SASCI

South African Society of Cardiovascular Intervention

Comment

by SASCI

on the HPCSA Ethical Rules, as proposed to be amended by GG No 46422, Board Notice 278 of 27 May 2022

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1. Introduction

The South African Society of Cardiovascular Intervention (SASCI) is an organisation of physicians, scientists, and allied professionals with the purpose to advance the development of technology-based cardiology to provide minimally invasive, image-guided diagnosis and optimal treatment of a variety of cardiac medical conditions for patients of all ages. SASCI is affiliated as a Special Interest Group with the SA Heart Association.

It also acts in an advisory capacity to funders; industry; members and the government on matters relating to interventional cardiology. The latter is a branch of cardiology that deals specifically with catheter-based treatment of heart diseases and includes a variety of procedures such as angioplasty, Trans Aortic Valve Implantation (TAVI) and correction of congenital heart abnormalities. The society is also a key enabler of CPD accredited education in interventional cardiology.

2. General comments

It is understood that the amendments aim to give effect to the Health Market Inquiry recommendations[1] in relation to alternative reimbursement models ("ARMs", such as global fees, fixed fees, per diems and event-fees. It is also understood that the amendments aim to facilitate health policy and legislative changes, such as the National Health Insurance, where multi-disciplinary practices and facilities would contract with the NHI[2] in so-called "Contracting Units for Primary Healthcare" ("CUPs"), and possible contracting via private hospitals, due to the absence of provisions on specialist contracting.

ARMs, as well as the NHI proposals all include entities and professionals over and above those persons registered at the HPCSA. The amendments to ethical rules 7, 8 and 8A refers to only a "practitioner". A practitioner is defined in the ethical rules as:

[1] Available at: https://www.compcom.co.za/wp-content/uploads/2020/01/Final-Findings-and-recommendations-report-Health-Market-Inquiry.pdf.
[2] https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf.

"a person registered as such under the Act and, in the application of rules 5, 6 and 9 of these rules, also a juristic person exempted from registration in terms of section 54A of the Act"

The objectives as set by the HMI, NHI and, in the draft ethical rules 7 and 8 the envisaged "multi-disciplinary" practices would be limited to:

- Only healthcare professionals registered at the HPCSA; and
- Only in relation to an Incorporated Practice (i.e. a company registered as an "Inc."), where the legal form of the multi-disciplinary or fee-sharing practice then would be concerned, which however only applies to ethical rules 5 (naming), 6 (itinerant practices) and 9 (covering).

The objectives of the HMI, and indeed existing global fee- and ARM arrangements, will therefore, not be achieved by means of these amendments. Certain global fees, or per event fees may also include the medical device- or health technology costs. Therefore medical device suppliers are to be part of such models.

SASCI does not necessarily support the corporatization of healthcare, but supports initiatives that strengthens the power of healthcare professionals and their practices.

One of the changes that would be necessary, is to clarify, in the ethical rules, the ability of healthcare professionals to employ nursing professionals, with the scope of their professions, as well as clinical technologists, in line with ethical rule 7(4) ("commensurate part of the service") and ethical rule 8(1) ("complete or supplement … the healthcare or treatment").

It is also important to remember that the Annexures to the Ethical Rules would similarly have to be amended. For example, there are limitations on what clinical technologists can, and cannot do, and who can employ them. The same applies to pathology, medical technology, radiology and radiography. These professionals all play a role in the work that SASCI's members, as interventional cardiologists, do, and would therefore be within the "multi-disciplinary" team that could be authorized by ethical rule 7, provided that Annexures 5 and 10 are not also amended.

3. Ethical rule 7 (Fees and Commissions)

A new ethical subrule 7(6) is added to the Rules. It contains the following elements:

3.1. Fee-sharing (incl. global fees, ARMs, etc.)

It allows a practitioner to:

- Share (presumably "with");
- Charge (presumably "to"); or

- Receive – From another practitioner, fees.

It is unclear how this would work in practical terms, given that the incorporate practice only applies to other ethical rules. Fee-sharing in a single corporate entity would therefore not be possible. It is also not clear how these charges between practitioners would work – will an anaesthetist, for example, charge a cardiologist for work in the catherisation lab, and the cardiologist then invoices the patient or the medical scheme? Or the therapist charge the cardiologist for pos-intervention care. This, in turn, would require the system of practice code numbers and medical schemes systems to change – as billing codes are linked to specific practices at present, and a cardiologist cannot charge billing codes associated with physiotherapy, or anaesthetics, or pathology, etc.

Section 53 of the Health Professions Act, however obligates "every person" registered under the Health Professions Act, to inform patients of fees (section 53(1)), charge those and render a detailed account (section 53(2)), challenge the amount charge at the specific professional board (section 53(3) & (4)).

Furthermore, and significantly so, ethical rule 7 would be ultra vires section 53 of the Health Professions Act, 1974. Compliance with section 53 would be impossible, where the "main practitioner" (the one who bills and then receives fees from, for example, a medical scheme, and share that, or on-charges it, or receive it from another practitioner) is the one issuing the account in terms of section 53. The specific professional board would also not be able to evaluate the account rendered by practitioner A, if part of their account is the accounts of practitioners B (with whom they share) and/or C (who has charged them), for example.

Section 34 also requires registration "to practice". To practice includes the activity of charging for services that form part of such acts that constitute "practicing". A practitioner who bills for a service not within their scope of practice, may therefore be acting in contravention of section 34.

The ethical rule as proposed to be amended would therefore authorize persons to practice under the Health Professions Act, without being registered, as such a person might be billing in terms of section 53 on behalf of a registered healthcare professional. This will be the case where the HPCSA-practitioner receives fees that were shared with someone not registered at the HPCSA.

3.2. "Express agreement, arrangement or model"

It is assumed that the phrase refers to an "express agreement, an *express* arrangement, or an *express* model", i.e. all three types of relationships would have to be explicit.

Whereas an agreement is understood to be a contract, the meaning of an "arrangement" is not so clear. Neither would the application of a "model". If there are to be (at least partial) compliance with section 53 of the Act, arrangements and models:

(a) would have to be agreed to (which implies an agreement, or a contract),

(b) so that it is clear what the fee communication requirements to patients are, and
(c) the quantum of billing, i.e. would be (that "charged"), as well as the quantum of fees to be "shared" and/or "received" by the other practitioners.

In order to protect patients and practitioners, in particular those who may be at the "receiving" end of a model or arrangement, it is recommended that the rule refer to written agreements. This is also important in light of the "structured to" conditions being place on these types of agreements.

3.3. "Multi-disciplinary based health-care services"

The HMI recommendations were that the HPCSA ethical rules must allow for multidisciplinary practices and global fees. But, as pointed out above, these multi-disciplinary practices could, due to the definition of a "practitioner", only cover professionals registered at the HPCSA.

It would also exclude the global fee, per diems, ARMs, etc., which would not only include practitioners registered at the HPCSA, such as clinical technologists, but hospitals or facilities into the single fee agreements.

The effect of ethical rule 7(6) will encourage employment of practitioners by such hospital and facilities, as such entities would otherwise not be able to participate, in terms of ethical rule 18. This will, in our view, further erode the clinical independence and clinical self-determination of practitioners, and force them into employment arrangements with corporates.

Due to the definition of practitioner that excludes incorporated practices for the bulk of the ethical rules, it also means that it would not be possible for an Inc. to become part of a "multi-disciplinary" service provider.

3.4. Structured to "contain costs"

The findings of the HMI – the Health Market Inquiry, in 2019 included that many of the ARMs are not effective in reducing costs.[3]

Whereas entities such as the Competition Commission, and the Council for Medical Schemes, may make pronouncements on "cost containment", the power of the HPCSA to analyse whether an agreement is aimed at cost containment, may be limited. The HPCSA's only pricing-related powers reside in section 53.

[3] At par 79, page 186. Also see the 2018 HMI Report at par 142 that ARMs having "not much effect".

Given that cost increases, and therefore the need for cost containment, seem, for the medical schemes industry to reside in hospitalisation mainly,[4] multi-disciplinary practices alone many not achieve such objectives. It is also unclear how entities apply for fee-sharing, receiving fees, or charging fees with other practitioners, will prove that the agreement, arrangement or model will contain costs. It is also not clear to whom these cost-containment would apply, e.g. to a medical scheme, or to the patient (then requiring the benefit to the scheme being passed on to the patient0.

3.5. Structured to "enhance access to appropriate, high-quality health care services or products"

It is unclear what the "products" are that are being referred to. Most interventional cardiologists do not own, and do not assume ownership over the products (e.g. stents) used in treating patients, are beyond the control of the cardiologist, and the owners of such products are not "practitioners", being medical device suppliers, who seems to be outside of the ambit of the amendments.

By referring to "products", ethical rule 23 on medicines and medical devices is also brought within the scope of the amendments, but is not in itself being amended. Cost-containment would, by its very nature, also have to cover the medical devices and medicines used. Ethical rule 23 however does not refer to cost-containment, it refers to "cost-effectiveness", which is different, technically, to cost-containment, or cost-minimisation.

A global fee, fixed fee, per diem fee or ARM would all be inclusive of not only the various professional- and facility fees, but also all products. In an attempt to save costs, there would be negotiations with suppliers to procure medical devices at lower cost. Competition law, however, limit these negotiations to circumstances that would not raise vertical integration concerns. The products being offered may not be "high quality" – which however is not defined in the proposed amendments, and will, in most cases, not be the lowest (acceptable) product model / range. For medicines, these arrangements would entail limitations to the specific medicines that may be prescribed and may include requirements of strict formulary compliance, again invoking ethical rule 23.

Given that the HPCSA would have to approve these agreements, the HPCSA would therefore have to know, up front, what these limitations on the clinical independence and freedoms of healthcare professionals would be, in order to measure it against the criteria of "appropriateness" and "high quality". It is unclear what information must be presented to the HPCSA, and how the assessment will be made. Given that medical schemes benefits have to be approved before the end of each year, and submitted to the CMS before 1 October annually, it means that the proposals would need to be available much earlier, and in time for the HPCSA to have made a ruling before 1 October. As the products included, or excluded, differ from year to year, this approval would have to be an annual approval.

It may be more practical and legally sound to keep the "exception" and approval in rule 7(6) shorter, and issue guidelines as to the various criteria that would need to be fulfilled to obtain such approval from the HPCSA. SASCI recommends the use of a principle of "evidence-based", rather than "cost-containment" and "high-quality", to remove any value judgements

[4] CMS Industry Report 2020/2021, figure 17.

when applying the rule. The guidelines would then state how that would be determined, and what would be required from applicant practitioners to prove this.

Many global fee, or similar arrangements contains a so-called "hardship" clause, which aims to create an escape for difficult cases, so that practitioners are able to treat such patients outside of the agreed framework, in order to give effect to what would be appropriate for a specific patient. HPCSA Guidelines could, for example, insert this as one of the principles that must be in an agreement to be approved by them.

3.6. Approval by the HPCSA

Apart from the matter relating to medical scheme approvals, raised above, various factors, such as –

(a) assessments of services or products;
(b) changes in participating practitioners, e.g. practitioners leaving an arrangement;
(c) breaches of agreements;
(d) the nature and extent of an agreement that changes;
(e) the duration of an agreement that changes or come to an end;
etc.

It is also not clear who has to apply: all, some or only one of the practitioners intending to fee-share. Or, can a model be approved and then, in principle grant it to all practitioners who may sign up to such a model?

Currently, applications under ethical rule 18 appears to take at least 12 to 18 months, due to the involvement of one, or mote professional boards, and committees of such boards. Unless this process is changed, it would be impossible to obtain the envisaged approval, or amendment to an approval, within the period of a year or to obtain permission for amendments to an agreement. It could be anticipated that large numbers of applications would be submitted annually, as medical schemes settle benefits for a following year.

The duration of an HPCSA approval is also not clear, and it appears to be indefinite. This can, however, not be the case, as agreements and models may change over time.

The effect of approval is also not clear: If an agreement is approved by the HPCSA under ethical rule 7(6), would that protect the practitioner from investigations and disciplinary action on the basis of ethical rule 7-, and conceivably ethical rules 3, -23, 27A (and general patient complaints on consent, including billing / financial consent), and possibly from section 53 complaints?

The reasons for such an approval, or rejection, is not known, and it is impossible to gauge on what basis certain entities have obtained approval, and others not.

4. Ethical rule 8 (legal structures for practices)

This amendment aims to allow "collaboration" with "other practitioners". All the other elements discussed above is also present in this context, apply here as well, and our comments above would apply *mutatis mutandis* in this regard as well.

The main difference in this proposed amendment seems to be that a new (legal?) structure would have to have as its "primary aim … to enhance the quality of health-care services". Given that incorporate practices are excluded from this rule through the definition of a practitioner, it seems that the "collaboration" envisaged would have to be in a form other than a formal legal entity (juristic person), and possibly be in the form of a joint venture, partnership or association.

Healthcare practitioners must, in any event collaborate (e.g. a clinical technologist in a cath lab and a cardiologist). This collaboration is not only with practitioners registered at the HPCSA, but also with those registered at other Councils. Such professionals are however excluded from the definition of a "practitioner" in the ethical rules.

It does noy make sense if this ethical rule is amended as proposed, without amendments to the legal structures within which a practitioner can practice.

There is also no definition of "quality of care", and it is also unclear what an applicant to such an arrangement to collaborate would have to prove, or what information would have to be submitted to the HPCSA.

5. Ethical Rule 8A (rooms)

This rule is being amended to, on approval, allow the sharing of rooms across professional councils, and with an incorporated practice (which however does not apply to this rule).

The sharing of rooms within the same professional category, irrespective of the legal structure, has always being permitted (e.g. having an Incorporate medical practice and solus medical practices in the same rooms).

Pharmacy may, however, not be included in the list of "other legislation". Both the Pharmacy Act and the Medicines Act prohibits a prescriber to co-operate or share rooms with a dispenser. The Pharmacy Act and Pharmacy Council licensing rules are explicit in that no other business may reside in a pharmacy, and no pharmacy may be based inside another business, and specifically not inside a practice where there are prescribers. Part of this also relates to the Pharmacy Council's ethical rules, where a patient's choice of dispenser must be preserved.

6. Ethical Rule 18 (employment)

Whereas the HPCSA has already approved numerous employment arrangements, it will now only approve those if the conditions, as discussed above (under porposed ethical rule 7(6)), are met, namely:

- Cost-containment
- Appropriateness of care and products
- High quality care and products.

The above concerns on the meaning and application of these criteria apply here as well.

In addition, the rule states that the arrangement must not be to "extract profit" to the "detriment of patients". It is suggested that the HPCSA rather use the well-established terms of "under-servicing" and "over-servicing" in this regard, and the criteria set in the Business Practices Policy. Any profit-assessment and any assessment on the detriment to patients / consumers are within the domain of the Competition Commission under the Competition Act, 1998.

It would be difficult to establish possible detriment *prior* to an employment agreement coming into effect. Employment contracts are unlikely to include, for example, the instructions to be issued to an employee as part of their employment. It would be in these instructions that harm might reside, or where the clinical independence of the practitioner may be severely curtailed. In this sense, many of the principles in the Business Practice Policy seem more apt in evaluating applications for employment.

It also seems unclear what transitional measures will be in place for applications currently in-process. Uncompleted assessment would mean that two systems of principles may be applied under the amended rule. It is also not clear on what basis applications have been made, or declines, and no reasons are publicly recorded, so as to allow applicants to know how an application will be evaluated.

7. Ethical Rule 23A (hospital shareholding)

Ethical Rule 23A(h) relates (as it did in the previous version of the sub-rule) not only to an individual practitioner (as a practice owner) but also to "associates". In law, an associate is a person or entity who stands in some contractual arrangement with another person or entity as a separate commercial entity.

Only partners, and not shareholders (i.e. juristic entities exempted in terms of section 54A) are mentioned. If the objective is to assess whether a practitioner would unduly benefit from shareholding in a hospital, all forms of practices in which the practitioner has a financial stake and which could refer to the hospital, would be relevant.

The amendment now requires the following to be submitted to the HPCSA:

- "the agreements … in relation to … the interest of shares";
- "how the acquisition … is funded and … other ancillary contractual relationships … [also] with related parties;
- "policies or peer review protocols", as well as "quality mechanisms", which should ensure that practitioners (who, so it is assumed, would be working in those facilities where they hold shares) "comply with the ethical rules of Council".

The contractual arrangements in transactions are confidential and commercially sensitive. These disclosures would mean that the HPCSA would be in possession not only of such information (protected under legislation such as the Promotion of Access to Information Act), but also the information of competitors. Unlike the powers of the Competition Commission to ensure the confidentiality of information and specific powers to assess such financial information, there are no similar provisions in the Health Professions Act.

As with the other amendments, it is a concern as to whether the HPCSA is able to evaluate these documents, and whether it would assist in protecting the interests of patients.

The criteria for shareholders appear to be much stricter and invasive in relation to the property and privacy rights of practitioners, than that of an employee. A practitioner would be severely constrained in being a co-owner of a health facility, but would face much more severe pressure as an employee. Under labour law, a practitioner would face the labour law pressure of having to adhere to the instructions of its employer.

The provisions of the amended Ethical Rule 23A would be overbroad, and in all likelihood violate the principles of administrative – and constitutional law.

8. Conclusion

SASCI appreciates the opportunity to comment o the draft amendments, and remain available to provide further information of the engage with the HPCSA on its experiences relating to the ethical rules.

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