with such measure of skill and competence as reasonably expected from a healthcare practitioner belonging to his or her branch of the profession. [641]

Jackson and Powell[642] indicated that in medicine a positive outcome cannot always be guaranteed, and by engaging a patient, a healthcare practitioner or a hospital does not offer an assurance that the patient will be cured, or the treatment intervention will be successful. However, a healthcare practitioner or hospital that fails to perform in accordance with or departs or deviates from the expressed or implied terms of the agreement is in breach of the contract.[643]

A healthcare practitioner is expected to exercise reasonable skill and care, hence if he/she performs his or her duties in a negligent manner, such conduct will amount to a breach of contract.[644] A healthcare practitioner or hospital that has breached a contract with a patient may be held liable for patrimonial loss.[645] A healthcare practitioner who breached the contract may

640 Coetzee, L. C.; & Carstens, P. (2011), *supra* note 636. p. 1269. Christie, R.H. (2006), *supra* 635. p. 22. indicated that agreement by consent is the foundation of a contract.

641 Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. pp. 115–116 and Coetzee, L. C.; & Carstens, P. (2011), *supra* note 636. p. 1269. See also *Mitchell v Dickson* 1914 AD 419. p. 525.

642 Jackson, R. M. & Powel, J. L (1987) *Professional Negligence.* 2nd Ed. London: Sweet and Maxwell. p. 288.

643 *Burger v Adm'r Kaap* 1990 (1) SA 483 (C). p. 590.

644 Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 116.

645 Patrimonial loss is described by Boberg as quoted by Claassen & Verschoor (1992), *supra* note 442. p. 121 as "a calculable pecuniary loss or diminution in the plaintiff's patrimony (estate) resulting from the defendant's unlawful and culpable conduct. Mere mental distress, injured feelings, inconvenience or annoyance can support an award of Aquilian damage." On the other hand, Claassen & Verschoor defined non-patrimonial loss as " the prejudicial change or factual intrusion of the legally protected personality interest of a person, which or intrusion does not influence his or her economic position." Patrimonial loss are example medical expenses incurred during hospitalisation. Non-pecuniary damages such as pain and

be denied an opportunity to recover any remuneration for the services that he/she had rendered to an aggrieved patient.[646]

Once an agreement between a healthcare practitioner and a patient has been concluded, a healthcare practitioner is not expected to terminate it unilaterally;[647] however once the treatment has been provided, the agreement comes to an end and the healthcare practitioner can no longer be expected to attend to a patient.[648] However, should the patient be the one making it difficult for a healthcare practitioners to provide the required treatment, he/she can exit from the contract.[649]

An agreement to treat the patient does not necessarily mean the healthcare practitioner should always be the one providing the required care.[650] In some cases, it may be necessary to involve other healthcare practitioners in the care of that patient and also sometimes by referring such a

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suffering cannot be recovered in contract. See Coetzee, L. C., & Carstens, P. (2011), *supra* note 636. p. 1270.

646 In *Recsei's Estate v Meine 1943* EDL 277 a healthcare practitioner's claim for the payment of his fees was dismissed because the patient has specifically stated that the operation to which he had performed on him should have been performed by two other physicians. A similar decision was made in *Hewat v Rendal* 1925 TPD 679 because a healthcare practitioner had negligently lost a patient's biopsy after he had undertaken to send it to the laboratory for examination and report. See also Claassen & Verschoor (1992), *supra* note 442. p. 116.

647 This may expose the healthcare practitioner to contractual claims and may also be held delictually responsible should the patient suffer any personal injury as a result of the delayed or the culpable interruption of treatment. See Strauss, S.A., & Strydom, M. J. (1967) *Die Suid-Afrikaanse geneeskungig reg.* Pretoria: JL van Schaik. Page 114. Certainly, if the patient refuses to subject him or herself to treatment, the practitioner may not coerce him or her to do so provided that, he/she has the required mental capacity to do so and well informed about the possible consequences of such a decision. See Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 117.

648 Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 117.

649 Strauss and Strydom as quoted by Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 117 mentioned the following examples: where a patient failed to keep appointment , where a patient disregarded the healthcare provider's advice and prescription or physically preventing the practitioner from administering the treatment provided that patient has the required mental capacity. Strauss, S. A (1984), *supra* note 517. p. 3. indicated that a patient may stubbornly or stupidly refuse treatment which is essential in order to preserve or save his or her life. All what a healthcare practitioner may do is to advise him or her to undergo treatment and if the patient is an adult of sound mind persist, there is nothing a healthcare practitioner can do. For all practical purposes, the law recognises the patient's right to die, and a healthcare practitioner must respect the patient's wishes. Subjecting a patient to treatment against his or her expressed will may amount to assault.

650 Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 117. See also Coetzee, L. C., & Carstens, P. (2011), *supra* note 636. p. 1271.

patient to another healthcare practitioner.[651] Such referral does not amount to a breach of a contact and, in fact, failure to refer a patient to someone more competent to provide the required care may amount to negligence.[652]

In terms of the patient safety matrix, the law of contract aims at preventing unsafe behaviour by controlling or influencing the interaction between the healthcare practitioner or a hospital and a patient and assigning liability to individual providers and apportioning damages for pecuniary loss suffered by victims.[653]

4.6.2 The law of delict

The law of delict belongs to the family private law which regulates the relations between individuals in the community.[654] Neethling *et al* defined a delict as an act of a person that by a wrongful and culpable manner causes harm to another person: all five elements i.e. an act, wrongfulness, causation and harm must be present before the contact complained about may be regarded as a delict.[655] The law of delict creates an obligation on the wrongdoer to compensate the prejudiced person for the damage he/she suffered and a corresponding right on the prejudiced person to claim for compensation from the wrongdoer.[656]

The law of delict is based on three pillars: action in terms of which damages for the wrongful and culpable act causing of patrimonial damages are claimed; action directed at satisfaction for

651 Coetzee, L. C.; & Carstens, P. (2011), *supra* note 636. p. 1271.

652 Coetzee, L. C.; & Carstens, P. (2011), *supra* note 610. p. 1271.

653 In the case of *Administrator, Natal v Edward* 1990 (3) SA 581 (A) a contractual claim for health services against the State was decided based on the law of contract because it was not open to the plaintiff to claim in delict because the law of contract was the preferred basis of the claim. The contract was for an elective sterilisation and therefore cantered around specific outcome as opposed to any other surgical procedure of which particular outcome is seldomly guaranteed.

654 By contrast, the purpose of public law is to regulate the relations between the state and the individuals, and between the organs of the State. See Neethling, J., & Potgieter, J. M. (2010), *supra* note 6. p. 3.

655 Neethling, J., & Potgieter, J. M. (2010), *supra* note 6. p. 3.

656 The law of delict therefore belongs to the part of private law referred to as the law of obligations. Idem.

wrongful and intentional damage to personality; and the action for pain and suffering by which compensation for injury to personality as a result of the wrongful and negligent impairment of bodily or physical or mental integrity is claimed.[657]

In terms of the law of delict, a healthcare practitioner and a hospital are expected to exercise reasonable care to prevent harm occurring to their patients.[658] Should they fail to do so, a patient who suffered damage or loss as a result of such wrongful failure may hold the healthcare practitioner or hospital liable for negligence.[659] A healthcare practitioner or hospital that intentionally violates the patient's physical integrity may be held liable for assault, while the healthcare practitioner or hospital who intentionally violates the patient's privacy may incur liability for injury to personality.[660]

The difference between delict and breach of contract is that the latter is only established by non-satisfaction by a contractual party of a contractual personal right or an obligation to perform.[661] The cure for a breach of a contract is directed at enforcement, fulfilment or execution of the contract and a claim for damages as remedy only comes secondary.[662] On the other hand, a delict is created by the violation of any legally recognised interest of another party, excluding the non-fulfilment of a duty to perform by a contractual party.[663] Delictual remedies are principally directed at damages or satisfaction, and not at fulfilment.[664] The law of contract therefore provides specific remedies for breach of contract that are not applicable to a delict, but a wrongdoer may be liable on contract and delict at the same time[665] and the

657 Neethling, J., & Potgieter, J. M. (2010), *supra* note 6. p. 5.
658 *Correira v Berwind* 1986 (4) SA 60 (Z) at 66; cf.
659 Coetzee, L. C., & Carstens, P. (2011), *supra* note 636. p. 1271.
660 Coetzee, L. C., & Carstens, P. (2011), *supra* note 636. p. 1271.
661 Neethling, J., & Potgieter, J.M. (2010), (2010), *supra* note 6. p. 5.
662 In *Administrator, Natal v Edouard* 1989 (2) SA 386 (D), Thrion J confirmed that a breach of contract does not give rise to a claim for non-patrimonial damage.
663 Neethling, J., & Potgieter, J. M. (2010), (2010), *supra* note 6. p. 5.
664 Neethling, J.,& Potgieter, J. M. (2010), (2010), *supra* note 6. p. 5.
665 Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 127.

injured party can choose to act on the one or the other.[666] While only patrimonial loss may be recovered on contract, both patrimonial and non-pecuniary damages are recoverable in delict.[667] The duty of care, which rests on a healthcare practitioner, is in addition to any existent contractual obligations between him or her and the patient, and the healthcare practitioner owes this duty to his or her patient even where no contract exists between them.[668]

The principle of vicarious liability is well established in modern law of delict. According to this principle, a person can be held delictually liable for the wrongful act of another by virtue of the doctrine of respondent superior.[669] Generally, at common law, a master or employer is vicariously liable for a delict committed by his or her servant or employee in the course of employment.[670] There must be a relationship of employment whereby one person, a master or employer, stands in a position of authority vis-à-vis another, the servant or employee in terms of which the former is legally capable of exercising control over the latter's actions.[671]

In the health field, a healthcare practitioner who is a member of staff of a hospital or health facility and occupies a firm and fixed position, is a servant of the hospital or health facility, and

666 For example, a healthcare practitioner who performed a medical procedure inappropriately may in the first place be guilty of breach of contract because the procedure was not performed properly in accordance with the agreement with a patient. Secondly, the commissioning of an unlawful act may also be present because the healthcare practitioner has injured the patient's personal integrity despite the contract. See Claassen, N.J.B., & Verschoor, T. (1992), *supra* note 442. p. 118.

667 Coetzee, L.C., & Carstens, P. (2011) *supra* note 636. p. 1271.

668 Jackson, R.M. & Powel, J.L (1987), *supra* note 642. p. 118.

669 A person can be held delictually liable if he/she has ordered or authorised another to commit a wrong act, however, authorisation to perform a negligent act will probably seldom occur. The question of vicarious liability normally arises in cases where a person employs another in order to perform a lawful activity and the servant then did not do so with the required or expected measure of skill and care and causes ham to others. See Strauss, S.A (1984), *supra* note 517. p. 343.

670 The leading cases in which this principle has been applied include: *Mkize v Martens 1914 AD 382; Union Government v Hawkins 1944 AD 556* and *Colonial Mutual Life Assurance Society Ltd v MacDonald 1931 AD 412*.

671 Relations between partners who are legally equal even if one of them may be more experienced than the other does do not stand in such a relationship and so do independent contractors. See Strauss, S. A (1984), *supra* note 501. p. 343.

the latter will be delictually liable for acts of professional negligence committed by the servant within the scope of his or her employment.[672]

The common law position on vicarious liability was codified in the Crown Liability Act, No. 1 of 1910 (which for the convenience of this study a new rubric 'State Liability' is used to substitute the time-honoured rubric 'crown-liability') was extended to SWA (South West Africa) by the Railway Management Proclamation 20 of 1920 and once so extended it remains the binding state liability legislation in Namibia to date.[673] The State Lability Act makes provision for delictual liability of the State in that a delictual claim against the State shall be cognisable by a court if the claim arises out of any wrong committed by any servant of the State acting in his or her capacity and within the scope of his or her authority.[674]

4.6.3 Criminal law

The relationship between a healthcare practitioner or hospital and a patient is not directly ruled by criminal law. This however does not mean that a healthcare practitioner cannot commit a criminal misdemeanour in the course of practising a healthcare profession.[675] The common law crimes that a healthcare practitioner may commit while taking care of a patient are such as

672 Strauss, S. A (1984), *supra* note 517. p. 344. See also *Esterhuizen v Administrator, Transvaal* 1957 (3) SA 710 (T) in which the court held that a hospital authority was liable for the unskilled professional acts of a doctor employed by the hospital who ordered excessive x-ray treatment of a patient suffering from sarcoma, resulting in necrosis which necessitated the amputation of both her legs and the left hand.

673 In the case of *Mwandingi v Minister of Defence* 1990 NR 363 (HC) at 377 C-D, the court confirmed that the Crown Liability Act No. 1 of 1910 was extended to SWA by the Railway Management Proclamation 20 of 1920. It was so extended for purposes of the Proclamation, but the Act applied in its entirety and once so extended, it was accepted by Namibian courts as also binding on all other. See Minister *of Defence v Mwandingi 1993* NR 63 (SC) at 77 C-F; *Hwedhanga v Cabinet of the Territory of SWA* 1988 (2) SA 746 SWA as well as *Binga v Cabinet of SWA & Others 1988* (3) SA 155 (A). See also LAC.(2010) *Index to laws of Namibia*. Windhoek: Legal Assistance Centre.

674 Sec 2 of the State Liability Act 1 of 1910.

675 Coetzee, L. C., & Carstens, P. (2011), *supra* note 636. p. 1272.

murder,[676] culpable homicide,[677]assault,[678] criminal defamation,[679] crimen injuria,[680] fraud,[681] perjury[682] and contempt of court.[683] A healthcare practitioner who intentionally caused or contributed to the death of a patient may be convicted of murder.[684] Active euthanasia would therefore be regarded as murder.[685] In the absence of intention, a professionally negligent healthcare practitioner can be held liable for culpable homicide.[686]

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676 According to Snyman, C. R. (2007). *Criminal Law.(* 4th ed.). Durban: LexisNexis Butterworths at page 442, murder is defined as an unlawful and intentional causing of the death of another human being.

677 Culpable homicide is the unlawful, negligent causing of the death of another human being" See Snyman, C. R. (2007), *supra* note 676. p. 425.

678 Assault consists in any unlawful and intentional act or omission (a) which results in another person's bodily integrity being directly or indirectly impaired, or (b) which inspires a belief in another person that such impairment of his or her bodily integrity is immediately to take place". See Snyman, C. R. (2007), *supra* note 676. p. 430.

679 Criminal defamation consists in the unlawful and intentional publication of matter concerning another which tends to injure his or her reputation" See Snyman, C.R. (2007), *supra* note 676. pp 425-459.

680 *Crimen injuria* consists in the unlawful, intentional, and serious violation of the dignity or privacy of another. See Snyman, C. R. (2007), *supra* note 676. p. 453. Claassen, N. J. B., & Verschoor, T. (1992), *supra* note 442. p. 128 indicated examples of where a healthcare practitioner takes abuse his or her patient sexually under the disguise of medical treatment; where a healthcare practitioner exposes a patient's body without his or her consent, to curious persons with no medical interest; and where a healthcare practitioner reveals to outsiders details about a patient's ailments. Crimen injuria requires the presence of intention and no negligent injury to a personality right may result in a conviction of crimen injuria. See also Strauss, S. A., & Strydom, M. J. (1967), s*upra* note 647. p. 350.

681 Fraud is an unlawful and intentional making of a misrepresentation which causes actual prejudice, or which is potentially prejudicial to another" See Strauss, S. A., & Strydom, M. J. (1967), s*upra* note 647. p. 520.

682 Perjury consists in the unlawful and intentional making a false statement in the course of a judicial proceeding by a person who has taken the oath or made an affirmation before, or who has been admonished by, somebody competent to administer or accept the oath, affirmation, or admonition. See Strauss, S. A., & Strydom, M. J. (1967), s*upra* note 647. p. 341.

683 Contempt of court consists in unlawfully and intentionally (a) violating the dignity, repute or authority of a judicial body or a judicial officer in his or her judicial capacity; or (b) publishing information or comment concerning a pending judicial proceeding which tends to influence the outcome of the proceeding or to interfere with the administration of justice in that proceeding. See Strauss, S. A., & Strydom, M. J. (1967), s*upra* note 647. p. 323.

684 Coetzee, L. C. & Carstens, P. (2011), *supra* note 636. p. 1272. See also *S v Hartmann* 1975 (3) SA 532 (C) in which the father of the accuse suffered from carcinoma of the prostate gland, and thereafter from a secondary cancer had manifested itself his bones, particularly his ribs. In the terminal stages of his illness with no cure available and suffering from severe pain, he was given a heavy dose of morphine and pentothal by his son, a doctor, and died within seconds. His son was charged with murder.

685 Van Oosten, F. W. (1986). *Professional Medical Negligence in Southern African Legal Practice,* 5 MED. & L. 17, 22 indicated that because culpable homicide is the only common law crime where proof of fault in the form of negligence is sufficient , it is the only common law crime for which a professionally negligent healthcare practitioner can be held liable.

686 See *R v Van Schoor 1948* (4) SA 349 (C); *S v Mkwetshana* 1965 (2) SA 493 (N); *R v Van der Merwe* 1953 (2) PH H124 (W) regarding the over prescription of drugs; *S v Berman* 1996 (T) (unreported) regarding blood transfusions performed on a wrong patient; *S v Kramer* 1987 (1)SA 887 (W) regarding failure to insert an endotracheal tube correctly and to monitor the patient properly during anaesthesia; and *S v Nel* 1987 (T) (unreported) on failure to call a specialist when complication ensured during delivery of a baby.

Where a healthcare practitioner treats a patient without a valid consent from the patient and or his or her legal guardian, and in the absence of a legally recognised ground of justification, he/she commits an assault.[687] The assault does not however stand where a healthcare practitioner has negligently injured the patient because the crime of assault requires fault in the form of intention.[688]

A healthcare practitioner who assisted a colleague during the performance of an illegal operation or treatment may be held liable as an accessory where he consciously rendered such assistance.[689]

4.7 Relationship between common laws on patient safety

The connection between the healthcare practitioner or hospital and a patient is naturally of a contractual nature.[690] Where there is no expressed or tacit contract between the parties, their association is governed by the law of delict.[691] But, the same act or omission by a healthcare practitioner or hospital may result in both contractual and delictual liability. This is the case because a breach of a duty of care and negligence by a healthcare practitioner may represent both a breach of contract and a delict.[692] Furthermore, a breach of contract, or the commission of a delict by a healthcare practitioner, may also result in criminal liability where his or her wrongful act complies with the requirements of the description of a common law crime.[693] Common law crimes that may coincide with a breach of contract or delict committed by a

687 Claassen, N.J.B., & Verschoor, T. (1992), *supra* note 442. p. 127. See also Strauss, S.A., & Strydom, M. J. (1967), *supra* note 647. p. 349.
688 Strauss, S.A., & Strydom, M.J. (1967), *supra* note 647. p. 349.
689 Strauss, S.A., & Strydom, M.J. (1967), *supra* note 647. p. 343.
690 Coetzee, L.C. & Carstens, P. (2011), *supra* note 636. p. 1273.
691 Pearmain, D.L. (2004). A Critical Analysis of the Law of Health Service Delivery in South Africa (Unpublished LLD thesis, University of Pretoria).
692 *Van Wyk v Lewis* 1924 AD 438 at 438, 443, 450 -51.
693 Coetzee, L.C., & Carstens, P. (2011), *supra* note 636. pp. 1273 – 74.

healthcare practitioner are such as murder, culpable homicide, assault, criminal defamation, fraud, and criminal injuria.[694]

4.8 Summative assessment of the Namibian regulatory framework

The Namibian regulatory framework for the healthcare professions is made up of both statutory and common law enjoined by the Bill of Rights in the Namibian Constitution. At the governance level Namibia has adopted a traditional model of professional self-regulation which took a form of an Act of Parliament that provides a legal framework for regulation of practice of registrable professions and spells out the ambit of legal authority delegated to regulatory bodies. However, the government maintains some degree of control over the practice of the healthcare professions making it a hybrid form of professional self-regulation. The approach of self-regulation used in Namibia includes registration and certification. The country has not yet introduced the licensure of healthcare practitioners.

In exchange to regulatory status, the regulatory bodies have developed, implemented, and enacted rules and regulations primarily aimed at public protection against its members. This includes strict registration and certification requirements,[695] rules governing the education and training of practitioners,[696] and standards on how the profession may be practiced competently and ethically.[697] With regards to distinctive ethical standards, Namibia has both rule-based codes of professional conduct[698] and principles-based code of ethics.[699] There is also a system of receiving and investigating complaints from the public, and disciplining healthcare

694 Coetzee, L.C., & Carstens, P. (2011), *supra* note 636. pp. 1273 – 74.
695 Para 5.3.1.
696 Para 5.4.
697 Para 5.3.2.
698 In the form of specific disciplinary rules on acts and omissions.
699 In the form of broader principles in the ethical guidelines.

practitioners whose professional conduct is found wanting, as well as dealing with impaired practitioners.

The Namibian legal framework for the healthcare professions is predominantly person-centred and premised on individual accountability with less or no regards for organisational let downs as postulated by Downie.[700] This form of compliance and control mode of regulation also bears some distinguished features of a responsive model of regulation, as applied to health by Healey,[701] which includes soft strategies in the form of professional standards, protocols and guidelines, and hard enforcement or rules and regulations against non-compliance.

To ensure accountability, regulatory bodies in Namibia report to Parliament, via the Minister of Health, on their activities and handling of finances. The appointment of public members to serve on regulatory bodies may not only strengthens the principle of accountability and public protection, but also signifies a departure from a pure form of professional self-regulation where the profession alone regulates itself without external scrutiny.

4.9 Summary

The law regulating the practice of healthcare professionals in Namibia, and more specifically the salient provisions that are relevant to patient safety, were discussed in the chapter through the prism of the professional self-regulation model. Also discussed was the governance design of health professions regulation with respect to the Constitution, composition and powers of the Council. A summative assessment of the regulatory framework was also presented. A comparative analysis of the regulation of healthcare professions in South Africa and the United Kingdom (UK) is presented in the next chapter.

700 Downie, J. (2006), *supra* note 39. p. 3.
701 Healy, J. (2013), *supra* note 33. p. 3.

CHAPTER FIVE

REGULATION OF HEALTHCARE PROFESSIONS IN SOUTH AFRICA AND THE UNITED KINGDOM: A COMPARATIVE ANALYSIS

5.1 Introduction

The regulatory framework for healthcare professions in South Africa and the United Kingdom (UK) are analysed in this chapter. These countries were selected because they have studies examining the incidence of unsafe acts in hospitals, and, in all, patient safety was identified as a policy priority within the management of health systems.

5.2 Regulation of healthcare professions in South Africa

The practice of healthcare professions in the Republic of South Africa is regulated by various statutory enactments in addition to the provisions of the Constitution of the Republic and the common law.[702] While there are many registrable healthcare professions in South Africa, most of them are governed by the Health Professions Act.[703] This Act for the sake of convenience is the focus of discussion in this chapter.[704]

The Health Professions Act provides for the establishment of the Health Professions Council of South Africa (HPCSA).[705] It is a statutory body responsible for controlling and exercising authority in respect of all matters affecting the training of healthcare professionals, and the manner in which they practice their professions in connection with the diagnosis, treatment, or

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702 These are such as the Nursing Act 50 of 1978, Pharmacy Act 53 of 1974; Social Service Professions Act 110 of 1978; Traditional Health Practitioners Act 22 of 2007; and the Allied Health Professions Act 63 of 1982.

703 Act 56 of 1974 (Hereinafter referred to as "the Health Professions Act").

704 The professionals registered under the Health Professions Act includes Medical Practitioners; Dentists; Medical Scientists; Dieticians; Nutritionists; Dental Assisting; Dental Therapists; Oral Hygienists; Emergency Care Practitioners; Environmental Health Practitioners; Occupational Therapists; Medical Orthotists; Prosthetists; Art Therapists; Optometrists; Dispensing Opticians; Physiotherapists; Podiatrists; Biokineticists; Psychologists; Radiographers; Clinical Technologists; Speech Therapists, Audiologists; and Hearing Aid Acousticians.

705 S 2 of the Health Professions Act.

prevention of physical or mental deficiencies in humans. The Health Professions Act also provides for control over the education, training, registration, and practices of a variety of healthcare professionals.[706]

5.2.1 The powers of the HPCSA

Section 4 of the Health Professions Act provides for general powers of the HPCSA, which may perform actions such as acquire, hire or dispose of property; borrow money on the assets of the HPCSA; accept and administer any trust or donation; render financial assistance to professional boards to perform their functions; consider any matter affecting the health professions registrable under the Health Professions Act after consultation with the relevant professional board; consider any matter consistent with national health policy determined by the Minister of Health and make representations or take such action on such a matter as the HPCSA considers necessary; make rules on all matters which the HPCSA deems expedient to achieve the objectives of the Health Professions Act; delegate to any professional board, committee or person some of its powers as the HPCSA may determine from time to time, but it shall not be divested of any power so delegated; and to perform such other functions and do all such other things as the HPCSA deems necessary or expedient to achieve the objects of the Health Professions Act within the framework of the national health policy determined by the Minister of Health.[707] Most relevant to this study, the HPCSA is also empowered to establish standing and ad hoc committees, disciplinary committees, and ad hoc disciplinary appeal committees.[708]

706 S 3 of the Health Professions Act.
707 S 4 (a) – (f) of the Health Professions Act.
708 S 10(1)(a)(2) of the Health Professions Act.

5.2.2 The constitution of the HPCSA

The HPCSA consists of the following members.

- Not more than sixteen (16) persons designated by the professional boards on a basis of proportional to the number of persons registered to practise the professions falling under each professional board.
- One (1) person in the employment of the Department of Health appointed by the Minister of Health.
- One (1) person in the employment of the Department of Education appointed by the Minister of Education.
- Nine (9) community representatives not registered in terms of the Health Professions Act and appointed by the Minister of Health.
- One (1) person from the South African Military Health Service appointed by the Minister of Defence.
- Three (3) persons appointed by the South African University Vice-Chancellors' Association.
- Two (2) persons appointed by the Committee of Technikon Principals.
- Nine (9) public representatives, one from each province, appointed by the Member of the Executive Council responsible for health in each province, provided that such representatives are not registered in terms of the Health Professions Act.
- One (1) person versed in law, appointed by the Minister of Health.[709]

The members of the Council hold office for a period of five (5) years but are eligible to re-designation or re-appointment for one more term.[710]

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709 S 4 (1) (a) – (i) of the Health Professions Act The names of the members of the HPCSA and the date of commencement of their term of office are published by the registrar in the Gazette as soon as possible after the constitution of the HPCSA. See s 4 (6) of the Health Professions Act.

710 S 4 (2) of the Health Professions Act.

5.2.3 Establishment of the professional boards

The HPCSA is also empowered to recommend to the Minister of Health the establishment of a professional board in respect of which a register is kept in terms of the Health Act.[711] The same process is followed when a professional board is being reconstituted or additional professional boards are established.[712] It is however important to note that before making a recommendation to the Minister of Health for the reconstitution of a professional board or establishment of other professional boards, the HPCSA must consult persons or bodies who, in the opinion of the HPCSA, are representative of the majority of persons to be affected by such change or establishment.[713] So far the Minister, on the recommendation of the HPCSA, has established twelve (12) professional boards: Medical, Dentists and Medical Science Board; Dietetic and Nutrition Board; Dental Assisting, Dental Therapy and Oral Hygiene Board; Emergency Care Board; Environmental Health Board; Occupational Therapy, Medical Orthotics, Prosthetics and Art Therapy Board; Optometry and Dispensing Optics Board; Physiotherapy, Podiatry and Biokinetics Board; Psychology Board; Radiography and Clinical Technology Board; and Speech, Language and Hearing Board.[714]

The Minister of Health, on the recommendation of the HPCSA, is expected to issue regulations relating to the constitution, functions and functioning of a professional board that should at least provide for the following.

- The appointment of the members to such a professional board by the Minister of Health on the basis of nominations made by the members of the health professions involved.
- The persons representing the community to comprise not less than 20% of the membership of a professional board, with a minimum of one such representative for

711 S 15 (1) of the Health Professions Act.
712 S 15 (2) of the Health Professions Act.
713 S 15 (3) of the Health Professions Act.
714 Professional Boards, HPCSA, http://www.hpcsa.co.za/board_overview.php (Date of use 25 Jan 2020).

every professional board and such representatives must not be persons registered with that board.

- Relevant educational institution to be represented.
- The health authorities to be represented.
- One or more persons versed in law to be appointed.
- The establishment by a professional board of such committees as it may deem necessary.
- The establishment of a professional conduct committees consisting of many persons as may be prescribed, but including at least two public representatives, one of whom must be the chairperson of the committee.
- The procedure to be followed for the nomination and appointment of the members of the professional board.
- The election of the chairperson and vice-chairperson and their functions and powers.
- The term of office of members of the professional board.
- The vacation of office by a member and the filling of vacancies in the professional board. [715]

5.2.4 The powers of the professional boards

Although the professional boards function under the overall control of the HPCSA, they have wide ranging powers such as:

- to remove a name of a registered person from the register and to restore such name to the register,
- to suspend a registered person from practising his or her profession pending the institution of a formal inquiry,

[715] S 15 (5) (a) – (j) of the Health Professions Act.

- to appoint examiners, moderators, conduct examination, grant certificates, and charge fees in respect of such examinations or certificate as prescribed,
- approve training schools,
- upon application by any person recognise qualification as being wholly or partly equal to the prescribed qualification in South Africa, and
- to consider any matter affecting any profession falling within the ambit of the professional board concerned and to perform such functions as may be prescribed or do all such things it deems necessary to achieve the objects of the Act.[716]

While the professional boards have to act in a prescribed manner and, in some cases, expected to make recommendations to both the HPCSA and the Minister, it is clear that they largely function independently.[717] A professional board, for example, does not need ratification by the HPCSA of any decision it has taken relating to a matter falling entirely within its ambit. However, should there be doubt on whether a matter falls within the ambit of a professional board, it remains the responsibility of the HPCSA to decide on such a case.[718]

5.2.5 Disciplinary powers of the professional boards

With regards to the management professional conduct cases, which is important to ensure patient safety, the professional boards have the power to institute an inquiry into any complaint, charge or allegation of unprofessional conduct against a health professional registered in terms of the Health Professions Act.[719] When a professional board is in doubt as to whether an inquiry should be held in connection with the complaint, charge or allegation lodged, it can seek information from any person, including the person against whom the complaint, charge or allegation has been lodged.[720]

716 S 15B (1) of the Health Professions Act.
717 Coetzee, L.C., & Carstens, P. (2011), *supra* note 636. p. 1264.
718 S 15B (2) of the Health Professions Act.
719 S 41(1) of the Health Professions Act.
720 S 41(2) of the Health Professions Act.

5.2.6 Manner in which certain investigations may be instituted

The registrar of the HPCSA is empowered to appoint an officer of the professional board as an investigation officer to establish more facts on a matter under investigation.[721] The registrar may also appoint any other person than a member of the professional board who is not in the full-time employment of the professional board, as an investigation officer or to assist the investigation officer with a particular investigation.[722] The registrar can institute an investigation into an alleged contravention of failure to comply with any provision of the Health Professions Act, in order to determine if any provision of the Health Professions Act applies to or has been contravened by a registered person; and into a charge, complaint or allegation of unprofessional conduct by a registered person.[723] The person who carried out the investigation should compile a report of the investigation and submit it to the registrar. Should a report reveal a *prima facie* evidence of unprofessional conduct, and no complaint or charge has been lodged for the purpose of an inquiry, such report shall be deemed to be the complaint made for that purpose, and the registrar may serve a copy on the registered person concerned.[724] If the report does not reveal preliminary evidence of unprofessional conduct, the registrar shall equally serve a copy on the registered person.[725]

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721 S 41A(1) of the Health Professions Act.

722 S 41A(2) of the Health Professions Act. Every person appointed as an investigation officer or an assistant to the investigation officer is issued with a certificate of appointment by the registrar. Such a certificate may be produced on demand during the investigation. See s 41A(5) of the Health Professions Act.

723 S (5) (a) – (c) of the Health Professions Act. The investigation officer may request any person to produce to him or her any document or thing which the investigation officer on reasonable grounds believes to relate to the matter being investigated or provide an explanations to him or her in relation to such document or thing. The investigation officer must apply for a search warrant from a magistrate or a judge for any premises on which he reasonably believes that the required documents or things may be found or for any person whom he/she reasonably believes to have in his or her possession or under his or her control the required documents or things. See s 41A(6)(a)(b) of the Health Professions Act.

724 It is important to note that if an investigation report reveals *prima facie* evidence which makes desirable that an investigation in respect of impaired registered person be instituted, the registrar must serve a copy of that report on the health committee to further investigate and deal with the matter in term of the Health Professions Act. The management of impaired practitioners is discussed later in this chapter. See s 41A(8)(b)(ii) of the Health Professions Act.

725 S 41A(8)(b)(iii) of the Health Professions Act.

The investigation officer or his or her assistant is expected to keep all information that came to his or her attention in the performance of his or her functions confidential and shall not disclose such information to anyone other than the registrar, the president of the HPCSA, the chairperson of the relevant professional board, or the public prosecutor in the case of an offence in terms of the Health Professions Act, or by order of a court.[726] However, no personal particulars regarding a patient shall ever be disclosed to any person, except by order of a court or, with the consent of the presiding officer at an inquiry by the professional board into a complaint, charge or allegation of unprofessional conduct against a registered person or an investigation in respect of an impaired registered person.[727]

Any person who refuses or neglects to produce the required documents for investigation, or obstructs the registrar, or an investigation officer, in the exercise of his or her powers or the carrying out of his or her duties, or pretends that he/she is the registrar or an investigation officer, is guilty of an offence and liable on conviction to a fine or imprisonment for a period not exceeding twelve (12) months or to both a fine and such imprisonment.[728] Interestingly, any person who fails to keep all information that came to his or her attention during the investigation confidential or discloses personal particulars regarding a patient to any person in contravention of the provisions of the Health Professions Act, is guilty of an offence and liable on conviction to a fine or imprisonment for a period not exceeding two years or to both a fine and such imprisonment.[729]

726 S 41A(9)(a) of the Health Professions Act.
727 S 41A(9)(b) of the Health Professions Act.
728 S 41A(11)(a) – (c)(i) of the Health Professions Act.
729 S 41A(11)(d)(ii) of the Health Professions Act.

5.2.7 Inquiry by professional boards

In practice, professional conduct inquiries are not conducted by the professional boards themselves; this is done by the professional conduct committees appointed by the professional boards for such purposes.[730] A health practitioner whose conduct is the subject of an inquiry is afforded an opportunity, by himself or herself or through his legal representative, to answer to the charges against him or her and to be heard in his or her defence.[731] The professional board may take evidence and may summon witnesses for the purposes of the inquiry.[732] Any person duly summoned to appear before a professional board is bound to obey the summon and should he/she refuse or without sufficient cause fails to attend or give evidence; refuses to take oath or make affirmation; or refuses to produce any book, record, document or thing which he/she per summon been required to produce, is guilty of an offence and on conviction liable to a fine as determined by the Minister of Health.[733] The chairperson of the professional board may appoint a person with adequate experience in the administration of justice to be present at the professional conduct inquiry as an assessor and to advise the professional board on matter of law, procedure or evidence.[734]

Should a health professional be found guilty of unprofessional conduct by the professional board, the board may impose one or more of the following penalties:

- a caution or a reprimand or a reprimand and a caution; or
- suspension for a specified period from practising or performing acts specifically pertaining to his or her profession; or

730 The professional conduct committee is appointed in terms of s 15(5)(f) of the Health Professions Act which provides for empowerment of a professional board by regulation to establish any committee as it may deem necessary. See also the regulations published in this respect as per GN R979 of 13 August 1999. See also s 15(5)(Fa) of the Health Professions Act which deals specifically with the establishment of the professional conduct committee.

731 S 42 (2) of the Health Professions Act.

732 S 42 (4) of the Health Professions Act.

733 S 42(4) (c) of the Health Professions Act.

734 S 42(5) of the Health Professions Act.

- removal of his or her name from the register; or
- a fine not exceeding R 10 000; or
- a compulsory period of professional service as may be determined by the professional board; or
- the payment of the costs of the proceedings or a restitution.[735]

Unlike in Namibia, in South Africa, if a registered person is alleged to be guilty of unprofessional conduct and the professional board on reasonable grounds is of the opinion that it shall impose a fine on a registered person on conviction after an inquiry, the professional board may issue summons to the registered person on which an endorsement is made by the board or registrar that the registered person may admit that he/she is guilty of the conduct stated on the summons and that he/she may pay the fine stipulated without appearing at the professional conduct inquiry.[736] Should the registered person admit being guilty to the conduct stipulated on the summons, he/she may pay the stipulated fine to the relevant professional board before the date indicated on the summons.[737]

The professional board may decide to postpone for such period, and on such condition as it may determine, the imposition of the penalty; or order the execution of any penalty or any part of the penalty to be suspended for such a period on such conditions as the board may

735 S 42 (1) (a) – (f) of the Health Professions Act. The same penalties may be imposed after a determination of guilty by a committee of preliminary inquiry on minor transgression. In terms of regulation 2(3) (d) of the regulations relating the conduct of inquiries into alleged unprofessional conduct under the Health Professions Act, 1974, a minor transgression refers to a conduct whereby in the opinion of the registrar, preliminary committee of inquiry, on the basis the documents submitted to the registrar or such committee, is unprofessional, but of a minor nature, and does not warrant the holding of a formal professional conduct inquiry. It is further worth noting that the committee of preliminary inquiry is established by the relevant professional board under s 15 (5) (f) of the Health Professions Act, 1974 to undertake preliminary inquiries into the complaints of alleged unprofessional conduct. According to s 42 (10) (b) of the Health Professions Act the imposition of a penalty has the effect of a civil judgement of the magistrate's court of the district in which the professional conduct inquiry took place.

736 S 42 (8) of the Health Professions Act.

737 S 42 (9) of the Health Professions Act.

determine;[738] or terminate any suspension before the expiry of the specified period or on payment of the prescribed fee, restore to the register any name which has been removed.[739] If at the end of the period for which the imposition of a penalty has been postponed, the professional board is satisfied that the registered person has observed all the relevant conditions, the professional board is to inform the registered person that no penalty will be imposed upon him or her. Should however the professional board be satisfied that the registered person failed to observe any conditions of suspension, the professional board is to put such penalty into operation, unless the registered person satisfies the professional board that the non-compliance was due to circumstances beyond his or her control. [740]

The effect of suspension or removal from the register is that the person concerned is disqualified from practising his or her profession and his or her registration certificate is deemed to have been cancelled until the period of such suspension has expired or his or her name has been restored to the register by the professional board.[741]

It is further interesting to note that in South Africa a registered person, who either before or after registration, has been convicted of any offence by a court of law may be dealt with by the professional board in terms of its disciplinary powers, if the professional board is of the opinion that such offence constitutes unprofessional conduct and the registered person is liable on proof of the conviction to one or more of the prescribed penalties and provided that the registered person, before the imposition of such penalties by the professional board, is afforded an opportunity of tendering an explanation to the professional board in extenuation of the conduct in question. [742] Should it appear to any court of law during its proceedings that there is *prima*

738 S 43 (1) of the Health Professions Act.
739 S 42 (7) of the Health Professions Act.
740 S 43 (2) (a), (c) of the Health Professions Act.
741 S 44 of the Health Professions Act.
742 S 45 (1) of the Health Professions Act.

facie proof of unprofessional conduct on the part of a registered person, the court is to direct that a copy of the record of such proceedings or such portion thereof as is material to the issue, be conveyed to the relevant professional board.[743]

Section 46 of the Health Professions Act, 1974 criminalises false evidence under oath at any professional conduct inquiry by the professional board. Any person who gives false evidence knowing that such evidence is false, is guilty of an offence and liable on conviction to the penalties prescribed by law for the crime of perjury.

5.2.8 Appeal to the high court

Any person, who is distressed by a decision of the HPCSA, a professional board or a disciplinary appeal committee, may appeal to the appropriate high court against such a decision.[744] It is worth noting that once a registered person has been suspended, or removed from the register by the professional conduct committee as penalty for unprofessional conduct, such a person is disqualified from carrying out his or her professional functions and his or her registration certificate is regarded as cancelled until the period of suspension has expired or until his or her name has been restored to the register by the professional board.[745] Should the person lodge an appeal against a penalty of suspension from practice or removal from the register, such penalty remains effective until the appeal is finalised.[746]

5.2.9 Registration of health practitioners

Like in the case of Namibia and in the interest of patient safety, the practice of a healthcare profession in South Africa is highly protected; no person may venture into performing activities

743 S 45 (2) of the Health Professions Act.
744 S 20 (a) of the Health Professions Act.
745 S 44 of the Health Professions Act.
746 S 42 (1A) of the Health Professions Act.

reserved for a health profession registrable in terms of the Health Professions Act without that person being registered by the HPCSA.[747] In addition, the Minister of Health may, on the recommendation of the HPCSA and the relevant professional board, issue regulations setting out the scope of any profession registrable in terms of the Health Professions Act specifying the acts which for the purpose of the implementation of the Act should be regarded to be the acts pertaining to that profession.[748] It however is important to point out that such regulations may only be made by the minister on condition that the relevant professional board had an opportunity to submit its recommendations to the minister through the Council, on the definition of the scope of the profession concerned, and should there be a difference of opinion on the matter between the Council and the professional board, the Council must mention that fact in its recommendations.[749]

Once the scope of a registrable profession has been defined by the Minister of Health, only persons registered in terms of the Health Professions Act, in respect of such a profession, are allowed to practice in South Africa; anyone who contravenes this provision commits an offence and on conviction liable to a fine or imprisonment for a period not exceeding twelve months, or both a fine and such imprisonment.[750]

5.2.10 Management of impaired students and practitioners

Section 51 of the Health Professions Act, 1974 empowers the Minister of Health, after consultation with the HPCSA and the relevant professional board, to make regulations relating to the investigation in respect of a student or a practitioner who appears to be impaired. These regulations prescribe the manner in which the assessment of an impaired person is to be carried

747 S 17 of the Health Professions Act.
748 S 33 of the Health Professions Act.
749 S 33 of the Health Professions Act.
750 S 34 (1), (2) of the Health Professions Act.

out, the condition to be imposed on the registration or practice of the person concerned, the removal or suspension from practising, the revocation of conditions imposed and on acts of unprofessional conduct committed by the registered person before or during the assessment or investigation.[751] To give effect to these regulations, the professional boards have established health committees under s 15 (5) (f) of the Health Professions Act, 1974, and a joint standing committee established under s 15B (1) (f) of the same Act.

The committee of preliminary inquiry or a professional conduct committee of the professional board may, if it deems fit, refer a case of suspected impairment in respect of a registered person, to the health committee for investigation. On the other hand, if the health committee is of the opinion that there are sufficient reasons to suspect that a student or practitioner may be guilty of unprofessional conduct, the health committee may refer the matter to the committee of preliminary inquiry.[752]

According to regulation 22 (1),[753] the powers of the health committee include:

- making a finding on whether or not a student or practitioner is impaired based on the assessment or investigation of the committee,
- resolving on the management of a student or practitioner who has been found impaired with a view to ensure patient safety and the rehabilitation or treatment of the impaired student or practitioner,
- imposing any condition of registration or practice of the impaired person which the committee may deem appropriate which may include conditions with regards to –

    a) his or her status as a registered person,

751 Regulations relating to impairment of students and practitioners GN R.495 of 6 June 2001.
752 Regulation 10 (1), (2). GN R.495 of 6 June 2001.
753 Regulation 22 (1)(a) – (c). GN R.495 of 6 June 2001.

b) the locality of his or her practice,

c) the scope of his or her practice,

d) permission to purchase, acquire, keep, use, administer, prescribe, order, supply or possess any or all scheduled substances in terms of the Medicines and Related Substances Control Act, 101 of 1965,

e) the prohibition of the use or abuse of dependence producing substances scheduled in the Regulations made under the Prevention and Treatment of Drug Dependency Act, 20 of 1992, including drugs other than medicine,

f) ensuring and securing the treatment and rehabilitation of the impaired student or practitioner; and

g) Securing supervision of the fitness to practice and the performance of the impaired student or practitioner.

The conditions, imposed by the health committee on a student or practitioner who has been found to be impaired, are subject to reports to be submitted by the relevant therapist or supervisor or both to the health committee at the regular intervals determined by the committee to decide whether a student or practitioner is impaired by reason of his or her physical or mental condition. The conditions are also subject to the review of the health committee and the position of each impaired student or practitioner is to be reviewed every three years.[754]

5.2.11 Penalty for impersonation and limitation in respect of unregistered persons

A person who impersonates any person registered in terms of the Health Professions Act, 1974; or supplies or offers to supply to any person not registered under Health Professions Act, or the Nursing Act, 2005, any instrument or appliances which can be used, or is claimed to be

[754] Regulation 22 (2)(a), (b). GN R.495 of 6 June 2001.

effective, for the purpose of diagnosing, treating or preventing physical or mental defects, illnesses or deficiencies in humans, knowing that such instruments or appliances will be used by such unregistered person for purpose of performing an act which such unregistered person is in terms of the provisions of the Health Professions Act, 1974, or the said Nursing Act, is prohibited from performing, is guilty of an offence and on conviction liable to a fine or imprisonment for a period not exceeding twelve (12) months or to both a fine and such imprisonment.[755]

The Health Professions Act, 1974 also provides that no person, other than a registered person having the necessary qualifications, is eligible for an appointment to any establishment, institution, body, organisation, or association, whether public or private, if such appointment involves the performance of any act which an unregistered person, in terms of the provisions of this Act, may not be performed for gain. This prohibition excludes the education and training of a health professional under the supervision of a registered health professional, or the employment in any hospital or similar institution, of any person undergoing education and training with a view to qualify him or her for registration in terms of the Health Professions Act, in respect of any supplementary health service profession, under the supervision of a health professional.[756]

5.2.12 Death of a patient due to unnatural causes

The death of a person undergoing, or as a result of a procedure of a therapeutic, diagnostic, or palliative nature, or of which any aspect of such a procedure has been contributory cause, should not be regarded to be a death from natural causes as contemplated in the Inquests Act[757]

755 S 55 (f), (g) of the Health Professions Act.
756 S 59 (2) of the Health Professions Act.
757 Act 58 of 1959.

or the Births, Marriages and Deaths Registration Act.[758] A formal inquest must be carried out to determine the actual cause of death.

5.2.13 Investigation of matters relating to education and training

A professional board can authorise any person in writing to investigate any matter relating to the education or training of any person who is undergoing such education and training for purposes of qualifying him or her to practice any profession to which the provisions of the Health Professions Act, 1974 applies. Such person is allowed to enter any premises utilised in the education or training of any of such person. Any person who prevents a person authorised by the professional board from entering any institution or premises or hinders him or her in carrying out the required investigation is guilty is guilty of an offence and, on conviction, liable to a fine or imprisonment for a period not exceeding twelve (12) months or to both a fine and such imprisonment.[759]

5.2.14 The Office of Standards Compliance

South Africa has introduced reforms that are specifically directed at quality improvement through the National Health Act.[760] Section 78 of this Act provides for the establishment of an Office of Standards Compliance which must include a person who acts as ombudsperson in respect of complaints relating to breaches of the prescribed norms and standards. The Office of Standards Compliance must:

- keep the Minister of Health informed of the quality of the health services provided throughout the South Africa as measured against prescribed health standards;

758 Act 51 of 1992.
759 S 60 (1), (2) of the Health Professions Act.
760 Act 61 of 2003.

- advise the Minister of Health on norms and standards for quality in health services;
- advise the Minister of Health on norms and standards for the certificate of need processes;[761]
- recommend to the Minister of Health any changes which should be made to the prescribed health standards;
- recommend to the Minister of Health new systems and mechanisms to promote quality of health services;
- monitor compliance with prescribed health standards by health establishments, healthcare providers, health workers and health agencies;
- monitor compliance by a health establishment, health agency, health worker and health care provider with any condition that may have been imposed on such establishment, agency, worker, or provider in respect of certificates of need issued in terms of the National Health Act;
- report to the Minister of Health any violation of a prescribed health standards and cases in which violation poses an immediate and serious threat to public health and make recommendations to the same Minister on the action to be taken in order to protect public health;
- prepare an annual report to the Minister of Health concerning its findings regarding compliance with prescribed standards and with conditions imposed in respect of certificates of need;
- institute monitoring activities and processes for quality assurance in health establishments;

761 Section 36 of the National Health Act 61 of 2003 provides that a person may not establish, construct, modify or acquire a health establishment or health agency; increase the number of beds in, or acquire prescribed health technology at, a health establishment or health agency; provide prescribed health services; or continue to operate a health establishment or health agency after the expiration of 24 months from the date this Act took effect, without being in possession of a certificate of need.

- provide advice to the national department and to provincial departments on quality of care provided by health establishments, health agencies, health workers and health care providers; and
- inspect a health establishment or health agency in order to determine level of compliance with prescribed health standards and conditions imposed by certificates of need.[762]

The Office of Standards Compliance, or its agent, is empowered to inspect every health establishment and health agency at least once every three (3) years to ensure compliance with the National Health Act and may conduct announced or unannounced inspections of a health establishment and a health agency at any time. The Office is empowered to investigate and deal with complains relating to breaches of prescribed norms and standards and, where necessary, refuse to certify establishments failing to comply therewith.[763] The Office may also recommend that persons responsible for the non-compliance be referred to the relevant authority, for disciplinary actions.[764] The Office is also authorised to order the total or partial closure of a health establishment or a health agency on grounds of noncompliance.[765] The date of commencement for the establishment of the Office of Standards Compliance is yet to be proclaimed.

It is necessary to point out that in 2016 the Department of Health of South Africa has issued a national policy on patient safety aimed at providing direction to the public sector regarding the management of patient safety incident reporting including the provision of appropriate

762 S 78 of the National Health Act 61 of 2003.
763 S 82 A of the National Health Act 61 of 2003.
764 S 82 (4) (c) of the National Health Act 61 of 2003.
765 S 79 (1), (2) of the National Health Act 61 of 2003.

feedback to patients, families, support persons and healthcare practitioners, with strong emphasis on lesson learned to prevent patient harm.[766]

5.2.15 The extent of medical malpractice in South Africa

Coetzee and Carstens indicated the difficulty in being able to find any empirical data on medical malpractice in South Africa.[767] In the same vein, Oosthuizen and Carstens pointed out a need for research into the prevalence of adverse events, negligence and medical malpractice in South Africa.[768] The HPCSA has indicated that more than 200 medical practitioners were found guilty in 306 cases of malpractice between 2008 and 2012.[769] The HPCSA also indicated that it issued 283 fines and 137 suspensions to medical practitioners for unprofessional conduct during 2008 and 2012.[770] It also indicated that 53 practitioners were removed from the register since 2005 due to unprofessional conduct.[771] According to the HPCSA from 2016 to 2019 there were n=7025 complaints of unprofessional conduct, namely: 2016/ 2017 (n=2755); 20117/2018 (n=2608); and 2018/2019 (n=1662).[772]

The then registrar and chief executive officer of the HPCSA, Dr Mjambe-Matsoba, is reported to have confirmed that the increase of medical errors was a huge concern to her organisation and that her office, together with the Department of Health, was investigating the situation.[773] The HPCSA was not only concerned about the decline in the level of professionalism among health practitioners, but also the increasing costs of medical negligence.[774] All these concerns

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766 Department of Health, South Africa (2016). *National policy for patient safety incident reporting and learning in the public health Sector of South Africa*. Pretoria: Department of Health. p.1.

767 Coetzee & Carsten, (2011), *supra* note 636. p. 1295.

768 Oosthuizen, W, T., & Carstens, P.A., (2015B) "Re-evaluating medical malpractice: A patient safety approach" 2015 (78) THRHR: 385.

769 Oosthuizen, W, T., & Carstens, P.A., (2015B), *supra* note 768. p. 270.

770 HPCSA (2011) Annual Report 2010/ 2011.

771 HPCSA (2009) Annual Report 2008/ 2009.

772 HPCSA (2018) Annual Report 2018/ 2019 (2018).

773 Oosthuizen, W, T., & Carstens, P.A., (2015B), *supra* note 768. p. 271.

774 Oosthuizen, W, T., & Carstens, P. A., (2015B), *supra* note 768. p. 271.

stimulated the desire for public awareness on patients' rights and responsibilities when accessing healthcare.[775] In 2012 the HPCSA carried out a public awareness campaign to educate the public and healthcare practitioners on their rights and responsibilities.[776] This decision was however not well received by the South African Private Practitioners Forum, and the South African Medical Association, who held the view that such awareness campaigns would inspire litigation and lead to an upsurge in the practice of defensive medicine.[777] Ironically, the HPCSA was criticised by both practitioners and patients for its perceived inability to protect the public and guide the profession.[778] Patients were particularly dissatisfied with their dealing with the HPCSA as some felt that the body unfairly protects members of the medical profession.[779] These feelings were aggravated by the fact that professional conduct inquiries take years to resolve.[780] The supreme court of appeal (SCA) also reflected on this matter noting that it reflects badly on the HPCSA and will affect the public confidence in the regulatory body.[781]

5.2.16 Summative analysis of the South African legal framework

Like in the case of Namibia, South Africa has an Act of Parliament which provides a legal framework for control over education, training, registration, and practice of healthcare professionals.[782] The core value of the regulatory framework is professionalist-independent

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775 Oosthuizen, W, T., & Carstens, P. A., (2015B), *supra* note 768. p. 271.

776 HPCSA Media Statement: HPCSA embarks on health and human rights awareness campaign, (2012-03-19).

777 Oosthuizen, W, T., & Carstens, P. A., (2015B), *supra* note 768. p. 271.

778 Oosthuizen, W, T., & Carstens, P. A., (2015B), *supra* note 768. p. 271.

779 Oosthuizen, W, T., & Carstens, P. A., (2015B), *supra* note 768. p. 272.

780 According to HPCSA Annual Report 2018/ 2019, complaints finalised by the HPCSA during 2016/ 17 were 638; in 2017/18 they were 798 and in 2018/19 were 744.

781 *Roux v Health Professions Council of South Africa* (786/2010) [2011] Z ASCA 132 (21 September 2011). At paragraph 34 of the judgement Mhlantla JA said "Finally, there is a disturbing aspect of this case that I am constrained to address. The purpose of establishing the HPCSA was to protect the public interest. The complaint was lodged in April 2005. The inquiry is yet to be heard, six years later. Such state of affairs reflects badly on the HPCSA and affects public confidence in it."

782 Para 5.1 & 5.1.13.

mode with an occupational structure exclusive to healthcare practitioners. The regulatory posture therefore does not accept unregistered persons into the practice of medicine and protects practitioners from non-licensees.[783] However, the governance architecture bears a resemblance to a hybrid approach with some degree of government control and community representation at both Council and professional board levels.[784] Similar to Namibia, the regulator focus of the South African system is on individual practitioner to the exclusion of the system and organisational factors that may compromise patient safety and bearing the nature of the traditional model of professional self-regulation.[785] Although the South African system does not seem to have an internal appeal structure for aggrieved clients but the High Court which can be expensive,[786] the system presents some good options for Namibia in respect to compulsory professional services,[787] admission of guilt and payment of a fine by a health care practitioner without appearing at an inquiry[788] as well as having a structure such as the Office of Standards Compliance to deal with complaints relating to breach of prescribed practice norms and standards. As is for Namibia, empirical data on medical malpractice are sketchy.[789]

5.3 Regulation of healthcare professions in the United Kingdom

Like the respective regulators in Namibia and South Africa, the aim of professional regulation in the UK is to ensure public protection through removing practitioner whose conduct falls short of the professional standards and by ensuring that high standards of professional practice are upheld to reduce the need for disciplinary actions. Professional regulation in the UK also focuses broadly on individual professionals rather than on organisational systems.[790] Unlike in

783 Para 5.1.11.
784 Para 5.1 & 5.1.2.
785 Para 5.1.10.
786 Para 5.1.8.
787 Para 5.1.7.
788 Para 5.1.7.
789 Para 5.1.15.
790 Law Commission, Scottish Law Commission and Northern Ireland Law Commission "*Regulation of Health Care Professionals. Regulation of Social Care Professionals in England*". Law Com No 345/

the case of Namibia in which unnatural death is limited undergoing anaesthesia, the UK provision is wider in terms of covering deaths as a result of therapeutic, diagnostic, and palliative care.[791] The UK also recognised the danger impaired practitioners may have on patient safety.[792]

5.3.1 The UK regulatory framework for healthcare professions

The history of the UK legal framework can be traced back to the establishment of the General Medical Council in 1858.[793] Since then it has grown steadily through various statutes and orders in the Council which have established and intermittently re-established regulatory bodies. Added to these are ranges of orders, rules, and regulations that have collected over the years.[794] There are nine regulatory bodies responsible for regulating 32 professions in the UK consisting of about 1.44 million professionals.[795] These are as follows: General Chiropractic Council; General Dental Council; General Medical Council; General Optical Council; General Osteopathic Council; General Pharmaceutical Council; Health and Care Professions Council; Nursing and Midwifery Council, and the Pharmaceutical Society of Northern Ireland.[796] It is worth mentioning that the UK has another body called the Professional Standards Authority that has its own separate statute and oversees the work of the nine regulators.[797] Each regulator is governed by its own Act of Parliament or Order in Council. The relevant governing legislations are set in Table 6 below.

Scot Law Com No 237/ NILC 18 (April 2014). http://lawcommission.justice.gov.uk/areas/Healthcare professions.htm, (Date of use: 11 February 2020).

791 Para 5.1.12.

792 Para 5.1.10.

793 Law Commission (2014), *supra* note 790. p. 2.

794 Law Commission (2014), *supra* note 790. p. 2.

795 Professional Standards Authority for Health and Social Care, (2013). Annual Report and Accounts 2012 -13. Available at www.professionalstandards.or.uk. p. 4.

796 Law Commission (2014), *supra* note 790. p. 2.

797 Law Commission (2014), *supra* note 790. p. 9.

Table 6: UK governing legislations

Governing legislation	Regulatory authority
Chiropractors Act 1994	General Chiropractic Council
Dentists Act 1984	General Dental Council
Medical Act 1983	General Medical Council
Opticians Act 1989	General Optical Council
Osteopaths Act 1993	General Osteopathic Council
Pharmacy Order 2010	General Pharmaceutical Council
Health and Social Work Professions Order 2001	Health and Care Professions Council
Nursing and Midwifery Order 2001	Nursing and Midwifery Council
Pharmacy (Northern Ireland) Order 1976	Pharmaceutical Society of Northern Ireland
National Health Services Reform and Health Care Professions Act 2002	Professional Standards Authority

Source: Law Commission, Scottish Law Commission and Northern Ireland Law Commission (2014).

5.3.2 Functions of the regulatory bodies

Each of the nine regulatory bodies in the UK has the same predominant functions which are as follows.

- Setting standards of behaviour, competence, and education that healthcare professionals must meet.

- Dealing with complaints from patients, the public and others about professionals who are not fit to practice due to poor health, misconduct, or poor performance.
- Keeping registers of professionals who are fit to practise.
- Setting the requirements for re-registration for each profession.[798]

The Pharmaceutical Society of Northern Ireland is however different from the other regulators because its functions include both professional regulation and professional representation.[799]

The functions of the Professional Standards Authority are also different from that of the nine regulatory bodies in that it is responsible for supervising and scrutinising the work of the nine regulators, and for advising the four UK governments' health departments on issues relating to professional regulation.[800] The Professional Standards Authority is discussed in more detail in paragraph 5.3.22 below.

5.3.3 Constitution of regulatory bodies

The nine regulatory bodies in the UK are each constituted by Order of the Privy Council which specifies matters such as the size and composition of the regulatory body as well as the term office of members of the regulatory body.[801] Before 2008 members of these regulatory bodies were elected by the registrants; a situation that created a perception that the interest of the public was given less attention than those of the professions.[802] This was changed in 2008 with the introduction of the appointment of all members of the regulatory authorities by the Privy Council.[803] The Privy Council appoints members of the regulatory bodies, but it is the

798 Law Commission (2014), *supra* note 790. p. 3.
799 The Pharmaceutical Society of Northern Ireland as established by the Pharmacy and Poisons Act (Northern Ireland) 1925 to regulate pharmacists and pharmacies in Northern Ireland. Additional powers and responsibilities were given to the society by the Pharmacy (Northern Ireland) Order 1976.
800 Law Commission (2014), *supra* note 790. p. 3.
801 S 25C of the Health and Social Care Act 2012.
802 Law Commission (2014), *supra* note 790. p. 47.
803 Health and Associated Professions (Miscellaneous Amendments) Order 2008, SI 2008 No 1174.

regulators that are responsible for spearheading the process of finding suitable candidates and to make recommendation to the Privy Council.[804] The Professional Standards Authority provides the quality assurance for the nomination process by providing advice to the Privy Council on whether the nomination process adopted by each regulator was open, fair and transparent.[805]

5.3.4 The oversight roles of the UK government

The UK government plays an important role in overseeing the work of the regulators through the Privy Council which is required to approve new rules and regulations made by the regulators.[806] The Privy Council also has a duty to intervene in cases of regulatory failure.[807] In the case of the Health and Care Professions Council, and the Nursing and Midwifery Council, the Privy Council has powers to initiate a public inquiry in any matter concerned with the Council's exercise of its functions.[808] In practice, however, when the Privy Council is unable to perform its functions due to reasons such as lack of resources, its functions are carried out by the relevant department of health making it the main player in the developing and securing approval of rules and regulations.[809] The regulators are accountable to the UK Parliament, and in some cases to the devolved assemblies. This accountability is naturally supposed to be achieved through the Privy Council, and also through the House of Commons

804 See for example schedule 1 regarding the amendment to section 1 of the Medical Act 1983 provides that the General Medical Council shall be constituted as provided for by order of the Privy Council.

805 Law Commission (2014), *supra* note 790. p. 48.

806 Law Commission (2014), *supra* note 790. p. 23.

807 The Privy Council has powers to direct a regulator that has failed to perform its functions and if the regulator fails to do so, the Privy Council may implement the directive itself. See for example s 34 of the Chiropractors Act 1994 and s 50 of the Medical Act 1983. The Dentists Act 1984 and the Pharmacy Order 2010 do not seem to have such a provision.

808 Health and Social Work Professions Order 2001, SI 2002 No 245, art 47 and Nursing and Midwifery Order 2001, SI 2002 No 253, art 53.

809 Law Commission (2014), *supra* note 790. p. 3.

Health Select Committee which reports on the performance of regulators such as the General Medical Council and the Nursing and Midwifery Council.[810]

5.3.5 Keeping of registers

Registration of healthcare professionals, in order for them to practise, lies at the heart of health professions regulation.[811] The establishment and maintenance of a register provides important information to the public and employers regarding healthcare professionals who are qualified and fit to practice their professions.[812] The register also provides information on healthcare professionals who are under sanctions as a result of fitness to practice proceedings.[813] Some UK regulators keep a single register for a given profession,[814] others have a single register divided into different parts,[815] and others have multiple registers.[816] Besides full registration, the regulators can register professionals on a conditional or temporary basis.[817] Some regulators are also allowed keep what is called a provisional register,[818] and others to make certain

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810 Law Commission (2014), *supra* note 790. p. 32.

811 Registration refers to the compilation of a list of professional and sometimes businesses, who have satisfied the registration requirements set by the regulator that there are appropriately qualified and fit to practise their respective professions. Regulators in the UK keeps various kinds of registers such as registers for persons who holds full registration; Specialist register, persons who hold provisional registration, persons who hols temporary registration, visiting practitioners, student registers; voluntary registers or non-practising registers. See ss 27 A, 27 B, 34C, 34C of the Medical Act 1983.

812 Regulation 5 of the GMC (Form and Content of the Registers) Regulations 2015 prescribes the information to be recorded in the register such as the identity of the practitioner, the qualification and year in which it was granted, the type of registration and whether or not a practitioner hold a licence to practise.

813 According to Regulation 2 of the GMC (Form and Content of the Registers) Regulations 2015 this includes interim orders, any order for erasure, suspension, any reprimand or admonishment, any warning, or undertakings.

814 For example, the General Chiropractic Council. See Law Commission (2014), *supra* note 790. p.55.

815 For example, the register of the Health and Care Professions Council has 16 parts.

816 The good example here is the General Medical Council which keep a main register for general practitioners and a register for specialist medical practitioners. See Medical Act 1983, s 30 (A1).

817 Conditional registration presupposes that the registrant can practise his or her profession subject to certain restrictions on the type of work to perform or a requirement that he/she must undergo retraining or a course of medical treatment. On the other hand, temporary registration allows the regulators to register oversees practitioners coming to the UK to provide services for a short period of time, the General Medical Council for example grant temporary registration to eminent specialists in a particular branch of medicine and those providing services exclusively to non-UK nationals for example, during Olympic Games. See the Medical Act 1983, ss 27A and 27B.

818 The General Medical Council for example can register a newly qualified medical practitioner provisionally to undertake the general clinical training he/she need to attain full registration, Such a

temporary changes to the register in the case of an emergency.[819] Some regulators are required to publish their registers from time to time or over twelve (12) months in such form, including electronic, as they consider appropriate, and to make the register available for inspection by members of the public at all reasonable times.[820] However, few legislative obligations are placed on the General Pharmaceutical Council as it has broad powers to stipulate most of these details in rules.[821]

Professional titles such as 'doctor' of medicine or 'midwife' are protected. Only those registered with the relevant regulator may use them. It is a criminal offence in the UK to use a protected title without being registered.[822] In some cases, specific activities or tasks are equally reserved for registered health professionals. Some regulators in the UK have different jurisdictions over business engagement in health enabling them to register premises, maintain lists of businesses, impose financial penalties on business and inspect premises. These are the following: General Dental Council; General Optical Council; General Pharmaceutical Council; and Pharmaceutical Society of Northern Ireland.[823]

5.3.6 Requirements for registration

Like in the case of Namibia and South Africa, in order to be registered, applicants in the UK are required to hold an approved qualification. The other requirements for registration differ

practitioner must work in a hospital or institution approved for the purpose of the preregistration programme. See Medical Act 1983, s 15.

819 According to the Law Commission (2014), *supra* note 790. p. 69, General Medical Council and the General Pharmaceutical Council can register persons and groups of persons who appear to be "fit, proper and suitably qualified" with regards to the emergency. See also Medical Act 1993, s 18 A and Pharmacy Order 2010, SI 2010 No 231, art 34. The General Pharmaceutical Council and Nursing and Midwife Council can also annotate their registers to indicate individual registrants or groups of registrants who are "fit, proper and suitably qualified "to order drugs, medicines, and appliances. See also Pharmacy Order 2010, SI 2010 No 231, art 34 and Nursing and Midwifery Order 2001, SI 2002 No 253, art 6A.

820 See, for example, Medical Act 1983, s 34, Dentists Act 1984, s 22 and the Nursing and Midwifery Order 2001, SI 2002 No 253, art 8 (1).

821 See Pharmacy Order 2010, SI 2010 N0 253, art 7.

822 According to S 49 (1) of the Medical Act 1983, it is a criminal offence to impersonate a doctor.

823 Law Commission (2014), *supra* note 790. p. 79.

between the regulators. For example, some regulators expect an applicant to demonstrate or confirm that he/she is in good health both physically and mentally, whereas for other regulators an applicant's ill health is only pertinent to the extent that it weakens their ability to practice.[824] The European Union (EU) law also has an influence in the UK registration processes. Directive 2005/36/EC (the qualifications directive) enables the recognition of professional qualifications when a person plans to engage in his or her profession in a member state other than in which the qualification was acquired.[825] Also relevant to the issue of patient safety is the fact that the directive also requires all registered health professionals, except social workers, to have appropriate indemnity arrangements in place before registration.[826]

5.3.7 Appeals against registration decisions of the regulator

The legislations governing regulatory bodies in the UK provide that most determinations to refuse registration and certain other registration decisions can be appealed. The main exclusions are decisions to refuse registration or remove a person's name from the register for having failed to pay the registration fee, make an application or provide the required certificate.[827] Most regulators have registration appeal panels or similar bodies for this purpose and are authorised to make regulations as to the procedures and rules of evidence which are to apply.[828] The right to appeal against the decision of the registration appeals body is to the county court or, in Scotland, the sheriff.[829] There seems to be no right to appeal to the higher courts.

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824 Chiropractors Act 1994, s 3(2)(c) and Medical Act 1983, s 3(1).

825 European Union (2005). Qualifications Directive 2005/26/EC, *Official Journal* L 255 of 30. 09. 2005 p 55.

826 European Union (2011). Patients' Rights in Cross-Border Healthcare Directive 2011/s2/EU, *Official Journal L* 88 of 04.04.211, p 45.

827 See, for example, Medical Act 1983, sch 3A, par 2(2) and Dentists Act 1984, sch 2A, para 2(2).

828 See, for example, Dentists Act 1984, s 50C, Medical Act 1983, sch 3A, par 4 and sch 3B, para 3, and Opticians Act 1989, sch 1A, par 4.

829 See, for example, Medical Act 1983, sch 3A, para 5.

5.3.8 Restoration to the register

A health professional whose name has been removed from the register can apply to be restored. In a case where a health professional's name has been removed from the register following the fitness to practise proceedings, the application for restoration is to be considered by the fitness to practice panel.[830] In such cases, there is a prescribed period of five (5) years during which an application for restoration cannot be made. Applications for restoration in cases not related to fitness to practise proceedings, for example, where a person has been removed from the register because he/she has been working outside the country; taken a break; not complied with continuing professional development (CPD; or failed to pay the registration fee, are handled differently. In most of these instances, the application for restoration is decided by the registrar, with the right to appeal to an appeals committee.[831]

5.3.9 Control over education and training

Regulators in the UK are expected to put in place standards and requirements for qualifications needed for initial registration.[832] A good example is that of the General Medical Council as it has the function of promoting high standards of medical education and, in doing so, ensures that teaching is adequate to empower students with the required knowledge and skills, and that the qualifying examinations secure the necessary standards of proficiency.[833] To ensure that education and training standards are met, regulators in the UK undertake activities such as inspections, auditing, performance review, and surveys.[834] Regulators also have the powers to supervise post-graduate qualifications. This function is frequently linked to CPD and, in some

830 See, for example, Medical Act 1983, s 41 (3) and General Medical Council (Fitness to Practise) Rules Order of Council 2004, SI 2004 No 2608, r 23 (1).
831 General Pharmaceutical Council (Registration) Rule 210, SI 2010 No 1617, r 16.
832 Law Commission (2014), *supra* note 790. p. 95.
833 Medical Act 1983, s 5(1) and (2).
834 Law Commission (2014), *supra* note 790. p. 95.

cases, may result in the annotation of the register in respect of specialisation.[835] Additionally, the General Medical Council, for example, accepts programmes and sets educational standards for provisional registration, which obliges a registrant to take on a foundational programme plus optional specialist training.[836]

5.3.10 Standards of professional conduct and practice

Regulators in the UK are expected to issue standards of conduct, practice, and ethics. This normally takes a form of a code of conduct which provides a summary of how a registrant is expected to behave.[837] This function is quite often complemented by the general power accorded to a regulator to issue directives on specific aspects of standards such as education and training. [838] With regards to practice, the regulators are required to determine, from time to time, the standards of aptitude for safe and competent performance.[839] These are the minimum professional standards which every healthcare professional must meet in order to get registered and must meet in order to remain on the register.[840] Of importance in relation to professional conduct and practice is ethics. In the UK there are diverse approaches to professional ethics across the relevant legislations; some have established a clear-cut separation between ethical guidelines, standards of conduct and performance, while others make no reference to ethical guidelines.[841]

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835 Examples are the Health and Social Work Professions Order 2001, SI 2002 No 251, art 19(4) and the Pharmacy Order 2010, SI 2010 No 231, art 4 (3) (e).

836 Medical Act 1983, ss 10 A and 34H.

837 For example, the GMC has about 32 pieces of ethical guidance providing a framework for ethical decision making in a wide range of situations such as good medical practice, confidentiality, maintaining professionalism, children, and protecting young people, prescribing, decision making and consent, care at the end of life, leadership and management, candour and raising concerns, cosmetic interventions, and research. Available at www.gmc-uk.org/ethical guidance.

838 See for example, Health and Care Professions Order 2001, SI2002 No 245, art 21(2).

839 Law Commission (2014), *supra* note 790. p. 101.

840 See Dentists Act 1984, s 36 D and Medical Act 1983, s 5.

841 Law Commission (2014), *supra* note 790. p. 101.

5.3.11 Continuing professional development

As in Namibia and South Africa, the regulators in the UK have put in place CPD systems through which registrants demonstrate that they are continuously keeping their knowledge and skills current in order to practise safely.[842] The registrants are required to keep a record of their CPD activities and to confirm that they have met the standards for CPD when renewing their registration or after the random selection of their names during a CPD audit.[843]

Regulators in the UK adopted different approaches to CPD requirements. For example, the General Optical Council runs a points-based system which requires registrants to gain 36 CPD points in a three-year cycle. Registrants are also required to take part in peer review and group discussions.[844] On the other hand, the General Medical Council introduced a revalidation system, which is a regular process whereby registrants must demonstrate that they are up to date and fit to practise.[845] To renew their licences to practise in the UK, registrants of the General Medical Council must maintain a portfolio of supporting information drawn from their practice which demonstrates how they are continuing to meet the principles and values set out in the Council's guideline called *Good medical practice.*[846] Registrants are also required to participate in a process of annual appraisal that is based on their portfolio. Every five years, and based on the outcome of the annual appraisal and information drawn from the clinical

842 Pharmacy Order 2010, SI 2010 No 231, art 43.

843 The Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations (Northern Ireland) 2012.

844 GOC. (2021). *Guidance for providers of CPD*. London: General Optical Council. p.4. Available at guidance_for_providers_v3_pdf.pdf.

845 S 29A(4)(d) of the Medical Act 1983 provides for revalidation of a medical practitioner whenever a licensing authority see it fit to do so, either for purposes of the practitioner's continuation to hold a license to practise or as requirement before the renewal of the practitioner's license to practise. See also the GMC (Licence to Practise and Revalidation) Regulations 2012, as amended in 2014 and 2015.

846 GMC. (2018). *Guidance for doctors: Requirements for revalidation and maintaining of your licence*. p. 3. In the *Good Medical Practice* four sets of standards for good medical practice were identified namely, knowledge, skills, and performance; safety and quality, communication, partnership, and teamwork; and maintaining trust. To earn trust from patients, medical practitioners must show respect for human life and make sure that their practice meet these standards. GMC. (2020). *Good Medical Practice*. Manchester: General Medical Council. www.gmc-uk.org/guidence. pp. 8-25.

governance system of the organisation in which a registrant works, a responsible officer makes a recommendation to the Council about a practitioner's fitness to practise.[847] The revalidation system, which is linked to the renewal of the licence to practice and not to the renewal of registration, was introduced by the General Medical Council and is applicable to all medical practitioners practising in the UK, including those from other EU member states.[848]

5.3.12 Management of impaired practitioners

The concept of fitness to practise is crucial to the regulation of health and social care professionals and to ensure patient safety.[849] In this respect, the investigation starts with an allegation of impaired fitness to practise made to the regulator; the case is managed by the fitness to practise panel appointed by the regulator.[850] The fitness to practise panel can only impose sanctions in cases of actual impairment and a registrant's fitness to practise is considered as impaired by reason only of one or more statutory grounds. The statutory grounds are groups of conduct or underlying reasons for impairments, which differ between various regulators, but in a broader context consist of wrongdoing, substandard professional performance, poor physical or mental health, criminal conviction or caution, and a determination by another regulatory body.[851] It must however be noted that not every finding of misconduct or deficient performance would inevitably mean that the registrant's fitness to practise is impaired. Other pertinent factors to be taken into consideration are whether the

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847 GMC. (2018). *Guidance for doctors: Requirements for revalidation and maintaining of your licence*. p. 17. See also GMC.(2018*). The GMC protocol for making revalidation recommendations: Guidance for responsible Officers and Suitable Persons*.

848 GMC (Licence to Practise and Revalidation) Regulations 2012, as amended in 2014 and 2015.

849 To practise safely, a healthcare practitioner must not only be competent in what he/she does but also be able to establish and maintain effective relationships with patients, respect their autonomy and act appropriately and responsibly. GMC. (2021). *Meaning of fitness to practise*. Manchester: General Medical Council. www.gmc-uk.org/guidence. p.1.

850 HCPC.(2019).*The fitness to practise process. Information for employers and managers.* London: Health and Care Professions Council. p. 9.

851 HCPC.(2019), *supra* note 850. p. 9.

issues are effortlessly remediable, whether actions have been taken to address the shortcomings, and the probability of such actions and omissions being repetitive.[852]

Any complaint or information, which falls within the definition of an allegation, will trigger an investigation by the regulator.[853] Once an allegation has been made some regulators have the formal powers of initial consideration to determine whether the case should proceed.[854] For example, the Health Care Professions Council can refer the matter to a panel of two screeners consisting of a lay and registered member, to decide whether the Council has the legal power to take forward the allegations. Council members and members of the fitness to practise committee cannot be screeners.[855] With other regulators, such as the General Medical Council, initial consideration is done by the registrar in order to sift out vexatious allegations. The registrar has the power to refer allegations based on serious criminal offences directly to the fitness to practice panel, cutting out the investigation stage.[856] With regards to the General Pharmaceutical Council, all allegations must be referred for investigation unless they are of the nature specified in the Council's threshold criteria.[857]

Some regulators such as the General Medical Council have established a time limit within which the allegation of fitness to practise should be reported and investigated. For example, an allegation reported to that Council cannot be investigated if more than five (5) years have

852 Law Commission (2014), *supra* note 790. p. 110.

853 HCPC. (2019). *supra* note 850. p. 10.

854 Nursing and Midwifery Order 2001, SI 2002 No 253, art 22 (5).

855 See for example, the Health and Social Work Professions Order 2001, SI 2002 No 254, arts 23 and 24, and the Health Professions Council (Screeners) Rules of Council 2003, SI 2003 No 153, rr 4 (2) and 5 (1).

856 General Medical Council (Fitness to Practise) Rules Order of Council 2004, SI 2004 No 2608, r4 (3).

857 Pharmacy Order 2010, SI 2010 No 231, art 52(1) and (2).The criteria includes statements such as the registrant's conduct or performance that has caused moderate to severe harm or death, or the registrant deliberately caused harm or was reckless and if one or more of these statements applies, the case is referred for an investigation. See the General Pharmaceutical Council, *The Threshold Criteria* (2011) and the General Pharmaceutical Council.(2011). *Guidance on the General Pharmaceutical Council's Threshold Criteria Policy*.

elapsed from the date giving rise to the allegation. But there is exception to this rule for cases considered by the regulator as being in the public interest.[858]

5.3.13 Investigation procedures

In the UK there are different legislative frameworks for carrying out investigation by the regulators. Regulators are obliged to set up investigation committees that must determine whether a case should advance to a fitness to practise hearing or should be settled in some other way.[859] Regulators, such as the General Medical Council, have adopted an approach of case examiners, who are professional or lay persons appointed by the regulator for the purpose of performing the role of the investigation committee. This approach was established with the intention to ensure that the investigation process is faster, more efficient and reduces the workload of the investigation committee.[860] Regulators have a specific method for undertaking medical and professional performance assessments. These assessments allow the regulator to obtain advice and information as it contemplates necessary to evaluate the performance of a registrant.[861] At some of the regulators, the registrant is expected to submit to examinations and conclusions can be drawn from a failure to co-operate.[862] Some regulators have general powers to require the discovery of information by any person except the registrant concerned.[863] Such powers can be used at the investigation and adjudication stage of fitness to practise proceedings. This is more important in cases where a complainant withdrew his or her co-operation, but the case is of a significant nature which may impact on public protection.[864]

858 General Medical Council (Fitness to Practise) Rules Order of Council 2004, SI 2004 No 2608, r4 (3).
859 HCPC. (2019). *supra* note 850. p. 9.
860 General Medical Council (Fitness to Practise) Rules Order of Council 2004, SI 2004 No 2608, r 8.
861 See s 5A of the Medical Act of 1983 on professional performance assessment.
862 See for example, the General Optical Council (Fitness to Practise) Rules Order of Council 2005, SI 2005 No 1475, rr 8 and 12 and General Osteopathic Council (Investigation of Complaints) (Procedure) Rules Order of Council 1999, SI 1999 No 1847, r 13.
863 See for example, Dentists Act 1984, s 33B.
864 Law Commission (2014), *supra* note 790. p. 130.

5.3.14 Disposal of reported cases

After carrying out the necessary inquiries, the regulator must decide whether a case should be referred to the fitness to practise panel.[865] In making such a decision, some regulators are guided by the test set out in their constituting legislation. A good example is that of the General Pharmaceutical Council which uses a 'realistic prospect' that a panel will be able to establish impairment.[866] In contrast, the Nursing and Midwifery Council must decide whether there is a 'case to answer'.[867] Some regulators however do not have specific tests in their legislation.[868]

In a case where the conduct of a registrant was found wanting, but the case was not referred to the fitness to practise panel, the regulator can still have it disposed of by issuing warnings or advice to a registrant and the third party.[869] The regulator can also reach consensus with the registrant for him or her to comply with such undertakings as the regulator may find appropriate or to grant him or her voluntary removal from the register.[870]

Some regulators such as the Health and Care Professions Council, and the Nursing and Midwifery Council, have powers to embark on mediation between a complainant and a registrant.[871] That means that when the investigation committee has determined that there is a case to answer, it can commence mediation or refer the matter to screeners for mediation.[872] The health committee, or the conduct and competence committee, can also mediate cases after

865 SWE. (2021). *A guide to fitness to practise*. London: Social Work England. p. 15.
866 General Pharmaceutical Council (Fitness to Practise and Disqualification etc)) Rule 2010, SI 2010 No 1615, r 9(.7)(a).
867 Nursing and Midwifery Order 2001, SI 2002 No 254, art 26(2)(d)(i).
868 Examples of regulators without a specified test are the General Dental Council, General Medical Council, and the General Optical Council.
869 SWE. (2021), *supra* note 865. p. 14 regarding accepted disposal and an order without a hearing.
870 Law Commission (2014), *supra* note 790. p. 136.
871 See the Nursing and Midwifery Order 2001, SI 2002 No 253, arts 26(6) and 29 (4) and Health and Social Work Professions Order 2001, SI 2002 No 254, arts 26(6) and 29 (4).
872 Law Commission (2014), *supra* note 790. p. 141.

the allegation has been declared to be appropriately established or refer to the screeners for mediation.[873]

5.3.15 Fitness to practise hearings

Since the UK is a member of the EU, the processes followed by its regulators in dealing with cases of fitness to practise must comply with requirements of article 6 of the European Convention on Human Rights.[874] In the same vein, the general approach adopted by the UK courts has been to regard the fitness to practise processes of the regulators as article 6 complaint and the legislation has provided for subsequent control of the fitness to practise decisions by the higher courts on both issues of law and facts.[875]

Regulators in the UK played the role of both the investigator and adjudicator of allegations of impaired fitness to practise. This is in addition to the same authorities being the generators of both professional education and practice standards resulting in the independence of these bodies to be questioned.[876] Subsequently, in 2004 the *Fifth report on the Shipman inquiry* advocated for a distinct separation of adjudication from other functions performed by the General Medical Council through the establishment of an independent judicial body.[877] This led to the enactment of the Health and Social Care Act 2008, which provided for the transfer of adjudication functions, from the General Medical Council, and the General Optical Council,

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873 Health and Social Work Professions Order 2001, SI 2002 No 254, arts 26(6) and 29 (4).

874 Article 6 on the right to fair trial states that "in the determination of his civil rights and obligations or of any criminal charge against him , everyone is entitled to a fair and public hearing within a reasonable time by and independent and impartial tribunal established by law". See the Council of Europe, European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols No. 11 and 14, 4 November 1950, ETS 5 available at: https:// www. Refworld. Org/docid/3ae63b04.html.

875 See for example, *Tehrani v UK Central Council for Nursing, Midwifery and Health Visiting* [2001] Scot CS 19, [2001] IRLR 208 at [52] and *Gosh v General Medical Council* [2001] UKPC 29, [2001] 1 WLR 1925 at [31].

876 Law Commission (2014), *supra* note 790. p. 148.

877 The Shipman Inquiry Fifth Report: Safeguarding Patients, Lessons from the Past Proposals for the Future (2004) Cm 6394, paras 27. 204 to 27.210.

to a new body called the Office of the Health Professions Adjudicator.[878] This approach was however short lived because it was found to not be cost-effective.[879] The Office of the Health Professions Adjudicator was abolished by the Health and Social Care Act 2012; the adjudication functions were returned to the respective regulators with an emphasis to enhance the independence of the adjudication processes in a cost-effective manner. As a result, the General Medical Council, for example, established the Medical Practitioners Tribunal Services to adjudicate on fitness to practise and interim order cases.[880] Although the Tribunal Service is part of the Council, and funded by the same authority, its operation is separate from the rest of the Council. Its functions include, but not limited to running hearings, providing administrative support and or the appointment and appraisal of panellists, case managers, special advisers, and legal advisers. This body reports directly to Parliament on an annual basis.[881] Efforts were being made by the General Medical Council, pursuant to section 60 of the Health Act 1999, to have the Medical Practitioners Tribunal Services given a statutory status responsible for the operation for the fitness to practise panel and interim order panels.[882]

In order to deal with allegations that a registrant's fitness to practise is impaired, regulators are expected to put in place relevant committees or panels. A fitness to practice committee can be made up of a pool of selected people from which members of a panel are drawn per individual

878 Health and Social Care Act 2008, ss 98 to 110. The Office of the Health Professions Adjudicator was to recruit and train panelists who will be responsible for running hearings and adjudications. The body was to be funded by the referring regulators.

879 Law Commission (2014), *supra* note 790. p.m. 149.

880 S 231 of the Health and Social Care Act 2012 abolished the Office of the Health Professional Adjudicator on the other hand s 35D of the Medical Act of 1983 provided for the Medical Practitioners Tribunal.

881 S 52B (2) requires that the Medical Practitioners Tribunal submit copies of its annual reports to Privy Council.

882 S 60 of the Health Act 1999 provides that "Her Majesty may by Order in Council make provision-
(a) modifying the regulation of any profession to which subsection (2) applies, so far as appears to Her to be necessary or expedient for the purpose of securing or improving the regulation of the profession or the services which the profession provides or to which it contributes". The professions referred to in subsection (2) are the professions regulated by the Pharmacy Act 1954, the Medical Act 1983, the Dentist Act 1993, the Opticians Act 1998, the Osteopaths Act 1993, the Chiropractors Act 1994, the Nurses, Midwifes and Health Visitors Act 1997 and by the Professions Supplementary to Medicine Act 1960.

case to be considered or fashioned as non-statutory committees for advisory purposes.[883] For example, the General Medical Council does not have a formal fitness to practise committee but must instead establish panels to consider cases.[884]

Regulators in the UK apply separate fitness to practise procedures depending on the nature of the statutory ground of impairment being considered.[885] However, under each procedure, adjudication was done by a separate committee dealing with either an issue regarding conduct, performance, or health. This holistic approach is however not followed by all regulators. For example, the General Medical Council opted for a single fitness to practise committee to consider all categories of impairment.[886] The common practice among the regulators is that a fitness to practise committee is made up of both health professionals and non-professionals. The chairperson of the committee can be a legally qualified person, but this is not mandatory. Legal and professional advisers are normally made available as a source of expertise to the committee.[887]

5.3.16 Case management system

Some regulators in the UK have adopted a pre-hearing case management system. A good example is that of the Health and Care Professions Council and the General Medical Council.[888] By statute, the Health and Care Professions Council is expected to deal with fitness to practise matters as swiftly as possible, and subsequently its practice committee is given power to give directions for the conduct of cases and for the consequences of failures to comply with such

883 Medical Act 1983, s 19 D.
884 Medical Act 1983, s 1(3A).
885 Law Commission (2014), *supra* note 790.
886 Medical Act 1983, s 19 F.
887 Health and Social Work Professions Order 2001, SI 2002 No 254, arts 34, 35 & 36.
888 Medical Act of 1983, s 7A & Health and Social Work Professions Order 2001, SI 2002 No 254. art 22 (7).

directions.[889] This Council has also issued standard directives relating to exchange of documentation, notices to admit facts, documents and witness statements, and the withdrawal of admissions. These directives apply inevitably in every case.[890] With regards to the General Medical Council, the Council allocates one or more legally qualified case managers for cases referred for fitness to practise, review, or restoration hearing. A case manager, rather than a panel, is empowered to issue directions to both parties on a range of issues.[891]

5.3.17 Rules of evidence and standard of proof

Regulators in the UK apply to both civil and criminal rules of evidence to fitness to practise hearings; a panel cannot admit evidence that would not be admissible in the civil or criminal proceedings. The relevant civil or criminal rules are normally those that apply in the region of the UK in which the hearing takes place.[892] It is however worth noting that the strict rules of evidence do not apply to fitness to practise hearings, and for that reason a panel has leeway to admit a wide array of evidence. For example, some panels may admit any evidence they deem fair and relevant to a matter before them or because of public safety, such evidence would be admissible in a court of law.[893] With regards to standard of proof, all regulators in the UK apply the civil standard of proof, namely, the balance of probabilities, to fitness to practise inquiries.[894]

889 Health and Social Work Professions Order 2001, SI 2002 No 254, art 32 (3).
890 Health and Care Professions Council, *Practice Note: Case Management and Directions* (2011).
891 General Medical Council (Fitness to Practise) Rules 2004, SI 2004 No 2608. r 16.
892 General Medical Council (Fitness to Practise) Rules 2004, SI 2004 No 2608. r 34 (2).
893 General Medical Council (Fitness to Practise) Rules 2004, SI 2004 No 2608. r 34 (1).
894 Law Commission (2014), *supra* note 765. p. 163.

5.3.18 Protection of witnesses

Regulators in the UK provide special protection and assistance to witnesses at the fitness to practise hearings who may experience challenges in giving evidence.[895] These are, for example, persons with mental disorders, impaired intelligence, physical disabilities, those who have been intimidated or sexually violated.[896] Witnesses that are under the age of 18 years are normally regarded as eligible for these measures.[897]

5.3.19 Sanctions for impairment

In the UK the fitness to practise panels have the powers to impose sanctions following the finding of impairment.[898] Case law in the UK has established that the main aim of sanctions imposed by fitness to practise panels is not punitive but to protect the public. This is the case even when such sanctions may have a punitive outcome.[899] The main sanctions imposed by panels in the UK include: removal from the register, granting of voluntary removal from the register, warnings, immediate or interim orders.[900]

5.3.20 Interim orders

Interim orders allow temporary measures to be enforced on a registrant while the regulator investigates the allegations made against him or her. This can also operate when an inquiry is adjourned, even though no case has yet been proven.[901] There are two interim orders: an order for interim restricted registration which allows the registrant to continue practising but in a

895 General Medical Council (Fitness to Practice) Rules 2004, SI 2004 No 2608, r 36.
896 General Medical Council (Fitness to Practice) Rules 2004, SI 2004 No 2608, r 36 (1).
897 General Medical Council (Fitness to Practice) Rules 2004, SI 2004 No 2608, r 36 (1) (a).
898 See for example s 36 P (7) the Dentists Act 1984.
899 *Raschid v General Medical Council* [2007] EWCA Civ 46, [2007] 1 WLR 1460 at [18] and *Meadow v General Medical Council* [2006] EWCA Civ 1390, [2007] GB 462 at [32].
900 S 27B (6)the Dentists Act 1984.
901 S 41 A of the Medical Act 1983.

constrained capacity; and an interim suspension order which prevents the registrant from practising at all until there is a final determination of the case.[902]

An interim order becomes operational immediately and can be reviewed where new evidence comes to light or on the request of the registrant. Should there be a need to extent the interim order beyond the initial set period, the regulator must apply to the court.[903]

Interim orders can be imposed by both fitness to practise panels and the interim order panels after a hearing.[904] No oral evidence is required during such a hearing except when the panel is of the opinion that such evidence is necessary.[905] This is because the panel does not make findings or resolve disputes, of facts. The panel can therefore hear evidence from a practitioner and not from a witness.[906] The panel dealing with an interim order is not expected to determine whether the allegations are true.[907] The test to employ is whether an order is necessary for public protection. An interim order can be imposed on the ground of public interest, or in the interest of the practitioner or a complainant, respectively. Interim orders are however used in urgent cases but seldom on the ground of public interest alone.[908]

5.3.21 Regulation of bodies corporate carrying out business as professionals

The General Optical Council in the UK is required to keep a register of bodies corporate carrying on a business as an optometrist or dispensing optician.[909] A business can therefore be

902 S 41 A (1) (a) & (b) of the Medical Act 1983.
903 S 41A(6) of the Medical Act 1983.
904 S 41 A (1) of the Medical Act 1983.
905 General Medical Council (Fitness to Practise) Rules Order of Council 2004, SI 2004 No 2608, r 27 (2).
906 General Medical Council, *imposing interim Orders: Guidance for the Interim Orders Panel and the Fitness to Practise Panel* (2009) para. 7.
907 *R (Ali) v General Medical Council* [2008] EWHC 1630 (Admin).
908 General Medical Council, *Interim Orders Committee: Referral Guidance* (2009), *R (Sosanya) v General Medical Council* [2009] EWHC 2814 (Admin), and *R (Sheikh) v General Medical Council* [2007] EWHC 297 (Admin).
909 Law Commission (2014), *supra* note 790. p. 196.

registered provided that it satisfies the Council that it is fit and proper to carry out business as an optometrist and a majority of its directors are registered optometrists. The Council is however expected to publish standards of conduct and performance required for business registrants.[910] A business registrant whose conduct is found wanting can be subjected to fitness to practise proceedings.[911]

The General Dental Council also regulates business of dentistry and at some point maintained a list of dental bodies corporate.[912] The registration of bodies corporate was however discontinued therefore such entities can now carry out their business in dentistry, without vetting, as long as they meet the legal requirements relating to directorship of such businesses.[913]

Generally, regulators have no power to deal with consumer complaints.[914] However, the General Optical Council has the power to allocate resources to any person or entity established to deal with consumer complaints relating to the supply of goods and services by its registrants.[915] To achieve this the General Optical Council has engaged the services of the Optical Consumer Complaint Services, which is mandated to deal with such complaints.[916] Similarly, the General Dental Council has established a dental complaint service, which provides complaint resolution services for private dental patients and somehow are operating at arm's length of the Council.[917]

910 Law Commission (2014), *supra* note 790. p. 196.
911 Opticians Act 1989, ss 5 (C) (b) , 9 and 13D (1)(b).
912 Dentists Act 1984, ss 43A to 44B.
913 S 34 of the Dentists Act 1984.
914 Law Commission (2014), *supra* note 790. p. 198.
915 Opticians Act 1989, s 32.
916 Law Commission (2014), *supra* note 790. p. 198.
917 Law Commission (2014), *supra* note 790. p. 198.

5.3.22 Professional Standards Authority for Health and Social Care

As indicated earlier in this chapter, the Professional Standards Authority (hereinafter referred to as 'the Authority') has been established to supervise and scrutinise the work of the nine UK health and social care regulators. It also enhances the sharing of good practice and knowledge with the regulators and advises the four UK governments, through their health departments, on matters pertaining to professional regulations.[918] Despite Black[919] having described the Authority as a 'meta-regulator' the institution does not regard itself as such, but rather an oversight and audit body aimed at improving professional regulation.[920] Its role can therefore be summed up as not to manage regulators, but to review and comment on their activities in order to uplift standards.[921] The general functions of the Authority, as set out in the National Health Service Reform and Health Care Professions Act 2002[922] are

- to promote the interests of patient;[923]
- to promote best practice in the performance of the regulator's function;[924]
- to formulate principles relating good self-regulation;[925]
- to promote co-operation between the regulators and between them and other bodies;[926]
- to investigate and report on how each regulator is performing its functions and recommending changes;[927]
- to accredit voluntary registers;[928]

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918 Law Commission (2014), *supra* note 790. p. 202.
919 Black, J. (2007) "Tension in the Regulatory State" *Public Law* 58, 63.
920 Law Commission (2014), *supra* note 790. p. 198.
921 Law Commission (2014), *supra* note 790. p. 198.
922 As amended by the Health and Social Care Act 2008 and the Health and Social Care Act 2012.
923 S 25 (2) (a) of the National Health Service Reform and Health Care Professions Act 2002.
924 S 25 (2) (b)of the National Health Service Reform and Health Care Professions Act 2002.
925 S 25 (2) (c)of the National Health Service Reform and Health Care Professions Act 2002.
926 S 25 (2) (d)of the National Health Service Reform and Health Care Professions Act 2002.
927 S 25 (2) (d)of the National Health Service Reform and Health Care Professions Act 2002.
928 S 25G of the Health and Social Care Act 2012.

- to provide advice to the Privy Council on whether the process adopted by each regulator for the process of appointment of members has been open, fair, and transparent;[929]
- to direct the regulators to make rules where it is desirable for the protection of the public;[930]
- to investigate complaints, it receives about the way in which a regulator has exercised its functions;[931] and
- to refer unduly lenient decisions of the fitness to practice panels to the higher courts provided that such referral is desirable for the protection of the public.[932]

The overarching objective of the Authority, in exercising these functions, is the protection of the public[933] and the pursuit by the Authority of this overarching objective involves the pursuit of the following objectives:

- to protect, promote and maintain the health, safety, and well-being of the public;
- to promote and maintain public confidence in the professions regulated by the regulatory bodies;
- to promote and maintain proper professional standards and conduct for members of those professions;
- to promote and maintain proper standards in relation to the carrying of retail pharmacy business as registered pharmacies as defined in art 3(1) of the Pharmacy Order 2010; and

929 Part 4 of the National Health Service Reform and Health Care Professions Act 2002.
930 S 27 (2) of the National Health Service Reform and Health Care Professions Act 2002.
931 S 28 of the National Health Services Reform and Health Care Professions Act 2002.
932 S 29 of the National Health Service Reform and Health Care Professions Act 2002.
933 S 25 (2A)of the National Health Service Reform and Health Care Professions Act 2002.

- to promote and maintain proper standards and conduct for business registrants as defined in s 36(1) of the Opticians Act 1989.[934]

The Authority is financed through a levy on the regulatory body that it oversees; it is also able to generate income from other sources such as accreditation of voluntary registers.[935] The Authority is independent and does not resort under the Department of Health or any other department.[936]

It is interesting to note that regulatory bodies may establish and maintain a voluntary register[937]of persons who are unregulated health professionals; unregulated healthcare workers, unregulated social care workers in England and participating in studies for purposes of becoming registered professionals.[938] Before establishing a voluntary register, a regulatory body must assess the possible impact of such a move and must consult such persons as it may consider appropriate. The assessment should particularly include the likely impact on persons who would be eligible for inclusion on the register, persons who employ those who would be eligible for inclusion in the register and on the users of healthcare.[939]

5.3.23 Summative analysis of the UK regulatory framework

The UK legal system is described by the Law Commission as neither systemic nor coherent; it does contain a wide range of inconsistencies. For example, some regulators are described as having powers to establish systems of case management, while others do not. Some are able to

934 S 25 (2B) of the National Health Service Reform and Health Care Professions Act 2002.
935 S 224 of the Health and Social Care Act 2012.
936 Law Commission (2014) *supra* note 790. p. 203.
937 A "voluntary register" means a register of persons in which a person is not required by an enactment to be registered in order to be entitled to, use a title, practise as a member of a profession, engage in work that involves the provision of health care, or participate in studies to become a registered health professional. S 25D of the National Health Service Reform and Health Care Professions Act 2002.
938 S 25D of the Health and Social Care Act 2012.
939 S 25F of the National Health Service Reform and Health Care Professions Act 2002.

screen allegations of impaired fitness to practice, while others use investigation committees for such purpose. The test for referring all complaints to the fitness to practice panel and powers to act against practitioners whose fitness to practice is impaired also varies. This system provides some innovative strategies of ensuring public protection. Examples are imposition of interim orders, monitoring the performance of the regulators, case management, protection of witnesses and revalidation.

5.5 Summary

The law regulating a majority of healthcare professions in South Africa was discussed in terms of the Health Professions Act 56 of 1974. Provisions that have direct or indirect bearings in ensuring patient safety were discussed. The discussion covered the constitution and the powers of the Health Professions Council of South Africa and its subordinate structures, the professional boards; the investigation and disciplinary powers of the professional boards; the inquiry by the professional board; the management of an impaired student or practitioner; the registration of a health practitioner; the penalty for impersonation and the limitation in respect of unregistered persons; the handling of unnatural deaths; and the investigation of matters relating to education and training. The extent of medical malpractice in South Africa was briefly presented as was the summative analysis of the South African legal framework.

Also discussed in this chapter was the regulatory framework of the UK; constitution and functions of the regulatory bodies; the oversight role of the UK government; the keeping of registers and requirements for registration; appeals against registration decisions and restoration to the register; control over education and training; standards of professional conduct and practice; continuing professional development and management of impaired practitioners; investigation procedures, fitness to practice inquiries, sanctioning of impairments and disposal of reported cases; case management system; rules of evidence; protection of

witnesses and interim orders; regulation of bodies corporate carrying out business as professionals; and the professional standards authority for health and social care. A summative analysis of the UK legal framework was also presented. In the next chapter consolidation and discussion of the study findings are provided.

CHAPTER SIX

CONSOLIDATION AND DISCUSSION OF STUDY FINDINGS

6.1 Introduction

The consolidated findings of this study are presented in this penultimate chapter. For clarity, the discussion comprises the following seven sub-headings.

- Historical context of health professions regulation in Namibia as discussed in chapter two.
- Medical malpractice incidents in Namibia as discussed in chapter three.
- Medical malpractice claims against the state as discussed in chapter three.
- Regulatory framework for healthcare professions in Namibia as discussed in chapter four.
- The comparative analysis of the Namibian legal framework to that of South Africa as discussed in chapter five.
- The comparative analysis of the Namibian legal framework to that of the UK as discussed in chapter five.
- Lessons learned from the UK and the South African jurisdictions.

The findings are augmented by relevant data from the literature review presented in chapter one.

6.2 Historical context of health professions regulation in Namibia

The development of health professions regulation in South Africa laid the groundwork for the Namibian regulatory framework for healthcare professions; at independence in 1990 the country had adopted the South African health-related laws as made applicable to the then

SWA.[940] For a few years after independence, healthcare professions in Namibia continued to be controlled by relevant regulatory bodies in South Africa. A desire for a home-based dispensation prompted the development of healthcare professions regulation in Namibia which resulted into the promulgation of the 1993 Acts.[941] The overall objective of the 1993 Acts, as indicated by the legislature during the debate, was to protect the public against medical malpractice.[942] This assertion by Parliament clearly reflects patient safety as justification for professional regulation.[943] Additionally, the 1993 Acts empowered the regulatory authorities to set professional standards for education, training and practice, recognise professional qualifications, register healthcare practitioners, inquire into complaints, charge or allegation of improper conduct and to impose sanctions against those found guilty.[944] This approach mirrors the key tenets of the traditional model of professional self-regulation, namely, the sharing of the ethos and standard of professional behaviour, the transmission of ethical standards for education and practice to members of the profession and the control over behaviour and conduct of healthcare practitioners who are found incapable of providing safe patient care.[945]

Nevertheless, the regulatory framework created by the 1993 Acts was largely disjointed and omitted some healthcare professions that ought to be regulated.[946] Members of the regulatory bodies were all healthcare professionals, and this created the perception that such bodies were established to protect the interest of healthcare practitioners as opposed to patient safety. The regulatory framework by then did not create an effective administrative structure; the mandate

940 Para 4.4.
941 Para 4.7.
942 Para 4.4.
943 Para 2.2.
944 Para 4.8.
945 Para 1.7.
946 Para 4.9.

of the regulatory bodies was thus poorly executed.[947] These inadequacies led to the enactment of the 2004 Acts which are currently in force in Namibia.

There is however a Health Professions Bill[948] in place intended at repealing the 2004 Acts and addressing some gaps identified during the implementation of the 2004 Acts. The Bill seeks, amongst other things, to do the following: introduce a unitary legal framework administered by a single regulatory authority;[949] introduce a compulsory public service registration category to make healthcare practitioners available where they are needed most;[950] the abolishment of Minister's power to authorise an unregistered healthcare professional for purposes of employment by the state, which created a dual admission to practice regime and sometimes compromised patient safety;[951] create a position of a mediator between patients and healthcare practitioners against whom medical malpractice complaints have been reported and investigated;[952] remove the ratification requirement by the Council of the decision made by the professional conduct committee which blurred the principles of fairness and impartiality in dealing with professional conduct cases by the Council; and introduce an option for admission of guilt by a healthcare practitioner against whom a malpractice complaint has been reported, without appearing before the professional conduct committee, with a view to expedite the

947 Para 4.9.

948 The Health Professions Council of Namibia Bill of 2020.

949 Clause 3 of the Bill proposes for the establishment of the "Health Professions Council of Namibia".

950 Clause 40 provides for registration in the category "Public Sector" before the person is registered in the category "Independent Practice".

951 Ministerial authorisation has been replaced with temporary registration in Clause 37 of the Bill which provides that the Council may temporarily register a person not permanently resident in Namibia at the written request of the Minister of Health, service provider or educational institution to practice in the public service, employment of the Service provider or provide teaching, training, educational demonstrations or to promote education, as the case maybe, in respect of the health profession.

952 Clause 61 of the Bill provides that where the Preliminary investigation committee recommends to the Council that the evidence, documents and information appear to not support the complaints of unprofessional conduct and the Council opts to close the matter, this outcome is to be explained to the complainant by a person qualified in that field. The person referred to must be a registered person who has been practising his or her profession for at least 10 years.

finalisation of professional conduct cases.[953] As discussed in chapter two (cf. 2.15) this Bill went through several consultations with stakeholders. In September 2021 the latest version of the Bill was recommended by the Minister to the Attorney-General for certification before tabling in Parliament, hopefully during its first session in 2022.

6.3 Medical malpractice incidents in Namibia between 2014 and 2019

Medical malpractice complaints reported to the Council are investigated by the professional conduct committee on behalf of the Council. The committee makes recommendations to the Council for closure of a case where there is no evidence of unprofessional conduct against the healthcare practitioner or for a professional conduct inquiry should there be evidence of unprofessional conduct. The latter is carried out by the professional conduct committee of the Council. The decision of the committee must be ratified by the Council to have force and effect. Any aggrieved person by the decision of the professional conduct committee may appeal against such a decision to the appeal committee of the Council and thereafter to the high court. Medical malpractice complaints from 2014 to 2019 are presented in Table 7.

Table 7: Number of medical malpractice cases per year

	2014/2015	2015/16	2016/17	2017/18	2018/19	Total
Complaints received	48	46	106	71	48	**319**
Complaints closed	40	21	61	33	19	**174**
Complaints referred to professional conduct inquiries	45	14	25	20	07	**111**

Source: HPCNA Annual Reports.

[953] Clause 63 of the Bill provides that if a registered person is served with a notice of inquiry, the registered person may submit to the Council a written admission of guilt to the charge of unprofessional conduct specified in the notice.

As shown in Table 7, a relatively low number (n=319) of medical malpractice complaints were reported to the Councils in five years. However, more than half (n=174) had to be closed due to lack of evidence for unprofessional conduct against the implicated healthcare practitioners. The balance (n=111) was referred to the professional conduct inquiries.

Analysis of the research data revealed the following.

- Reporting cases of medical malpractice complaints to the regulators, mainly by public members, is currently the exclusive source of knowing the existence of patient safety cases in Namibia. There is a great possibility that the relatively low number of such cases reported to the regulators over a period of five years reflects unreported medical malpractice cases in the Namibian health system.
- There has been nevertheless an increase in complaints against medical practitioners making the Medical and Dental Council the recipient of a high number of complaints over the five years. This may be attributed to the fact that although some patients may have received sub-standard care, it is inherently in the nature of medicine that tragic outcomes are often inevitable and successful treatment outcomes may not be guaranteed.
- There has been a decline in complaints of still births against nurses. This may be attributed to efforts by government to address issues surrounding the way expectant mothers are being care for. There seems however to be a lack of expertise or willingness to provide acceptable general care to patients that involves effective communication, advocacy, and education.
- There seems to be a lack of understanding of the roles of psychologists and psychological counsellors despite defined scopes of practice in place. This may be

attributed to a shortage of psychologists in some parts of the country and patients are attended to by psychological counsellors.

- The data also reveal a high rate of complaints relating to inappropriate advertising by pharmacists. It would appear as if parameters on advertising, as laid down the acts and omissions for the pharmacy profession, may not be known and the business arm of the pharmaceutical industry may have created the desire to advertise.
- The demographic representation of the complaints is mostly people who reside in urban and peri-urban settings. This casts more doubt as to whether the general public is aware of the existence of the Councils and their rights to seek recourse in the event of mistreatment.
- More medical malpractice cases are very old for several reasons: insufficient funds; reluctance of healthcare practitioners to co-operate with the Council during investigation; shortage of medical practitioners willing to provide expert opinions; and perpetual delays by hospitals and health facilities in releasing medical records for patients.
- Some practitioners charged with unprofessional conduct explained that they were mostly overworked and experienced a high level of pressure in their working environment due to shortage of staff amidst a high number of patients needing care.
- Various penalties were imposed by Councils on practitioners found guilty of unprofessional conduct. For example, suspension from practice for a specified period of time; payment of a fine ranging from N$ 500.00 to N$ 100 000.00; mandatory practice inspection and passing of additional examination.

6.4 Medical malpractice claims against the State between 2014 and 2019

As indicated in chapter three, Namibia does not have a statutory law specifically dealing with medical malpractice claims. Hence claims based on medical negligence are dealt with under

common law. This system also assumes that patients must be familiar with existing legal recourse, should be able to secure legal representation, commence proceedings in the correct court, prove their cause of action and prove damages in an area that requires complex expertise.

As presented in Table 5 in chapter three there were 28 compensation claims paid by the State from 31 March 2014 to 31 March 2018. This number however does not include the unsuccessful medical-negligence claims instituted against the State as such data could not be found. When compared with the number of medical malpractice complaints (n=319) reported to the Councils over the same period as presented in Table 7, it is clear that most medical malpractice complaints did not result into compensation claims. This poor correlation between medical negligence and medical malpractice claims suggests that patients who suffered injuries due to medical negligence are rarely compensated due to challenges in pursuing such claims. The latter, as indicated in chapter three are: litigation cost, burden of proof, lack of suitable expert witness, and State limited liability. These findings do not only cast doubt on the ability of Namibia's medical malpractice system to deter sub-standard care, but also on the accessibility of her compensation and liability system to restitute the negligently injured patients and to exacts corrective justice.

It is the finding of this study that the value of the compensation claims paid by the State over the period of five years was six million one hundred sixty-three thousand nine hundred and forty-nine dollars and thirty two cents (N$ 6 163 949. 32). Although this five-year amount does not appear exorbitant, it remains a worrying factor to discover that no specific budgetary allocation is made for medico-legal claims in the budget of the ministry of health and social services. Money paid for such claims are simply diverted from other budgetary apportionments. This practice may result in a vicious cycle in which more claims would have been paid with the result there will be less money available for service delivery. This in turn could result in

poor quality of services rendered by hospitals and thus lead to more opportunities for negligence and errors. Put differently, the end results will be more claims.

Data were not found as to how much of what was paid by the State in compensation claims went to legal fees. Equally, no information was obtained indicating whether such payments were made as part of court orders or an out of court settlement. What is however clear from the results of this study is the existence of patient safety cases in Namibia and the impact they have on the public purse. In Namibia, the people who make use of State health services are the indigents who cannot afford private legal representations. It is highly probable therefore that not many cases of medical malpractice claims reach the court of law.

6.5 Evaluation of the regulatory framework for healthcare professions in Namibia

Namibia has an Act of Parliament which provided a legal framework for the regulation of health care professionals.[954] This Act spells out the ambit of the legal authority delegated to the regulatory body called the Council which is a juristic person established by the same Act.[955] It appears that Namibia does not have a pure form of professional self-regulation where the profession alone regulates itself, but a co-regulatory system where the profession underwrites the internal control by way of education and practice standards, guidelines, and professional development while the government, through legislation, provide external control over the practice of healthcare professions and services provided by their members.

This study therefore suggests that the regulation of medical professions in Namibia resemble a hybrid form of professional self-regulation in a significant way. However, its regulatory focus is primarily on individual healthcare professionals rather than on their places of work reflecting the nature of the traditional model of professional self-regulation.

954 Para 5.1.
955 Para 5.2.

This study also suggests that patient safety remains the concern of the State, and therefore despite the Council having acquired significant authority from the government, the Namibian regulatory framework has provided mechanisms through which the government can still ensure accountability for the powers and functions delegated to the regulatory body. In this respect, the Council is expected to report to Parliament through the line minister on its activities and handling of finances each year.[956] The other accountability approach adopted by Namibia is through the appointment of public members to serve on the Council.[957] The involvement of the government and public members in the regulation of healthcare professions underlines the importance of patient safety in the sense that while professional self-regulation may provide healthcare professions with some degree of autonomy, the members of the professions may not be trusted to always put patient safety first above their own interest.

The regulatory bodies have developed, implemented, and enacted rules and regulations primarily aimed at public protection against its members. This includes strict registration and certification requirements,[958] rules governing the education and training of practitioners,[959] and standards on how the profession may be practiced competently and ethically.[960] With regards to distinctive ethical standards, Namibia has both rule-based codes of professional conduct[961] and principles-based code of ethics.[962] There is also a system of receiving and investigating complaints from the public, and disciplining healthcare practitioners whose professional conduct is found wanting, as well as dealing with impaired practitioners.[963] Unfortunately, the

956 Para 5.2.
957 Para 5.2.
958 Para 5.3.1.
959 Para 5.4.
960 Para 5.3.2.
961 In the form of specific disciplinary rules on acts and omissions.
962 In the form of broader principles in the ethical guidelines.
963 Para 5.5.

retrospective nature of this approach provides no means of preventing harm to patients before occurring.

The registration and certification system adopted by Namibia does not only make the occupational structure exclusive for healthcare professionals and intolerant to the unregistered, but also limits the exposure of patients to unqualified members of the public and incompetent members of the profession. Despite having a pre-registration evaluation in place, Namibia has not yet introduced the licensure approach, which would require a specific level of competency and the passing of a licensing and re-licensing examination by a healthcare practitioner. However, in order for healthcare practitioners to maintain professional knowledge, skills competency, a mandatory continuing professional development (CPD) system was introduced in Namibia.[964]

In Namibia, patient safety is mainly achieved as follows: through strict registration requirements of healthcare practitioners; keeping the registers of healthcare practitioners who are fit to practice; removal from the register the names of healthcare practitioner whose conduct is found wanting or suspend such person from practice; putting in place acceptable standards of professional behavior and practice, standards of education and training; guiding healthcare practitioners with respect to the code of conduct and ethical standards of professional practice; investigating all complaints, accusations or allegations relating to conduct of registered healthcare practitioners whose fitness to practice are in doubt; enforcement of continuous professional development for healthcare practitioners to keep their knowledge and skills current; instituting disciplinary proceedings against a healthcare practitioner whom a charge, complaint or allegation of unprofessional conduct has been laid; restricted registration of healthcare practitioners with limited skills and those in need of supervision; additional training

964 Para 5.4.

and examination for those whose competencies are in doubt; and regular inspection of approved educational institution, training facilities, pharmacy practices to ensure compliance with set standards. Education and training inspections are carried out by all five Councils in Namibia, but only the Pharmacy Council registers and inspects pharmaceutical facilities.

In summary, the governance architecture of the Namibian regulatory framework for healthcare professions generally bears a resemblance to a hybrid form of professional self-regulation with emphasis on professionalism and independence of practitioners as part of the core ethical values. The system is exclusive for healthcare practitioners with less tolerance for unregistered health practitioners. The regulatory focus is on individual healthcare practitioners and with less regards to place of practice.

6.6 The Namibian regulatory framework compared to South Africa

As discussed in chapter five, healthcare professions in South Africa are regulated by various statutory bodies: most of them fall under the HPCSA. Those that do not fall under the HPCSA are the pharmacy, nursing and social work professions.[965] Although healthcare professions are also regulated by various bodies in Namibia, as is the case in South Africa, the five Councils in Namibia are jointly administered.[966] This arrangement is not only appropriate for a country with a smaller population of healthcare professionals, but also the most economical and beneficial in sharing the best practices of dealing with common problems relating to professional education and practice.

The legal framework of the HPCSA, which was the focus of the comparative analysis in this study, is largely similar to that of Namibia. Similarities can be found with regards to the

965 Paras 5.2 & 5.2.3.
966 Para 2.14.

recognition of registrable qualifications;[967] registration of healthcare practitioners;[968] removal from the register and restoration of names to the register;[969] approval of educational programmes and training schools;[970] disciplinary powers of the Council;[971] dealing with persons impersonating as registered healthcare practitioners;[972] dealing with deaths from unnatural causes;[973] appeals against the decisions of the Council;[974] and management of impaired practitioners.[975]

It is however important to note that, unlike in Namibia, in South Africa a person who refuses or neglects or obstructs the registrar or an investigation officer in the execution of an investigation, is guilty of an offence and on conviction liable to a fine or imprisonment.[976] This approach is very necessary especially in the case of Namibia where malpractice complaints are sometimes very old for the following reasons. Healthcare practitioners are not willing to co-operate with the preliminary investigation committee. Hospitals and health facilities are not willing to provide medical records to the Councils for purposes of medical malpractice investigation.

Most of the penalties, imposed by the HPCSA professional boards on healthcare practitioners found guilty of unprofessional conduct, are significantly similar to the ones prescribed in Namibia. However, in South Africa, a healthcare practitioner may be ordered to perform compulsory professional service for a specified period, as may be determined by the

967 Para 5.2.4.
968 Para 5.2.9.
969 Para 5.2.4.
970 Para 5.2.4.
971 Para 5.2.5.
972 Para 5.2.11.
973 Para 5.2.12.
974 Para 5.2.8.
975 Para 5.2.10.
976 Para 5.2.6.

professional board or pay the costs of the professional conduct proceedings or a restitution.[977] While the payment for costs of proceedings is absolutely necessary, given the high costs for professional conduct enquiries in Namibia, claims for restitution should be left to the domain of civil proceedings in an ordinary court of law.

It is also the finding of this study that in South Africa a registered healthcare practitioner who is alleged to be guilty of unprofessional conduct, and the professional board on reasonable ground is of the view that it shall impose a fine on him or her upon conviction after an inquiry, the professional board is empowered to issue summons to that healthcare practitioner on which an endorsement is made by the professional board or registrar that the healthcare practitioner may admit that he/she is guilty of the conduct stated on the summons and that he/she may pay a fine stipulated without appearing at the professional conduct inquiry.[978] This option is currently not available in Namibia albeit necessary for the speedy finalisation of professional conduct cases in Namibia.

Professional conduct inquiries in South Africa are carried out by the professional boards on behalf of the HPCSA, but the decisions of the professional board are not subject to ratification by the HPCSA.[979] This is different in Namibia where professional conduct inquiries are predominantly carried out by the professional conduct committee of the Council and the decisions of the committee have no legal effect until ratified by the Council.[980] The South African approach is the most preferred for two reasons. First, in Namibia, the professional conduct committee is chaired by the person who is also the president and the chairperson of the Council. In addition, some members of the same professional conduct committee are also

977 S 42 of the Health Professions Act 56 of 1974.
978 S 42 of the Health Professions Act 56 of 1974.
979 Para 5.2.5.
980 Para 4.5.

members of the Council. It would therefore mean that the Council is literally ratifying its own decision when being presented with the recommendations made to the professional conduct committee. Such overlapping powers cannot be executed in a fair and just manner. Second, an approach similar to that of South African may create a cheaper and swifter avenue for the disposal of professional conduct cases in Namibia.

Medical malpractice complaints reported to the HPCSA are investigated by the committee of preliminary inquiry. This is the equivalent of the preliminary investigation committee in Namibia. However, the preliminary committee of inquiry of South Africa has more powers to act swiftly in cases where the safety of patients is at stake.[981] Regrettably, in Namibia, the preliminary investigation committee has no power whatsoever to take any action against a healthcare practitioner, in the interest of patient safety, and pending the finalisation of the investigation.

As pointed out above regarding the Namibian regulation model, South Africa also adopted a traditional professional self-regulating approach for healthcare professions, which is chiefly focused on individual accountability. Reforms were nevertheless made through the enactment of the National Health Act 61 of 2003, which provided for the establishment of the Office of the Standards Compliance to deal with quality improvement matters.[982] However, it would appear that the date of commencement of this part of the legislation is yet to be proclaimed. It is also worth noting that unlike in the case of Namibia, the Department of Health in South Africa has produced a national policy for patient safety incident reporting and learning. Namibia is yet to reach this milestone.

981 Para 5.2.7.
982 S 78.

6.7 The Namibian regulatory framework compared to the UK

There are similarities between the Namibian and the UK regulatory framework for healthcare professions. Like in the case of Namibia, the aim of professional regulation in the UK is to ensure public protection through standard setting and removal of registered healthcare practitioners whose conduct fall short of such standards.[983] The UK regulation model focuses broadly on individual responsibility as opposed to organisational systems.[984] As in the case of Namibia, there are several regulatory bodies for healthcare professions in the UK, each one of them with their own separate statute.[985]

While the functions of all regulatory bodies in the UK are primarily to advance the interest of patient, the functions of the Pharmaceutical Society of Northern Ireland also include professional representation.[986] Such dual function is not preferred as it likely to add impetus to public perception that regulatory bodies were established to advance the interest of their members at the expense of public safety and defeat the purpose of a professional self-regulation model.

Unlike in the case of Namibia, the UK government plays a more active role in overseeing the work of the regulators through the Privy Council, which surprisingly has a duty to intervene in cases of regulatory failure.[987] The same body can also initiate public inquiry in any matter concerned with the exercise of functions of the regulator. This approach is viewed by the researcher as useful in cases where the regulator fails to execute its statutory mandate and, on condition, that it is not abused to undermine the value of professional-self regulation. In addition to the State oversight function indicated above, and in what may be described as a

983 Para 5.3.
984 Para 5.3.
985 Para 5.3.1.
986 Para 5.3.2.
987 Para 5.3.4.

duplication of functions, the UK has another statutory body. The Professional Standards Authority for Health and Social Care was established to supervise the work of the nine regulatory bodies.[988] For Namibia with her limited financial resources and smaller population of healthcare professionals, a similar body would likely to be expensive to administer.

Keeping of registers of healthcare practitioners in the UK presents some good examples for Namibia. The registers that are kept by some regulators in the UK include information on registrants who are under sanctions as a result of fitness to practice proceedings.[989] This information is important to the public when choosing their service providers. Some regulators are allowed to keep provisional registers, temporary registers, or conditional registers, but some are also given additional leeway to make changes to the registers in the case of emergency.[990] This kind of flexibility is very important especially in cases where patient safety is at stake or in cases where more healthcare practitioners are needed for the provision of emergency care as witnessed recently in Namibia with the outbreak of Covid-19 pandemic. Furthermore, although the registration requirements prescribed by most regulators in the UK are generally like that of Namibia, most of them have a requirement for appropriate indemnity arrangement in place before registration. This is absolutely necessary in cases of delictual claims in Namibia.

It is interesting to note that regulators in the UK may establish and maintain voluntary registers for persons who are unregistered healthcare practitioners.[991] This avenue is not available in Namibia despite the growing number of such practitioners providing healthcare services in the communities as counsellors, community health workers, first aiders, home-based care providers, and traditional birth attendants, whose unregulated conducts may put the patient

988 Para 5.3.22.
989 Para 5.3.5.
990 Para 5.3.5.
991 Para 5.3.22.

safety in jeopardy. They may be subjected to government control without professional-self regulatory status.

Like in the case of the Pharmacy Council of Namibia, some regulators in the UK have jurisdiction over business engagements in health enabling them to register premises, maintain registers of businesses, inspect business premises, and impose financial penalties on such entities.[992] These entities are normally body corporates carrying on business as healthcare practitioners. Although regulators do not have powers to deal with consumer complaints emanating from business transactions with such entities, the registration and inspection of premises of such body corporates somehow brought the organisational and systemic issues of their activities within the purview of the regulatory bodies. This practice is worth replicating to other public facilities providing care to patients.

Similar to the Namibian system, there are opportunities for appeals in the UK against the registration decisions of the regulator.[993] It is also understood that such opportunities are also extended to decisions of the regulator on medical malpractice cases. The appeals are made to the county court or the sheriff and not to the internal appeals committee as in the case of Namibia. There seem to be no right for appeal to the high court in the UK with respect to the decisions of the regulators.

With regards to the control of education and training, and the setting of standards of professional conduct and practice, the approach adopted in the UK is similar to that of Namibia.[994] However, in the UK regulators are also required to determine, from time to time, the standards for safe and competent performance.[995] Similarities can also be found with

992 Para 5.3.5.
993 Para 5.3.7.
994 Para 5.3.9.
995 Para 5.3.10.

regards to the CPD system in Namibia and the UK.[996] Some regulators in the UK have however gone a step further to introduce a revalidation system.[997] This system requires registered healthcare practitioners to demonstrate that their knowledge, skills, and competency are up to date, and they are professionally fit to practice. The UK also has a system of licensure in place in addition to registration and certification.[998] To renew their licences to practice in the UK, registrants must henceforth comply with CPD requirements; some regulators require participation in the process of annual appraisal information drawn from a governance system.[999] Both the revalidation system and the licensure regime, which are currently not in Namibia, are necessary in ensuring patient safety. The licensure is however part of the Health Professions Bill discussed in chapter two (cf. 2.15) which is yet to be tabled before the Namibian Parliament.[1000]

The other significant difference between the Namibia and the UK regulatory framework is that of the definition of an impaired fitness to practice. As discussed in chapter four the Namibian definition of impairment is limited to a mental or physical condition or the abuse of, or the dependence on, any medicine, scheduled substance, dependence-producing substance, chemical substance or any other substance, which negatively affected the competence, attitude, judgement or performance of any registered person.[1001] This definition is certainly very narrow when compared with that of the UK, which includes misconduct, deficient performance, adverse physical or mental health, criminal conviction or action and demonstration by another regulator.[1002] While the wider definition of the UK is preferable, it is comforting to note that

996 Para 5.3.11.
997 Para 5.3.11.
998 Para 5.3.11.
999 Para 5.3.11.
1000 Para 2.15.
1001 S 48 (1)(a) of the Medical and Dental Act, 2004.
1002 Para 5.3.12.

not every finding of misconduct or deficient performance would inevitably mean that the registered person's fitness to practice is impaired.

In the UK different processes are being followed by regulatory bodies to investigate medical malpractice complaints but, as is the case in Namibia, the main purpose of such investigations is to determine whether the case should proceed to a professional conduct inquiry or whether it should be settled in some other way.[1003] Some regulators in the UK, for example, make use of a case examiner to perform the task of the investigation committee.[1004] This process makes the investigation process faster, more efficient, and reduces the workload on the investigation committee.

After carrying out an investigation on a medical malpractice case, the regulator must decide on the way forward. Some regulators in the UK are guided by tests such as the realistic prospect to establish the impaired fitness to practice or whether there is a case to answer.[1005] This is typically similar to the tests being used by the regulators in Namibia. What is however different from the Namibian approach is that in the UK should the regulator decide that a formal inquiry on a matter is not necessary, the regulator can dispose it off by issuing warnings or some kind of an advice to the healthcare practitioner or reach a consensus with the healthcare practitioner for him or her to comply with such an undertaking as the regulator may find appropriate or grant the healthcare practitioner a voluntary removal from the register.[1006] Some regulators in the UK have the powers to institute mediation processes between a complainant and a healthcare practitioner.[1007]

1003 Para 5.3.16.
1004 Para 5.3.16.
1005 Para 5.3.14.
1006 Para 5.3.19.
1007 Para 5.3.14.

In Namibia the regulator has no power whatsoever to issue warnings or conclude an undertaking with a healthcare practitioner being investigated without holding a professional conduct inquiry. There is no option in Namibia for voluntary removal from the register on account of a medical malpractice investigation or for mediation between a complainant and the healthcare practitioner.[1008] The lack of these alternatives to resolve complaints makes the Namibian system purely adversarial, costly, and less efficient.

Regulators in the UK are empowered to use case management approaches as part of the medical malpractice investigation processes as discussed in chapter five. This includes the holding of pre-hearing sessions, issuing directives on how investigations should be carried out, and on the consequences for non-compliance.[1009]

The other similarities between Namibia and the UK regulatory systems for healthcare practitioners are that the regulators in both countries played the roles of both the investigator and adjudicator of medical malpractice cases in addition to being the generator of standards for professional education, training, and practice. This is typically a characteristic of the traditional model of professional self-regulation.[1010] This approach however caused some questions in the UK about the independence and objectivity of the regulators in executing these functions and led to the establishment of Office of the Health Professions Adjudicator in the UK to enhance the independence of the adjudication process.[1011] This effort was however short-lived due to lack of funds and the adjudication function had to be returned to the regulators. Subsequently, some regulators such as the General Medical Council (GMC) had to come up with an alternative through the establishment of the Medical Practitioners Tribunal Services to deal

1008 Para 4.5.
1009 Para 5.3.16.
1010 Paras 1.7 & 1.8.
1011 Para 5.3.15.

with medical malpractice cases and interim orders.[1012] Although it is part of the GMC, the operations of the Tribunal are independent from that of the GMC.[1013] It would appear as if Namibia is also in the process of reforming its processes in this respect by establishing a professional conduct committee independent of members of the Council as proposed in the Health Professions Bill discussed in chapter two (cf. 2.15) and yet to be tabled in Parliament.[1014]

As is the case in Namibia, the purpose of sanctions imposed by the UK regulators against healthcare practitioners whose conduct is found wanting is not punitive but to protect the public.[1015] This is the case even when such sanctions may have some punitive outcome. Sanctions that are available in the UK, and not in Namibia, are voluntary removal from the register[1016] as well as the interim orders.[1017] Interim orders would particularly be helpful in cases where patient safety is at stake because such orders would allow for temporary measures to be enforced on a healthcare practitioner while the regulator is busy investigating the allegations made against him or her. Such orders may include restricted registration, which allows a healthcare practitioner to continue practising but in a constrained capacity, or an interim suspension order which prevents the healthcare practitioner from practising until there is a formal determination of the case.

6.8 Lessons from the UK and the South African jurisdictions

Similarities can be found between the UK, South Africa and the Namibia's regulatory framework for healthcare professions especially with regards to the recognition of registrable

1012 Para 5.3.15.
1013 Para 5.3.15.
1014 Para 2.15.
1015 Paras 4.1 & 5.3.
1016 Para 5.3.19.
1017 Para 5.3.20.

qualifications; registration of healthcare practitioners; removal from the register and restoration of names to the register; approval of educational programmes and training schools; disciplinary powers of the Council; dealing with persons impersonating as registered healthcare practitioners; dealing with deaths from unnatural causes; appeals against the decisions of the Council; and management of impaired practitioners. However, Namibia can draw good lessons from these jurisdictions in respect to the importance of having a national policy for patient safety to facilitate the reporting and management of adverse events in health care settings; putting in place mechanisms for monitoring and regulating the quality of care rendered to patients in health facilities; acting swiftly in cases where the safety of patients is at stake; determining the standards for safe and competent practice in health care settings; dealing with complaints relating to breach of prescribed practice norms and standards; and introducing revalidation and licensure regimes for healthcare professionals to ensure patient safety .

6.9 Summary

The purpose of this penultimate chapter is to consolidate and discuss the main findings of the study. The discussion cover the historical context of healthcare professions regulation in Namibia; the medical malpractice incidents and claims in Namibia; the appraisal of the Namibian regulatory framework for healthcare professions; the comparative analysis of the Namibian regulatory framework for healthcare professions to that of the UK and South Africa; and finally, the best practice Namibia can draw from the UK and the South African jurisdictions. In the next chapter, the main conclusion and recommendations of the study are presented.

CHAPTER SEVEN

CONCLUSIONS AND RECOMMENDATIONS

7.1 Introduction

The previous chapter deals with consolidation and discussion of the study findings. In this ultimate chapter, the researcher briefly reflects on the purpose and objectives of the study before focusing on the main conclusions and recommendations emanating from the findings. Contribution to the body of knowledge and recommendations for future research are covered in the last part of this chapter.

7.2 Restatement of the purpose and objectives of the study

The purpose for conducting this study is to evaluate the appropriateness of the legal instruments regulating the healthcare professions in Namibia with a view to ensure patient safety. To fully appreciate the magnitude of patient safety problems in Namibia, it is equally important to establish the medical malpractice complaints reported to the regulatory authorities, as well as the quantity and value of medical malpractice claims against the state in Namibia. The study is motivated by public reports of medical malpractice and negligence involving healthcare professionals, the need to find out how the current legal framework of regulation healthcare professions is helping in ensuring patient safety, and how it may be improved. The purpose of this study is generally achieved.

There are four objectives of this study.

- To evaluate the appropriateness of the Namibian regulatory framework for healthcare professions to contribute to the improvement of patient safety.

- To undertake a situational analysis of medical malpractice complaints reported to the regulatory authorities for healthcare professions in Namibia as well as the quantity and value of medical malpractice claims against the State between 2014 and 2019.
- To compare the Namibian regulatory framework for healthcare professions to South Africa and the UK with a view to identify similarities and differences in dealing with patient safety and to draw best practices from these countries.
- To recommend a legal framework for improving patient safety in Namibia.

In terms of the discussions in chapter six the researcher is of the opinion that the objectives of this study have been met.

7.3 Summary of the main conclusions

The main conclusions of the study are as follows.

a) Namibia has adopted a hybrid form of traditional model of professional self-regulation spearheaded by five independent regulatory bodies with a joint secretariat.

b) Due to the independent nature of the current legal framework, the five regulatory bodies for several healthcare professions in Namibia are not capable of combining their investigations for medical malpractice complaints if such incidents occurred as a result of a multidisciplinary approach. Such adverse events are investigated using a single incident approach which creates inefficiencies.

c) The current legislative framework for professional regulatory inquiries in Namibia lacks a system perspective and has no alternative processes that minimise the punitive nature of the inquiries while still addressing patient safety concerns.

d) At present, when an unsafe act occurs in the Namibian healthcare system, the legal response is focused on assigning fault to the actions of the healthcare practitioner and compensating victims. This focus creates a tendency towards blaming and penalising individuals, which in turn inhibits disclosure and learning from unsafe acts. The

retrospective nature of this approach provides no means of preventing harm to patients before occurring.

e) The strength of a civil liability system in Namibia is that those who are wronged can be fully compensated for loss when fault is proven. However, the weakness of this system is the difficulty and expense of proving fault resulting in many legitimate claimants potentially not receiving compensation at all. It is also possible that patients who suffer an adverse event that was not due to negligence have no other avenues to seek redress.

f) There has been a tremendous increase in complaints against medical practitioners over the same period.

g) Namibia does not have a national policy on patient safety.

h) Namibia has no separate budget to pay for litigation and compensation for medical malpractice claims and such payments are made from the budget reserved for other important activities. Such a practice is likely to compromise the delivery of healthcare services and further compromise patient safety.

i) The regulatory bodies are insufficiently funded and as a result unable to effectively ensure patient safety.

j) The current legal framework of regulating healthcare practitioners can be regarded as appropriate in ensuring patient safety but not adequate as it excludes health facilities and systems. There is a need to introduce a regulatory framework that enables the Councils to regulate the standard of care provided by hospitals and health facilities.

k) The types of professions and occupations that deliver health care in Namibia are expanding and new healthcare providers are largely unregulated creating risks for patients. Like in the UK there may be a need to subject these to government control without professional-self regulatory status.

l) Unlike the efforts made in the UK and South Africa, there is currently no independent institution in Namibia empowered to monitor and regulate the quality of care rendered to patients in public hospitals and health facilities.

m) The only means of discovering unsafe acts in Namibia is through patient complaint mechanisms. There are no mechanisms to encourage and support healthcare providers to bring forward safety and quality concerns. This situation does not only lead to underreporting of unsafe acts but also deprives healthcare workers an opportunity to be assisted in preventing such unsafe acts and learn from their mistakes.

n) No legislation currently exists in Namibia to specifically deal with legal claims in the medical fields. Such claims are dealt with in terms of the common law through the courts resulting in inevitable delays due to full court rolls, sluggish legal processes, and unavailability of witnesses.

7.4 Recommendations to improve administrative systems on patient safety

a) The Namibia Public Health Authority should formulate a national policy for patient safety to facilitate the reporting of adverse events and learning from them.

b) Public hospitals and health facilities should put in place practice protocols, standard operating procedures and guidelines aimed at ensuring patient safety and hold staff accountable if such protocols, standard operating procedures, and guidelines are not complied with.

c) The Namibia Public Health Authority should determine the staff complement required per hospital and health facilities and fill vacancies in order to prevent understaffing which may compromise patient safety. It is also important to ensure that junior staff and students are adequately supervised and socialised to prevent the occurrence of adverse events.

d) There is a need to expedite the investigation of adverse events and medical malpractice complaints reported to regulatory bodies. This is necessary not only to improve on efficiency and ensure patient safety but also to safeguard public confidence in the abilities of the regulatory bodies to execute their mandate.

e) The Namibia Public Health Authority should have a separate budget to pay for litigation and compensation claims for medical malpractice to avoid the use of money meant for service delivery.

f) The Namibia Public Health Authority should make use of in-house medical experts to assess the medico- legal claims and determine whether such claims can be defended or settled.

g) The Namibia Public Health Authority should exercise proper case management once litigation has been instituted.

h) The Namibia Public Health Authority should collect information on adverse events and develop a database for information sharing in order to determine trends, and to assist with the ascertainment of compensation.

i) The Namibia Public Health Authority should develop a comprehensive patient safety management approach aimed at different targets, namely, persons, teams, tasks, workplaces, and institutions.

j) There is a need to develop and strengthen the standards of healthcare delivery focusing on quality of care, who delivers care, where it is it being delivered, the type of services being delivered, and the tools/ amenities required to deliver such care.

k) There is a need to regularly increase funding to the regulatory bodies, consolidate their resources and strengthen internal capacities to cut costs on external consultancies.

l) Regulatory bodies should not rely only on patient complaints to identify patient safety problems but should actively supplement patient complaints with other forms of

detection, including practitioner-initiated complaints, regular testing of practitioner competency and periodic practice inspections.

7.5 Integrated regulatory framework for improving patient safety in Namibia

This study offers an integrated regulatory framework to improve patient safety. This is done based on the conclusion of this study that the traditional way of regulating healthcare professions must be changed to include systemic and organisational determinants of patient safety and simultaneously ensure that individuals and systems can be held accountable when appropriate. The characteristics of the framework signify the departure from dealing with patient safety issues in silos to a more integrated approach. The regulatory framework consists of the following eleven elements: The Act; regulatory body; registration; standards; oversight; reporting; accountability; enforcement; individuals; systems; institutions; and safe patient care. These elements are illustrated in Figure 8 below.

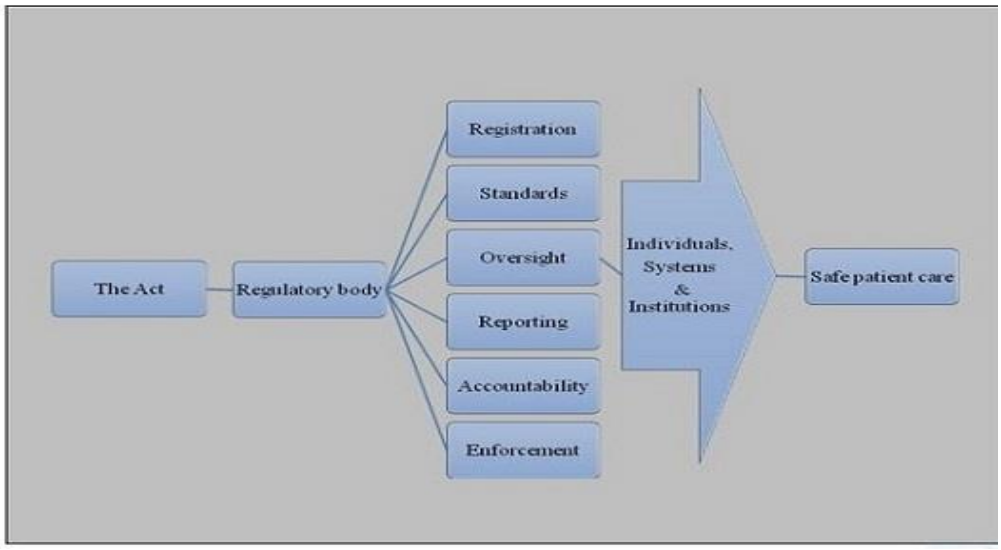

Figure 8: Intergrated regulatory framework on patient safety. *Source: Owner's construct.*

The elements of the integrated regulatory framework to improve patient safety are explained as follows.

A. The Act

This element refers to the promulgation of a single Act establishing a regulatory body for all healthcare professions in Namibia. It enables the shift from the current individual accountability approach to a systems perspective, so that when an unsafe act occurs, the response involves the identification of system deficiencies that contributed to the unsafe act and creating improved practices and processes in the system in order to prevent future occurrence. This is the legislation to deal with medical malpractice claims in Namibia and it creates synergy with other patient safety laws in the country.

B. Regulatory body

There should be one juristic body with statutory powers to regulate the conduct of individual healthcare practitioners and systems/institutional factors relating to patient safety. This body will be in charge of regulating the conduct of healthcare practitioners in Namibia and also monitor patient safety at the point of care.

C. Registration

The element includes registration, certification, and licensure, which are the embodiments of professional-self regulation. The regulatory body shall have the powers to register, issue licences and certificates, as the case may be, to individuals, educational and training facilities as well as to hospitals and health facilities. This is to prevent unregistered, uncertified, or unlicensed individuals and facilities from offering healthcare services to patients and putting their safety at risk.

D. Standards

The regulatory body is to set standards, issue policies and directives on matters concerning patient safety in the areas of education and training as well as professional practice. These standards are two-fold. They are helpful in improving knowledge, skills and competencies of healthcare practitioners or the quality of services rendered by hospitals and health facilities; and also, the yardstick against which the successes and failures of practitioners and institutions in ensuring patient safety are to be determined.

E. Oversight

The regulatory body is to play an oversight role on the implementation of patient safety standards, policies, and directives through regular inspections of hospitals and health facilities with a view to monitor outputs and quality of outcomes for patients. Monitoring of how approved training programmes are executed in order to produce safe and competent practitioners is also part of the oversight element. This should also include compliance with the requirements on CPD for individual practitioners.

F. Reporting

This element includes the empowerment of patients, families, and relatives to make individual and system-related complaints to the regulatory body. It further includes a mandatory adverse event reporting system, which is non-punitive, confidential, and allows for anonymous reporting by healthcare practitioners. It should also be made a positive duty for a healthcare practitioner, hospital or health facility to ensure that a patient is fully informed about the facts of a critical incident that happened, its consequences for the patient, and actions for addressing its consequences. There should also be a corresponding right of a patient to be informed by a healthcare practitioner, hospital, or health facility, as soon as possible of any accident that has

actual or potential consequences for his or her health and the measures to be taken to address any consequence he/she suffered, as well as steps to prevent such an accident from recurring. A patient complaint mechanism for the unregulated healthcare providers, and the legal authority to investigate the quality of care they provide, also falls under this element.

G. Accountability

The regulatory body should have powers to evaluate all approved education programmes based on their ability to improve patient outcomes through the use of methods that can produce measurable changes in professional practice. Educational institutions and training facilities should be accountable to the regulatory body and the public for the effectiveness of their programmes. The regulatory body should also be empowered to demand accountability across the spectrum of healthcare providers, institutions, and actors who collectively are responsible for the delivery of safe care to individual patients. This should include being empowered to close a hospital or health facility on the grounds of poor outcomes for patients.

The regulatory body should be empowered to use alternative dispute resolution, such as mediation, to resolve concerns. An apology system, which does not constitute admissions of civil liabilities or unprofessional conduct, can be one of such alternatives.

This element of the framework advocates for the creation of a compensation system-based restorative justice and financial sustainability and characterised by the following tenets.

i. A medico-legal claims and restitution scheme closely linked to the patient complaints and disciplinary process of the regulatory body.
ii. Direct access to the compensation system by patients, family, and relatives without a legal practitioner as an intermediary.

iii. A medico-legal tribunal to screen and evaluate the viability of claims and to adjudicate such claims.

iv. Different methods of compensation

- Free treatment in state hospitals.
- A no-fault system for payment of compensation without the need to institute a medical malpractice claim and proving causality as an element of delict.
- A fixed awards system and capping of claims for general damages.[1018]
- A lump sum payment to a maximum amount for general damages.[1019]
- Structured settlements and periodic payments as the default position for all future special damages.[1020]

H. Enforcement

This element of the framework speaks to the enforcement of laws, regulations, directives, standards, policies, guidelines, and protocols relating to patient safety. The element also refers to the powers of the regulatory body to enforce compliance with sanctions, conditions, or penalties it has imposed on individuals and institutions.

1018 General damages are such as pain, suffering, emotional distress, and loss of amenity of life.

1019 Lump sum payments refer to "an award granted by court that covers past losses and losses likely to be suffered in the future. When calculating a lump sum award, future losses are normally reduced to the present value bay taking a variety of factors into account. US Legal Inc *Law and Legal Definition* available at https://definitions.uslegal.com. (Date of use: 13 April 2020).

1020 Structured settlement is an agreement to settle a personal injury claim, where the claimant accepts a defined package of financial products, generally cash and periodic payments, on specified terms. On the other hand, periodic payment is a commitment to make future payments to a claimant according to an agreed schedule on specified terms. Future special damages are such as loss of earnings, cost of care, medical care, treatment, assistive devices, and therapy that are expected occur. See Dehner, J.J., Hindert, D.W..D., & Hindert, P.J. (2005), Structured Settlements and Periodic Payment Judgements. *Law Journal Press*, New York. p: 1-3.

I. Individuals, institutions and systems

This part reflects the subjects of the framework which are: individual healthcare practitioners, their places of work, and systems in which they find themselves. These multiple targets are also manifestations of an integrated regulatory framework which is both patient and system-centred. It also underlines the conclusion of this study that patient safety cannot be achieved through disjointed approaches.

J. Safe and effective patient care

This part signifies the goals and outputs of the integrated regulatory framework.

7.6 Contribution to the body of knowledge

While patient safety may have been investigated elsewhere, there has not been any other study besides this one that has looked at issues of patient safety in Namibia through the lenses of the law. This study in itself is therefore a unique contribution to the field of medical law, which is the area that lacks empirical research findings in Namibia**.**

This study has generated baseline data on the number of medical malpractice cases in Namibia, as well as on the quantity and value of medical negligence lawsuits on the public purse in the aftermaths of reported medical errors. In this respect, the study did not only produce information peculiar to Namibia but also assisted in narrowing the void of the required data upon which future research and strategies on patient safety can be grounded.

This study is also unique in that it used a system governance approach to patient safety with a view to identify a body of laws that can be described as patient safety law in Namibia. This was done by looking at the actual interface between different types of laws on patient safety. In doing so, this study has traversed the traditional approach of legal scrutiny focusing on

bodies of law, rather than on a problem such as patient safety to which such bodies of law may apply.

The regulatory framework proposed by the researcher represents a distinctive outcome of this study that will serve as a source of knowledge for the improvement of healthcare professions regulation and patient safety in Namibia. This regulatory framework is particularly advancing a departure from the traditional approach of dealing with patient safety issues in silos towards an integrated system.

7.7 Recommendations for future research

This research study recommends further research should be undertaken in the following areas:

- One of the research areas worth exploring is the relationship between medical malpractice claims and adverse events due to negligence. Such research is important in determining the number of patients exposed to adverse events due to medical negligence against those who filed medical malpractice claims.
- The incidence of adverse events and negligence in hospitalised patients in Namibia are also yet to be determined. Not only will such a study expose the nature of adverse events that occur among hospitalised patients but also the percentage of such adverse events due to negligence.
- This study has provided information on the number and value of medical malpractice claim against the State in Namibia.[1021] It would be interesting to determine the extent of medical malpractice claims in the Namibian private sector.
- The other possible focus area of research is to determine the prevalence of adverse events, negligence and medical malpractice in Namibia.

[1021] Para 6.4.

- Finally, the consequences of medical malpractice to patients in Namibia is also worth evaluating. This may include the assessment of causal effects of medical malpractice on doctor-patient relations as well as the impact of adverse medical outcomes of patients' health-seeking behaviour.

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