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SECTION27 SUBMISSION ON REGULATIONS RELATING TO THE SURVEILLANCE AND THE CONTROL OF NOTIFIABLE MEDICAL CONDITIONS IN GN 604 GG 40945 of 30 June 2017.

30 September 2017

INTRODUCTION

1. SECTION27 is a public interest law centre that seeks to use and develop the law to advance social justice in healthcare, basic education, food and good governance and accountability. Our submission contribution is grounded in the constitutional requirement to realise the right of access to healthcare services and the related right of everyone to an environment that is not harmful to health or wellbeing.[1] Moreover, our input is informed by the implications that these Regulations have for other constitutional rights such as freedom and security of the person, bodily integrity, privacy and freedom of movement.[2]

2. SECTION27, and its predecessor the AIDS Law Project, have made four formal submissions on previous iterations of the Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions ("the Regulations") since the first draft was published on 25 January 2008. Since that time, we have also contributed formally and informally to this process and participated in several public forums. We trust that what has been an inordinately and unjustifiably lengthy process of finalising these Regulations is coming to an end.

[1] See section 24(a) of Constitution of the Republic of South Africa, 1996.
[2] See section 12, 14 and 21(1) of the Constitution.

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We urge the Minister to ensure that there are no further delays in finalising, bringing into force, and implementing the Regulations.

3. We welcome the opportunity to make this submission. We commend the Department for including much of our previous input. We are concerned, however, that fundamental and uncontroversial issues continue to be unaddressed. It is troubling, for example, that after almost ten years of development, basic formatting, typographical and other such errors still persist. This is not a minor issue because it suggests that the Department has simply and repeatedly failed to apply its mind despite the incontestable importance of the Regulations.

4. The Regulations provide basic and critical legal infrastructure for the health system. SECTION27 has been and remains committed to their successful implementation. We will continue to support the process and trust that the Department will engage with our concerns constructively.

5. In this submission, we will first broadly discuss the importance of regulating notifiable conditions and then focus on the following provisions:

    - Definitions
    - Regulation 13 – Notification and Reporting Process
    - Regulation 14 – Voluntary Medical Examination, Prophylaxis, Treatment, Isolation and Quarantine
    - Regulations 15 – Mandatory Medical Examination, Prophylaxis, Treatment, Isolation and Quarantine
    - Regulation 16 – Control and Spread of Notifiable Medical Conditions
    - Regulation 20 – Offences and Penalties

6. We have attached for your convenience the following submissions, which should be read together with this submission:

6.1. SECTION27's Submission on the Draft Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions 2016, 7 March 2017; and

6.2. SECTION27's Submission on the Draft Regulations Relating to Communicable Diseases and Notifiable Medical Conditions, 22 May 2015.

7. We have attached a Word version of the Regulations in track changes, in order to address grammatical errors in the most convenient manner.

8. We have also attached a timeline of our engagement with the Department since 2008, when the first draft of these Regulations was published for comment. The timeline highlights the considerable lengthy process of the development of these Regulations.

PART A: GENERAL ISSUES

Empowering Legislation

9. The State is required in terms of section 27 of the Constitution to take reasonable legislative and other measures to ensure the progressive realisation of the right of access to healthcare services. This right extends, as we have previously noted, to "an environment that is not harmful to health and wellbeing". In pursuance of that obligation, subsection 21(2)(k) of National Health Act 61, of 2003 directs the national department to "facilitate and promote the provision of health services for the management prevention and control of communicable and non-communicable diseases".

10. These Regulations also flow from the Minister's powers to make subordinate legislation as granted in terms of section 3(2) of the International Health Regulations Act 28 of 1974, which was enacted to apply the International Health Regulations ("IHR"). The IHR is a legally binding instrument, adopted by the World Health Organisation, with the objective to "prevent, protect against,

control and provide a public health response to the international spread of disease, in ways that are commensurate with and restricted to public health risks".

Regulating Notifiable Medical Conditions

11. We echo from our previous submissions that the right to healthcare services and its attendant entitlement to a non-hazardous environment must be respected, protected, promoted and fulfilled through a regulatory framework. The effective prevention and control of notifiable conditions requires a strong regulatory framework.

12. Specifically, the purpose of these Regulations is to provide for the control of communicable conditions. The control of notifiable conditions requires that structures and processes must be in place to enable the health system to respond swiftly and appropriately to an outbreak of a notifiable medical condition. It is also vital that all players in the health system are aware of the limits of the application of mandatory measures that are prescribed to protect public health and the circumstances which necessitate such coercion.[3] This is an urgent objective especially in the light of the measles outbreak in Kwa-Zulu Natal, Gauteng and the Western Cape in 2017, for example. [4]Also, in view of other mortal communicable conditions such as TB, which killed 33 063 people in 2015 and remains the leading cause of death in South Africa.[5]

13. Another function of these Regulations is the monitoring of notifiable conditions. This is achieved first, by identifying notifiable conditions and designating persons to report on these conditions.[6] This as we highlight below needs to respond to the country specific public health needs. For example, South Africa has one of

[3] Roger Magnusson, "Advancing the Right to Health: The Vital Role of the Law" (2017) available at http://apps.who.int/iris/bitstream/10665/252815/1/9789241511384-eng.pdf?ua=1.
[4] "Measles Outbreak in Kwa-Zulu Natal Province" (19 September 2017) NICD, available at http://www.nicd.ac.za/index.php/update-measles-outbreak-in-kwazulu-natal-province/.
[5] "Mortality and causes of death in South Africa, 2015: Findings from death notification", (2017) Statistic South Africa, available at http://www.statssa.gov.za/publications/P03093/P030932015.pdf at page 30 - 31.
[6] See above note 3 at page 60.

the highest burdens of TB in the world with more than 454 000 new cases in 2015.[7] The community level monitoring of TB is crucial and requires the involvement of community health workers.

14. The burden of communicable conditions poses a great risk to public health especially in the absence of effective and operational Regulations to monitor and control these conditions.

The Need for an Intergovernmental Approach

15. The determinants of health extend beyond the provision of health-related services. As such, the approach to the monitoring and control of notifiable conditions must be intergovernmental. The Department must engage different ministries and different levels of government to ensure a coordinated approach is employed in addressing the complex and intersecting challenges to public health. [8]

16. The establishment of an intergovernmental approach should be guided by assigning specific responsibilities to the different departments to ensure accountability of each.[9] For example, the Department of Social Development would be a key stakeholder and duty bearer in the response to notifiable conditions by improving access and the quality to social services. As we have previously recommended, the Department should have a dedicated person to facilitate the intergovernmental response. [10]

Advisory Committee

17. Prior iterations of these regulations provided for an advisory committee and subcommittees to advise and support the Minister on notifiable medical conditions. Those provisions have been removed from this iteration. Those

[7] Global Tuberculosis Report 2016 (2016) WHO, available at http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1 at page 155.
[8] See above note 3 at page 60.
[9] Ibid, page 80.
[10] SECTION27 submission made on 22 May 2015, page 15.

structures, however, are critical and the rationale for removing them is not clear to us. For example, the Minister does not have the capacity alone to determine how coercive measures can be tailored to comply with legal requirements or how to respond to outbreaks of certain notifiable conditions. We have made submissions on the composition of the advisory committee and suggested that it should include an expert in constitutional law. These members would be essential in ensuring that "the protection of public health is appropriately balanced with the rights to freedom of movement, bodily integrity and privacy".[11]

PART B: SELECT REGULATIONS

Definitions

Quarantine and Isolation

18. The definitions of "quarantine" and "isolation" are:

> ***"Quarantine"*** *means the restriction of activities and/or separation from others of a suspect person who is not ill or of a suspect baggage, container, conveyance or goods in such a manner as to prevent the possible spread of infection or contamination*
>
> ***"isolation"*** *means the separation of an ill or contaminated person or affected baggage, a container, conveyance, goods or a postal parcel from others in such a manner as to prevent the spread of infection or contamination*

19. The terms "suspect", "ill person" and "contaminated person" are used in the definitions of "quarantine" and "isolation". However, these terms have not been defined in the Regulations. As such, they are broad, vague and ambiguous and could result in differing interpretations of what "isolation" and "quarantine" should entail. The inconsistent interpretations of these definitions could have serious implications for public health and would undermine the objectives of the

[11] See above note 10 at page 3.

Regulations. We recommend that definitions for "suspect", "ill person" and "contamination" be included in these Regulations as they are defined in the IHR.

20. The use of mandatory measures such as isolation or quarantine have implications for the constitutional rights to freedom of movement and bodily integrity. It is thus important that the definitions for "quarantine" and "isolation" are clear. As the Regulations stand, officials will have unfettered power to decide who is a "suspect", "ill person" or "contaminated person". The Constitutional Court has held that "law must be sufficiently clear so that people bound by them are capable of complying with them".[12] The failure to amend the definitions of "quarantine" and "isolation" could render them invalid.

Category 1, 2 and 3 notifiable medical conditions

21. The meaning of the following sentences specifies different requirements for notification:

    "diagnosis by health care providers [as] well as private and public health laboratories" (as it now is)*; versus*

    "diagnosis by health care providers, private health laboratories, or public health laboratories"; versus

    "diagnosis by health care providers as well as private or public health laboratories".

22. We would like to draw your attention to this variation and suggest that the drafters consider the requirements of the definition to ensure that the phrasing communicates what is intended.

[12] See above note 10 at page 13. The legal principle prohibiting vague laws is affirmed in *Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others* 2006 (8) BCLR 872 (CC) at paragraph 246, which reads: *[L]aws must be written in a clear and accessible matter. What is required is reasonable certainty and not perfect lucidity. The doctrine of vagueness does not require absolute certainty of laws. The law must indicate with reasonable certainty to those who are bound by it what is required of them so that they may regulate conduct accordingly.*

23. It appears that a rigorous reading of the Regulations is all that is required to identify and address the problems with the use and definitions of these terms. SECTION27 has repeatedly drawn these concerns to the Department's attention during the nearly ten years that these Regulations have been in development.

Chapter 2 – Notification and Reporting Process

A lack of clarity on the notification and reporting process

24. The Regulations should outline the process for reporting at every level. In Regulation 13, the notification and reporting process provides for health care providers, pathologists or laboratory personnel to report notifiable conditions to the "focal person at the health sub-district level". While this is in line with Regulations 8 and 10, it is not clear how the information is passed from the health sub-district level to the national level.

25. Chapter 1, which details the principles and responsibilities relating to notifiable conditions, directs the health sub-district level, district level and the provincial level to "designate a person for coordinating the surveillance and control of notifiable conditions". However, it is not clear if this person will report from the health sub-district level to the next level or directly to the national department. There is also no process or timeframes set out for how and when this reporting should take place.

The need for an infographic to illustrate the notification and reporting chain

26. The reporting process should be set out in an infographic. This will assist the implementers to comply with the required process. As it stands currently, the reporting structure and process remains very confusing and complex and it is likely that those bound by these Regulations will be unable or find it difficult to comply with them. This is especially the case beyond the health sub-district level.

The need to be vigilant regarding parallel reporting

27. Regulation 13 directs medical schemes to report notifiable conditions to the national department. It seems that the medical scheme reporting process is a parallel process to the reporting by health care providers, pathologists or laboratory personnel. It is not clear to us whether there will be a central record for information relating to notifiable conditions to guard against repeat reporting. While annexure B, which sets out the data elements to be reported, includes comprehensive detail on a person's distinctiveness and their condition, there may be further need to protect against double reporting if the relevant information is not consolidated.

28. For instance, the White Paper on the National Health Insurance has identified a health patient registration system ("HPRS") as one of the systems that must be developed concurrently with the legislative process.[13] The HPRS will be used to track the usage of health services for the lifecycle of the population and NHI.[14] This will be a useful system to ensure against repeat reporting and which the Department has already started to operationalise.[15]

The requirements related to the disclosure of personal information

29. Any sharing of information will have implications for people's rights to privacy and the concomitant duty on health care providers to respect confidentiality[16] and must be safeguarded accordingly.[17] This is necessary to "create trust and to encourage all members of the population to access health care services".[18] The sharing of sensitive information can lead to people deciding not to seek

[13] White Paper on the National Health Insurance Policy (2017) at paragraph 316.
[14] Ibid, paragraph 325.
[15] See the HPRS website at https://hprs.health.gov.za/.
[16] See section 14 of the National Health Act 61, of 2003.
[17] The section 14 constitutional right to privacy was affirmed in *Tshabalala-Msimang and Another v Makhanya and Others* (18656/07) [2007] ZAGPHC 161; 2008 (6) SA 102 (W); 2008 (3) BCLR 338 (W); [2008] 1 All SA 509 (W) (30 August 2007) paragraph 2, which recognised that "human beings have a right to have a sphere of intimacy and autonomy that should be protected from invasion. This right serves to foster human dignity".
[18] See above note 3 at page 20.

information or treatment. [19] The requirements for the disclosure of personal information are outlined in the Protection of Personal Information Act 4 of 2013 ("POPIA"), which also defines the exceptions to the protection of personal information as they may be required by these Regulations.[20]

30. POPIA makes provision for the dissemination of personal information relating to a person's health, if the subject of the information consents to such disclosure, or if the processing of such information is necessary for the exercise or defence of a right or obligation in law.[21] Also, POPIA authorises the processing of medical information for statistical purposes, to the extent that the purpose serves a public interest and the processing is necessary for the purpose concerned.[22]

Chapter 3 – Prevention and Control of Notifiable Medical Conditions

Regulation 14 – Voluntary Medical Examination, Prophylaxis, Treatment, Isolation and Quarantine

31. The terms "carrier", "case" and "contact" are defined as follows:

> ***carrier*** *means a person who is confirmed to be infected with a notifiable medical condition through laboratory tests or other medical procedures, but does not show any clinical signs and symptoms of the disease at the time;*
>
> ***case*** *means a person who is diagnosed with a notifiable medical condition either as a clinical case or a laboratory confirmed case*

[19] See above note 3 at page 20.
[20] Protection of Personal Information Act 4 of 2013. Section 15(1) of the National Health Act also makes provision for the disclosure of personal information, which permits health workers or health care providers to disclose personal information "as is necessary for any legitimate purpose within the ordinary course and scope of his or her duties where such access or disclosure is in the interest of the user".
[21] Ibid, section 27 (1)(a) and (b)
[22] Ibid, section 27 1(d).

contact *means a person who has been exposed to [a] notifiable medical condition but does not show any clinical signs and symptoms of the disease at the time.*

32. Sub-regulation 14(2)(a) and (b) requires that a 'case' or 'carrier' "*must subject himself or herself to a medical examination*", which "*may include but is not limited to, a clinical examination followed by the taking of biological specimens necessary for laboratory confirmation*". The use of these terms does not make sense as a "carrier" and "case" is defined as a person who has already been diagnosed or confirmed through laboratory tests or other medical procedures. Therefore, the requirement for a medical examination should not be necessary.

33. Further, sub-regulation 14(2)(a) and (b), which prescribes a medical examination for a "case" or "carrier", excludes a "contact" from this requirement. It is not clear what the rationale is for excluding a "contact" from requiring a medical examination, particularly as the definition of "contact" does not indicate that the term refers to a person who has already been diagnosed.

34. Sub-regulation 14(7) reads:

The likelihood of a carrier or contact becoming a case, based on the extent and duration of exposure with a known case, must be considered in determining and implementing appropriate isolation and quarantine.

35. This provision is inconsistent with the definitions. A "carrier" is defined as a "person who is confirmed to be infected with a notifiable medical condition through laboratory tests", which describes a "laboratory confirmed case" and is, therefore, already a "case". It is unclear whether there is a difference applied in the use of the words "confirmed" and "diagnosed" as they are used in the respective definitions of "carrier" and "case". It seems that the only difference between the terms is that a "carrier", unlike a "case", is not showing clinical signs and symptoms. It is unclear to us what the import of not showing clinical signs and symptoms is.

36. The use of the terms "case", "contact" and "carrier" in the sub-regulations above should be reviewed.

Regulation 15 – Mandatory Medical Examination, Prophylaxis, Treatment, Isolation and Quarantine

37. We welcome the changes made to sub-regulations 15(1) and 15(2)(c) substituting the purpose of mandatory measures from personal protection to "in order to prevent transmission". This is in line with section 36(1)(e) of the Constitution which requires that any limitation of a right in the bill of rights must take account of the "least restrictive means to achieve the purpose" and appropriate in that the purpose of these Regulations is the protection of public health. The mandatory measures outlined in the Regulations restrict the freedoms of an individual in order to protect public health. The rights of the public must be balanced against the individual's rights to freedom and security of the person as entrenched in section 12 of the Constitution and the right to freedom of movement in section 21, being the most directly affected.

Counselling for Voluntary Measures

38. We note that sub-regulation 15(4)(c) makes provision for counselling services before mandatory measures may be taken. This is an essential mechanism for ensuring that people are informed about their conditions and their legal rights. This provision should also be specified for those who voluntarily subject themselves to medical measures.

The need to provide for those who are unable to consent to medical measures

39. Sub-regulation 15(4)(b) provides that before mandatory measures are taken, a person "must have expressly, impliedly or by conduct refused voluntary measures". There is no provision made for people who are unable to give consent to voluntary or mandatory measures for that matter.

The need for a system to pursue mandatory measures

40. Sub-regulation 15(2) provides for mandatory measures to be pursued through court orders. We anticipate that the process by which such mandatory measures will be implemented will be complex, and the need to pursue these measures will perhaps be regular. As such, we reiterate our previous submission that the Regulations should provide for a system and structure to assess the need for, pursuance of, and monitoring of mandatory measures.

Providing for the review of court orders

41. The head of a provincial department is required through sub-regulation 15(5) to revise "[a] decision to apply for a court order" when the conditions for mandatory action change. The heads of provincial departments should further be required to approach a court to amend a court order as conditions change. In other words, it is not only the decision to apply for a court order that must be reviewed by the provincial head of department, but also the court order itself.

The need to provide for other rights during quarantine and isolation

42. As we have previously recommended, the Regulations must make provision for conditions of detention that are consistent with the Constitution, most directly the provisions of section 35. The detention contemplated in these Regulations must take place in a different context to the criminal justice system and for a different purpose, which is the protection of public health. We have highlighted before that these Regulations should provide for:[23]
    42.1. Access to social workers and psychosocial support;
    42.2. Access to nutrition;
    42.3. Access to recreational opportunities; and
    42.4. Pass outs and family visits.

[23] See above note 10 at page 49.

43. Also, a person's religious and cultural rights should be respected and protected to the extent possible in the pursuance of protecting public health.[24]

Regulation 16 – Control and Spread of Notifiable Medical Conditions

The need for clarity on the role of other institutions

44. Sub-regulation 16(3) appoints the "head of an institution" at a "training or education institution, a care or residential institution, barracks or a correctional services institution" to report notifiable medical conditions at the health sub-district level. There is a need to clarify what an "institution" refers to and the defining characteristics should be connected to the risk such places pose to public health in the event of an outbreak. For example, it does not appear that "barracks" could reasonably be considered to be an "institution". It is further not clear who the "head of an institution" is or how that would be determined. It is unlikely that such a person will have the skills to detect or report a notifiable medical condition as required and so cannot be expected to report in the same manner as qualified health care providers.

45. The Regulations should also consider the closure of such "institutions" should the circumstances require it. The determination should be based on considerations of the risk posed to public health.

46. The requirements of reporting prescribed for those who are not health providers is especially concerning as they, along with health providers, could be subject to harsh criminal penalties, in terms of Regulation 20, for failing to comply with these Regulations, including imprisonment of up to 12 years.

The role of community level reporting

47. We understand that there is an important role for community level reporting especially in a country such as ours where many people still have limited or

[24] See above note 3 at page 161.

remote access to healthcare services. However, reporting by people outside of the health profession must be simple and requires detailed guidance, especially because of the sensitive nature of controlling notifiable medical conditions. In other words, the "person on the street" must be able to know what they are supposed to do and be able to do it. Those who are assigned the responsibility to report should be well informed on issues relating to protecting the dignity and confidentiality of persons suspected of having a notifiable condition. These people should only be expected to report on conditions where the symptoms are easily and clearly recognisable.[25]

48. In addition, there could be a condition that allows for the reasonable suspicion of the "head of an institution" to be confirmed by a health care worker. This level of response would particularly benefit from support from community health workers, in both detecting and reporting notifiable medical conditions. The involvement of community health workers in the control of notifiable conditions would be especially constructive in monitoring and controlling communicable conditions at community level.

49. Further, we consider the participation of community level health workers as a useful way of monitoring notifiable conditions. A community level focus on monitoring would be useful in preventing an outbreak of a communicable condition and could appropriately inform allocation of resources and inform community and population level prevention strategies.[26]

Chapter 4 – General Matters

Regulation 20 – Offences and Penalties

50. We believe that the criminal sanction set out in Regulation 20, which provides for up to 12 years' imprisonment for those who "fail to comply with a provision of these Regulations" is excessive. This is especially when one considers the

[25] See above note 3 at page 143.
[26] Ibid, page 141.

complexity of monitoring and controlling notifiable conditions. This provision is particularly concerning as it applies to all persons who are required to report notifiable conditions, including those who are neither medical professionals nor in a position of authority.

CONCLUSION

51. It is concerning that at this stage of the process certain sections of these Regulations still do not meet the constitutional requirements we have continually highlighted. The need for an effective and operational regulatory framework to monitor and control notifiable conditions is urgent to effectively respond to South Africa's high burden of communicable disease. There can be no further delays in finalising and bringing these Regulations into effect, especially in light of the time that has already passed in drafting them.

This submission is endorsed by:

The Treatment Action Campaign

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