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DEPARTMENT OF SMALL BUSINESS DEVELOPMENT

NO. 5870 **14 February 2025**

INVITATION FOR THE PUBLIC TO COMMENT ON THE DRAFT INTERIM BLOCK EXEMPTION FOR TARIFFS DETERMINATION IN THE HEALTHCARE SECTOR, 2025

1. By virtue of the powers vested in me in terms of section 10(10) of the Competition Act, 1998 (Act No. 89 of 1998) as amended (the Competition Act), I, Mr. Mpho Parks Tau, Minister of Trade, Industry and Competition, after consultation with the Competition Commission, hereby publish for public comments the draft regulations in terms of section 78(1) as set out in the Schedule hereto.

2. The purpose of these Regulations is to give effect to the purposes of the Act as set out in section 2 of the Act by exempting the following categories of agreements or practices from the application of sections 4(1)(a), 4(1)(b)(i) and 5(1) of the Act in respect of both Prescribed Minimum Benefits (PMBs) and non-Prescribed Minimum Benefits (non-PMBs) in the healthcare sector –

   2.1. the collective determination of healthcare services tariffs;

   2.2. the collective determination of standardised diagnosis, procedure, medical device and treatment codes; and

   2.3. the collective determination of quality measurements/metrics, medicines formularies and treatment protocols/guidelines

   with the purpose of contributing to affordability of quality healthcare services across both PMBs and non-PMBs, contributing to reducing costs and contributing to the prevention of overutilization of healthcare services.

3. Stakeholders and interested persons are invited to submit comments in writing on the proposed regulations within a period of 30 business days of the publication of this notice to the Minister of Trade, Industry and Competition, for the attention of Dr Ivan Galodikwe, email IGalodikwe@thedtic.gov.za OR hand delivered at 3rd Floor, Block E, 77 Meintjies Street, Sunnyside, 0132.

MR MPHO PARKS TAU, MP
MINISTER OF TRADE, INDUSTRY AND COMPETITION
DATE: 12/02/2025

SCHEDULE

Definition

1. In these Regulations any word or expression to which a meaning has been assigned in the Act shall bear that meaning and, unless the context otherwise indicates –

"Act" means the Competition Act No. 89 of 1998, as amended;

"Coding Committee" means the committee appointed by the Minister of Health which is responsible for developing and maintaining appropriate coding systems for diagnoses, procedures, medicines and medical devices;

"CMS" means the Council for Medical Schemes in terms of the Medical Schemes Act 131 of 1998;

"Competitively sensitive information" means information that is important to rivalry between competing firms and likely to have an impact on one or more of the dimensions of competition (price, output, quality, and innovation) and which includes, *inter alia*, prices, customer lists, production costs, sales volumes, capacities, business plans, pricing methodology, procedures for addition, deletion or change of items, calculation of responsibility values taking into account experience and knowledge, judgment and mental effort, skill and physical effort as well as risk and stress to the patient and investment plans;

"Firm" includes a person (juristic or natural), association, partnership or a trust;

"HDP Firms" means firms owned and controlled by historically disadvantaged persons in terms of section 3(2) of the Act;

"Health Establishment" means as defined in the National Health Act, 61 of 2003;

"Healthcare sector" includes health professionals registered with a health professions council, businesses that provide medical services, health products (including equipment, consumables and medicines) and health insurance, or otherwise facilitate the provision of healthcare services and products to patients;

"HTA Committee" means the committee appointed by the Minister of Health which is responsible for coordinating the conducting of health technology assessments;

"Minister" unless otherwise specified, means the Minister of Trade, Industry and Competition;

"**NDoH**" means the National Department of Health as defined in the National Health Act, 61 of 2003;

"**PMB**" means the Prescribed Minimum Benefits as defined in the Medical Schemes Act 131 of 1998;

"SMMEs" means small business, micro business or medium-sized business as defined by the Minister in Government Gazette No.987 of 12 July 2019 or its successor in title, or business, as the context dictates and as defined by section 1 of the Act;

"standardized codes" means alphanumeric or numeric codes used in the healthcare sector to represent various medical diagnoses, procedures, treatments, and services and which codes are part of a standardized system designed to streamline healthcare administration, billing, and communication among healthcare professionals, insurers, and government agencies;

"tariffs" means the predetermined list of prices or fees that healthcare providers may charge for specific healthcare services and procedures;

"the Commission" means the Competition Commission, a juristic person established in terms of section 19 of the Act; and

"the DTIC" means the Department of Trade, Industry and Competition.

Background to the interim block exemption

2. The Competition Commission's Health Market Inquiry (HMI), in its findings, recognised the need for a structured tariff determination process and recommended a shift towards a multi-stakeholder negotiations process to improve pricing transparency and competition in the healthcare market. These recommendations emphasize the need for multilateral action in tariff setting to prevent anti-competitive practices and to support the sustainability of healthcare services in South Africa. The proposed interim block exemption is aimed at contributing towards the progressive realisation of the right to access to healthcare embedded in section 27 of the Constitution.

3. The healthcare sector in South Africa has experienced significant challenges in determining tariffs for healthcare services, leading to concerns about the affordability and accessibility of quality healthcare. To address this, the proposed interim block exemption aims to enable a structured, multilateral tariff determination process that would allow healthcare providers, funders, and other stakeholders to collectively determine tariffs for healthcare services, diagnosis and treatment codes, and quality metrics. *A multi-stakeholder tariff determination framework for healthcare services is at the centre of the proposed interim block exemption consistent with the recommendations of the HMI.* A multi-stakeholder tariff determination framework is intended to establish a more equitable and transparent framework for tariff determination, contributing to the long-term goal of reducing costs, promoting universal access to health and enhancing the quality of healthcare.

4. Since 2003, there has been a notable vacuum in tariff regulation, resulting in fragmented negotiations conducted on a bilateral basis between some healthcare providers and funders. This status quo has limited the ability to create standardized tariffs that ensure consistent pricing. The absence of a formal tariff determination process has also led to inefficiencies and disparities in the pricing of healthcare services across the sector.

5. The promulgation of the National Health Insurance (NHI) Act signals a significant long-term restructuring of the healthcare sector, with the aim of universal health coverage. The NHI Act will introduce new regulatory and funding models, but until the NHI framework is fully operational, there remains an immediate need to address the current gaps in tariff determination.

6. As an interim measure, the proposed block exemption provides a system wide regulatory framework to facilitate multilateral tariff determination. This exemption will apply to specific categories of agreements or practices related to tariffs and quality standards, ensuring that the sector can transition smoothly into the NHI framework while addressing present challenges in healthcare pricing.

Purpose

7. The purpose of these Regulations is to give effect to the purposes of the Act as set out in section 2 by exempting the following categories of agreements or practices from the application of sections 4(1)(a), 4(1)(b)(i) and 5(1) of the Act, in respect of Prescribed Minimum Benefits (PMBs) and non- Prescribed Minimum Benefits (non-PMBs) –

   7.1. the collective determination of healthcare services tariffs;

   7.2. the collective determination of standardized diagnosis, procedure, medical device and treatment codes; and

   7.3. the collective determination of quality measurements/metrics, medicines formularies and treatment protocols/guidelines.

   with the purpose of contributing to affordability of quality healthcare services across both PMBs and non-PMBs, contributing to reducing costs and contributing to the prevention of overutilization of healthcare services.

Category of agreements or practices exempted

8. Subject to regulations 9, 10, 11 and 16, the Minister hereby exempts the following categories of agreements or practices in the healthcare sector from the application of sections 4(1)(a), 4(1)(b)(i) and 5(1) of the Act in respect of both PMBs and non-PMBs:

8.1. Collective determination of healthcare services tariffs; or

8.2. Collective determination of standardized diagnosis, procedure, medical device and treatment codes; or

8.3. the collective determination of quality measurements/metrics, medicines formularies and treatment protocols/guidelines.

The framework for collective determination of tariffs

9. The following process shall be adopted for the collective determination of tariffs:

Appointment of Tariffs Governing Body (TGB)

9.1. The National Department of Health (NDoH), in consultation with the CMS, shall establish and oversee a healthcare services tariffs governing body ("Tariffs Governing Body" / "TGB").

9.2. The TGB will be chaired by a Chief Tariffs Manager, who shall be a senior official of the National Department of Health appointed by the Director-General of Health.

9.3. The Director-General of Health will appoint no more than eight additional members of the TGB through a public nomination process, which members shall:

9.3.1. be fit and proper persons;

9.3.2. have no conflict of interest; and

9.3.3. whose qualifications, skills and experience include tariff determination methods and practice.

9.4. The TGB shall, *inter alia*:

9.4.1. issue terms of reference, guidelines and rules for tariff determination and agreements contemplated in sub-regulation 8;

9.4.2. consult with the NDoH Coding Committee and NDoH Health Technology Assessment (HTA) Committee respectively;

9.4.3. establish rules for tariff determination in cases where MLNF members are:

9.4.3.1. unable to reach an agreement on tariffs; or

9.4.3.2. unable to reach an agreement on the process to determine the tariffs; or

9.4.3.3. deviate from the determined tariffs;

9.4.4. collaborate with the CMS on the review of PMBs;

9.4.5. conduct a price-cost assessment to validate the tariffs determined by the MLNF; and

9.4.6. perform any other functions reasonably necessary to meet the purpose of this Regulation as agreed by the Director-General of Health.

The Multilateral Negotiating Forum (MLNF)

9.5. The Director-General of Health shall appoint members of the MLNF following a nomination process, which will include representatives from the government, associations representing healthcare practitioners (HCPs), healthcare funders, civil society, patient and consumer rights organisations, and any other regulatory body within the healthcare sector.

9.6. The MLNF shall be responsible for, *inter alia*,:

9.6.1. collectively determine the maximum tariffs for PMBs and non-PMBs for healthcare services;

9.6.2. in the absence of codes as developed by the NDoH Coding Committee, collectively recommend standardized codes to the NDoH Coding Committee;

9.6.3. collectively recommend quality measurements/metrics, to the Office of Health Standards Compliance (OHSC) and recommend medicines formularies and treatment protocols/guidelines to the NDoH; and

9.6.4. in the absence of HTAs as developed by the NDoH HTA Committee, collectively source relevant evidence on applicable HTAs from other contexts for presentation to the NDoH HTA Committee.

9.7. The MLNF shall agree on the process to be followed to determine the tariffs.

9.8. For the purposes of this regulation, the MLNF tariff determination process will not apply to services provided by health establishments with practice codes 47 Drug & Alcohol Rehab, 49 Sub-Acute Facilities, 55 Mental Health Institutions, 56 Provincial Hospitals, 57 Private Hospitals ('A' – Status), 58 Private Hospitals ('B' – Status), 59 Private Rehab Hospital (Acute), 76 Unattached operating theatres / Day clinics, 77 Approved Unattached Operating Theatre Units / Day clinics and 79 Hospices. Tariffs for health establishments with practice codes 47, 49, 55, 56, 57, 58, 59, 76, 77 and 79 shall continue to be determined through bilateral negotiations between funders and the respective health establishments.

9.9. Decisions by the MLNF shall be taken by consensus.

9.10. In the event that MLNF members are unable to make a determination on tariffs or deviate from the determined tariffs, the TGB shall have the authority to make a final determination of the tariffs and may request claim line data, cost structures or other data relevant to confirming the veracity of proposed tariffs.

Tariffs Determination Process

9.11. All tariffs proposal submissions to the MLNF must be made through the CMS for validation and archiving.

9.12. Stakeholders must submit to the CMS any data and/or supporting evidence they intend to rely on during tariffs determination, in advance, to facilitate a fairer and more transparent process. This should include claim line data, cost structures or other data relevant to confirming the veracity of the proposed tariffs.

9.13. The CMS shall provide aggregated cost and pricing data to the MLNF.

9.14. All interested parties shall have an opportunity to make submissions to the CMS on the tariff determination process.

9.15. The CMS must, to the extent possible, provide a data repository/warehouse for all submitted information and analytical support essential for the MLNF tariff determination process.

Validation

9.16. Prior to the implementation of the determined tariffs, such tariffs shall be validated by the MLNF and the TGB respectively, as follows:

9.16.1. the MLNF shall ensure that the determined tariffs are cost-based; and

9.16.2. the TGB shall conduct a price-cost assessment within a maximum period of 60 business days to validate the determined tariffs.

Publishing

9.17. The NDoH, CMS, relevant health sector statutory bodies, healthcare funder associations, and healthcare professionals shall publish the tariffs determined by the MLNF for easy access by consumers, patients and other interested stakeholders.

Bilateral Negotiations

9.18. Funders and healthcare professionals may engage in bilateral negotiations only for the purpose of concluding an agreement on reductions, but not increases, on the tariffs for PMBs and non-PMBs as determined by the MLNF process.

9.19. Outcomes of bilateral negotiations must be documented in written contracts, not limited to risk, quality, and outcomes metrics.

9.20. These contracts must be submitted to the TGB and lodged with the CMS for monitoring.

Requirements for agreements made in terms of these Regulations

10. The agreements and practices made in terms of these Regulations must:

10.1. Be legally enforceable;

10.2. Include a provision stating that the TGB has the authority to report on, monitor and enforce the tariffs determined by the MLNF;

10.3. Include a provision granting the TGB the power to make a final determination if MLNF members are unable to determine tariffs or deviate from the tariffs; and

10.4. State that the tariffs determined by the MLNF are binding on all parties to the agreement.

Exclusions

11. These Regulations exclude:

11.1. Collusive tendering;

11.2. Market allocation;

11.3. Agreements or practices by health establishments with practice codes 47 Drug & Alcohol Rehab, 49 Sub-Acute Facilities, 55 Mental Health Institutions, 56 Provincial Hospitals, 57 Private Hospitals (‘A’ – Status), 58 Private Hospitals (‘B’ – Status), 59 Private Rehab Hospital (Acute), 76 Unattached operating theatres / Day clinics, 77 Approved Unattached Operating Theatre Units / Day clinics and 79 Hospices; and

11.4. Tariffs and codes for medicines.

HDP and SMME Participation

12. HDP Firms and SMMEs at all levels of the value chain must be afforded an opportunity to opt-in to agreements and/or practices entered into in terms of these Regulations.

Scope of the exemption

13. The scope of these Regulations is limited only to agreements and/or practices specified under regulation 8.

14. These Regulations apply to health funders (medical schemes, administrators and managed care companies), and all health professionals registered in terms of the Health Professions Act (Act No. 56 of 1974), or the Nursing Act, 2005 (Act No. 33 of 2005), Allied Health Professions Act, 63 of 1982, or the Dental Technicians Act, 1979 (Act No. 19 of 1979); and the agreements and/or practices exempted in these Regulations can vary on a per healthcare sub-sector or clinical discipline basis.

15. The agreements and/or practices exempted in these Regulations include the exchange of information strictly necessary for the purposes of the conclusion and implementation of the agreements and/or practices. After consultation with the NDoH, the CMS may appoint an independent facilitator to, *inter alia*, facilitate the sharing of competitively sensitive information by individual firms, and the aggregation of such competitively sensitive information amongst firms in the sector.

Monitoring

16. The CMS and/or the MLNF must supply the Commission, the DTIC and the NDoH with the record of determined tariffs, the minutes of meetings held, correspondence related to the exempted agreements and practices, exchanges of competitively sensitive information strictly necessary for the purposes of the conclusion and implementation of the agreements or practices, and all agreements or practices entered into in terms of these Regulations on a quarterly basis. Such submission must be made to the following:

    16.1. Submissions to the Commission should be sent to exemption.conditions@compcom.co.za.

16.2. Submissions to the DTIC should be sent to exemption.conditions@thedtic.gov.za.

16.3. Submissions to the NDoH should be sent to nhi.info@health.gov.za

17. Firms who participate in any agreements or practices falling within the scope of these exemptions must keep accurate written records of meetings held, correspondence related to the exempted agreements and practices, exchanges of competitively sensitive information strictly necessary for the purposes of the conclusion and implementation of the agreements or practices, and all agreements or practices entered into in terms of these Regulations.

18. The Commission and/or CMS may, at any time, request from all participants of the exemption the record of determined tariffs, the minutes of meetings held, correspondence related to the exempted agreements and practices, exchanges of competitively sensitive information strictly necessary for the purposes of the conclusion and implementation of the agreements or practices, and all agreements or practices entered into in terms of these Regulations.

Amendments to Regulations

19. The areas of collaboration exempted in these Regulations may be expanded or reduced by the Minister, after consultation with the Minister of Health and the Commission, by notice published in the Government Gazette in terms of these Regulations.

Short Title

20. These Regulations shall be called the *Interim Block Exemption for Tariffs Determination in the Healthcare Sector, 2025*.

Commencement and duration

21. These Regulations come into effect on the date of publication in the Government Gazette and shall endure for a period of 3 years, which period can be extended by the Minister, after consultation with the Minister of Health and the Commission, by notice in the Government Gazette.

Winding down of agreements and practices

22. The Minister, after consultation with the Minister of Health and the Commission may, by notice in the Government Gazette, provide a reasonable period to Firms that have participated in any agreements or practices falling within the scope of these exemptions to wind-down agreements or practices referred to in regulation 8 after the lapse of these Regulations.