



**HCLS Pulse** – A bi-weekly update on regulations impacting the healthcare and life sciences industry

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### KPMG in South Africa

**Scope of coverage:** **Africa** (South Africa, Botswana, Ethiopia, Ghana, Rwanda, Uganda, Libya, Kenya and Nigeria); **North America** (the US and Canada), **Europe** (the UK), **ASPAC** (Australia), **International agencies** (WHO and OECD)

**Time period:** October 12, 2017 – October 25, 2017

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[South Africa](#)

### **Draft national health insurance bill on track**

The draft National Health Insurance (NHI) Bill will be placed before cabinet for approval in November 2017. The health department revealed this during a briefing in Parliament on its 2016/17 Annual Report. The proposed legislation will then be published for comment. The department plans to table the draft bill in Parliament in March 2018. The white paper focuses on structural problems in the health sector, the burden of disease, the rationale and benefits of NHI, NHI coverage, organisation of the health care system and services under the NHI, financing of NHI, purchasing of health services and phased implementation. [Sabinet](#)

### **Department of Health published Annual Report 2016-17**

The report reflects on the achievements and highlights of the National Department of Health (DoH) for the period 2016 – 17. According to the report, achievements around health regulation and compliance management include:

- Listing of South African Health Products Regulatory Authority as a public entity
- Approval of National Public Health Institute of South Africa Bill by Cabinet for tabling in Parliament.

In addition the Compensation Commissioner for Occupational Diseases and Occupational Health delivered on the following during 2016/17:

- An electronic database of 600 000 claimant files;
- Provided 18 145 benefit medical examinations, 20 149 certifications and 5 296 paid claims amounting to 204 million ZAR, inclusive of 76 million ZAR in neighboring countries;
- Hosted the Integration of Compensation Systems Summit

The report also provides updates around the department's administration, health planning and system enablement, HIV and AIDS, tuberculosis, maternal, child and women's health, primary health care services, hospitals, tertiary services and workforce development among others.

[Sabinet](#)

### **Health Products Board appointment**

Members of the South African Health Products Regulatory Authority Board have been appointed. South African Health Products Regulatory Authority (SAHPRA) has a wider mandate than its predecessor in that, in addition to medicines, it will also regulate medical devices and complementary medicines. The health department published the appointees in the Government Gazette 41171. The appointments were made in terms of the Medicines and Related Substances Amendment Act. The members will serve a three-year term ending on 30 September 2020. [FSlegalsnapshot](#)

### **Update on Health Promotion Levy (HPL) consultation process**

The document describes the 2017 Draft Rates Bill consultation process, activities undertaken by the health ministry post the last briefing of the National Treasury (NT) on HPL, NT consultation process on sugary beverage tax and the proposed tax design. [Sabinet](#)

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## **US**

### **Clinical Laboratory Improvement Amendments of 1988 (CLIA); Fecal Occult Blood (FOB) Testing**

Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires any facility performing examinations of human specimens for diagnosis, prevention, or treatment purposes to be certified by the Secretary of the Department of Health and Human Services (HHS). The Centers for Medicare and Medicaid Services is responsible for the administration of CLIA. This final rule amends the CLIA regulations to clarify that the waived test categorization applies only to non-automated fecal occult blood tests. [Federal Register](#)

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## **Australia**

### **New report outlines residential aged care funding reform options**

The report, prepared by Applied Aged Care Solutions, undertook a comprehensive review of aged care funding instruments, focusing on ways to improve the current tool, including adapting it for external assessments of funding needs and updating it to bring it into line with current care practices. The next step in the long-term reform process includes a Resource Utilisation and

Classification Study, now underway at the University of Wollongong's Australian Health Services Research Institute. This study is investigating the drivers of residential care costs, according to location and the varying needs of individuals in care. [Ministry of Aged Care](#)

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## UK

### **Personalised health and care 2020: service user vision**

The policy paper discusses how the government and national health and care organisations aim to use information technology within current programmes, to improve patient, carer and service user experiences of health services and social care services in England. [Department of Health](#)

### **The regulation of medical associate professions in the UK**

This consultation seeks views on the following proposals:

- To introduce statutory regulation for Physician Associate (PAs);

- To seek further evidence on the most proportionate level of regulation for PA(A)'s;

- To seek views on the position that statutory regulation of the Surgical Care Practitioner (SCP) and Advanced Critical Care Practitioner (ACCP) roles is not proportionate, and whether alternative options for professional assurance should be considered; and

A consultation document and a risk assessment profile from Health Education England (HEE) are published alongside this consultation. [Department of Health](#)

### **Pharmacopoeial biological standards assure the quality of biological medicines**

The work programme relates to key activities that the health department is committed to undertaking to implement its strategy for pharmacopoeial standards for biological medicines. The activities fall into 3 broad categories: standards development; engaging with users and building knowledge; our international peers. Key points are:

- Establishing three working parties with representatives from MHRA regulatory, British Pharmacopoeia, NIBSC and experts from industry and academia to explore alternative approaches, ATMPs and Raw materials

- A number of activities to continually engage stakeholders in the work including a 2018 symposium; Maintaining our active roles and relationships internationally. [Department of Health](#)

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## Other African Countries

### **Ministry of Health launches new campaign dubbed “Catch UP” to increase access to health services (Kenya)**

The Ministry of Health launched a campaign dubbed “Catch Up” to increase access and utilization of essential package of health services in counties that are most impacted by ongoing health workers strike. The campaign targets more than 300,000 women and children in the counties where there are minimal alternatives to services offered by public health care workers. The campaign will ensure that most people are reached with the necessary health services that will include immunisation services, nutrition screening and care services, well child and sick child services, adult outpatient services and referrals and antenatal and postnatal services. [Ministry of Health, Kenya](#)

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## US

### **FDA clears new robotically-assisted surgical device for adult patients**

The Food and Drug Administration cleared the Senhance System, a new Robotically-Assisted Surgical Device (RASD) that can help facilitate minimally invasive surgery. The Senhance System is intended to assist in the accurate control of laparoscopic instruments for visualisation and endoscopic manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, mobilization and retraction in laparoscopic

colorectal surgery and laparoscopic gynecological surgery. The FDA granted clearance of the Senhance System to TransEnterix Surgical. [FDA](#)

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## South Africa

### **Health Professions Council of South Africa (HPCSA) public awareness campaign**

The focus of the awareness campaign will be amongst others; to inform the public on the role and responsibilities of the HPCSA; to educate the public in terms of their rights as patients, to outline the Department of Health's complaint management process, to educate the public on the role of mediation in Medical Negligence. This awareness campaign will also educate the public on how to identify bogus practitioners and work closely with the HPCSA to root out and report these fake practitioners. [HPCSA](#)

### **REVEALED: SA's biggest medical schemes**

The article states that Discovery continued to dominate South Africa's medical insurances industry with almost a million more beneficiaries than the Government Employees Medical Scheme (GEMS). This is according to the latest statistics released by the Council for Medical Schemes (CMS), the regulator of the medical schemes industry. The report stated that there are 82 schemes with a total subscription of 8.879 million members as at 31 December 2016. This figure included a total of 22 open schemes and 60 restricted schemes. [Fin24](#)

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## WHO

### **2018 Medicare advantage and Part D prescription drug program landscape**

The data released with the 2018 Medicare Advantage and Part D plan landscape provides important and premium information for both programs:

Enrollment in Medicare Advantage is projected to be at an all-time high in 2018 with 20.4 million Medicare beneficiaries. This represents a 1.7 million (nine percent) increase from 18.7 million in 2017.

CMS estimates the Medicare Advantage average monthly premiums will decrease by 1.91 to 30 USD in 2018. Over the past three years, the average monthly premiums in Medicare Advantage have decreased, from 32.91 USD in 2015.

Access to Medicare Advantage will remain nearly universal, with 99 percent of Medicare beneficiaries having access to at least one health plan in their area.

More than 85 percent of Medicare beneficiaries will have access to ten or more Medicare Advantage plans in 2018.

The average number of Medicare Advantage plan choices per county will increase by 2 plans – up to approximately 29 plan choices per county – and access to popular supplemental benefits, such as dental, vision, and hearing, continues to grow.

Approximately 77 percent of Medicare Advantage enrollees in 2017 will have the same or lower premium in 2018 if they continue in the same plan.

The average monthly premium for a basic Medicare prescription drug plan in 2018 is projected to decrease by 1.20 to an estimated 33.50 USD per month. The basic premium for an average Medicare prescription drug plan is projected to decline for the first time since 2012.

All Medicare beneficiaries will have access to at least one stand-alone Medicare prescription drug plan. [CMS](#)

### **Kuwait Fund and WHO in 4 million USD multi-year agreement to tackle Neglected Tropical Diseases (NTDs) in Africa**

The announcement was made at a Donors' meeting on how to end NTDs, hosted by the Kuwait Fund for Arab Economic Development (KFAED) and the World Health Organization Regional Office for Africa. The meeting brought together an extended network of funders and other stakeholders committed to supporting the Expanded Special Project for Elimination of Neglected Tropical Diseases (ESPEN), a five year project which was launched by the WHO in 2016 to support African countries in tackling the diseases. [WHO Afro](#)

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## Other African Countries

## Ministry embarks on "Green Dot" road show (Nigeria)

The aim of the road show was to increase the visibility for the New National Family Planning Logo, as the official marker for all the public and private health facilities. The initiative was aimed at sustaining the on-going multi-media and outdoor person to person national family planning communication campaign towards achieving the targeted 36% contraceptive prevalent rate in Nigeria by 2018. [Ministry of Health](#)

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