
**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:** January 2018

**In This Issue:**



## South Africa

**Allied Health Professions Council of South Africa has placed unprofessional conduct in the spotlight**
The Health Professions Council of South Africa has issued notices in the Government Gazette which highlights its scope of practice for allied health practitioners:

- Notice 1: The prohibition of multilevel marketing, perverse incentives and franchising; and
- Notice 3: Practice of live blood analysis to be used only as an adjunct to the scope of practice of homeopathy, naturopathy or phytotherapy *Sabinet*

**Claw back by Medical Aid schemes**
The Professional Board for Physiotherapy, Podiatry and Bio kinetics (PPB) under the boundary of the Health Professions Council of South Africa (HPCSA) raised concern over certain medical schemes that are alleged to be behaving and or conducting themselves in an unethical manner towards registered practitioners, in particular, physiotherapists in private practice. This unethical practice is termed as claw back. It has been advised that if the medical aid schemes suspect any act of criminality such as theft or fraud, they should report it to the necessary authorities to investigate and prosecute. *HPCSA*

**Regulations relating to surveillance and the control of notifiable medical conditions**
The Department of Health published regulations relating to the surveillance and the control of notifiable medical conditions in the Government Gazette. The regulations focus on implementation principles and responsibilities in relation to notifiable medical conditions, declaration of notifiable medical conditions, prevention and control of notifiable medical conditions and general matters. *Department of Health*

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## US

**CMS announces new policy guidance for States to test community engagement for able-bodied adults**
The Center for Medicare and Medicaid Services (CMS) has published guidance that supports efforts to improve Medicaid enrollee health outcomes by incentivising community engagement among able-bodied, working-age Medicaid beneficiaries. The policy has been formed in response to state requests to test programs through Medicaid demonstration projects under which work or participation in other community engagement activities would be a condition for Medicaid eligibility for able-bodied, working-age adults. The new policy guidance will help the state design demonstration projects that promote the objectives of the Medicaid program and are consistent with federal statutory requirements. *CMS*

**CMS announces new payment model to improve quality, coordination, and cost-effectiveness for both inpatient and outpatient care**

The Centers for Medicare & Medicaid Services (CMS) innovation Center has launched a new voluntary bundled payment model called Bundled Payments for Care Improvement Advanced (BPCI Advanced). Under the new model, providers will have an incentive to deliver efficient, high-quality care. BPCI Advanced seeks to support and encourage participants who are interested in:

- Continuously redesigning and improving care;

- Decreasing costs by eliminating care that is unnecessary or provides little benefit to patients;
- Encouraging care coordination, and fostering quality improvement;
- Participating in a payment model that tests extended financial accountability for the outcomes of improved quality and reduced spending;
- Creating environments that stimulate rapid development of new evidence-based knowledge; and
- Increasing the likelihood of better health at lower cost through patient engagement, education, and on-going communication between doctors and patients. *CMS*

**Draft Trusted Exchange framework released**
As required by the 21 Century Cures Act, to achieve interoperability, the Department of Health and Human Services (HHS) released the draft Trusted Exchange Framework. According to the framework, building and maintaining trust is an important core element in ensuring that health information is available where and when it is needed to manage patient health and care. The

framework is designed to help achieve interoperability for all. The principles, combined with the support of providers, existing health information networks, health IT developers, and federal agencies, are designed to help improve patient care, care coordination, and the overall health. *HHS*

**FDA ushering in new era of 3D printing of medical products**
In his statement, the Commissioner of the Food and Drug Administration (FDA) spoke about how the FDA has issued guidance to help advise device manufacturers on technical aspects of 3D printing, referred to as additive manufacturing, that clarifies what the FDA recommends manufacturers include on submissions for 3D-printed medical devices. *FDA*

**Advancing new digital health policies to encourage innovation, bring efficiency and modernisation to regulation**
The Food and Drug Administration (FDA) has come up with three significant policy documents to advance the FDA's approach to the development and proper oversight of innovative digital health tools. The first draft guidance, Clinical and Patient Decision Support Software, outlines the FDA's approach to clinical decision support software (CDS). This draft guidance is intended to make clear what types of CDS would no longer be defined as a medical device, and thus would not be regulated by the agency. The second draft guidance, Changes to Existing Medical Software Policies Resulting from the Century Cures Act, addresses other digital health provisions included in the Cures Act. The FDA also is issuing a final guidance document, Software as a Medical Device: Clinical Evaluation, in fulfillment of the international harmonisation efforts. *FDA*

**FDA proposes new, risk-based enforcement priorities to protect consumers from potentially harmful, unproven homeopathic drugs**
The Food and Drug Administration (FDA) has proposed a new, risk-based enforcement approach to drug products labeled as homeopathic. To protect consumers using homeopathic products, this proposed new approach would update the FDA's existing policy to better address situations where homeopathic treatments are being marketed for serious diseases and/or conditions but where the products have not been shown to offer clinical benefits. It also covers situations where products labeled as homeopathic contain potentially harmful ingredients or do not meet current good manufacturing practices. *FDA*

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## Australia

**Research framework for the National Scheme published**
The National Boards and the Australian Health Practitioner Regulation Agency (AHPRA) have published a research framework to help transform health practitioner regulation to improve patient safety. The framework includes the priority research areas of:

- Defining harms and risks related to the practice of regulated health professions;
- Regulatory taxonomy or classification scheme;
- Risk factors for complaints and/or poor practitioner performance,
- Evidence for standards, codes and/or guidelines;
- Evaluating regulatory interventions;
- Stakeholder satisfaction and engagement;
- Work readiness and workforce capacity and distribution. *AHPRA*

**Updates to the Australian Immunisation handbook 10th edition**
The National Health and Medical Research Council (NHMRC) has approved updates to the Australian Immunisation Handbook 10th Edition under the National Health and Medical Research Act. The Australian Immunisation Handbook provides clinical information for Australian immunisation providers on the safest and most effective use of vaccines, new vaccines and vaccine-preventable diseases in Australia. The updates relate to the infant pneumococcal vaccination schedule and are available on the Immunise Australia website. *NHMRC*

**New national plasma agreement ensures supply for Australian patients**
With the signing of an important new agreement, the Government of Australia guaranteed the provision of a safe, secure and affordable supply of plasma products and services. The National Blood Authority has executed a new national contract with CSL Behring Australia for the manufacture and supply of fractionated blood plasma products. The new contract will also deliver savings to government of more than 200 million AUD as a result of improved manufacturing processes and efficiencies. *Department of Health*

**New comprehensive guidance on medicinal cannabis**
The Australian Government has published five disease-specific clinical guidance documents, developed as the first set of considered information available for general practitioners and specialists in Australia. Australian prescribers of medicinal cannabis will have access to up-to-date information to help inform their decision-making about patient treatment options for a number of conditions. The documents provide clinical information on the effectiveness of medicinal cannabis and guidance for its use in treating symptoms for a number of conditions. A summary document on the evidence and use of medicinal cannabis for patients has also been developed. *Department of Health*

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## UK

**MHRA streamlines services for devices customers**
The Medicines & Healthcare products Regulatory Agency (MHRA) launched a new online service to support customers of the devices division. The new online service:

- Offers customers a more convenient way to conduct business with MHRA;
- Provides a single online account with MHRA;
- Provides access to Devices Registration (DR) and Certificates of Free Sale (CFS) services via a new online portal;
- Allows the staff to access and provide information to customers more quickly and in a more joined-up way;
- Enhances MHRA's customer service for the device owners. *MHRA*

**Updated guidance on the fit and proper person requirement**
The Care Quality Commission published guidance which provides a more detailed explanation of what CQC interprets as serious mismanagement and serious misconduct. It also offers greater clarity about the obligations and responsibilities of holding director roles. The fit and proper persons requirement (FPPR) were introduced in response to concerns raised following investigations into a hospital. All providers registered with the CQC have been requested to assure themselves that all directors who are responsible and accountable for delivering care are fit to carry out their responsibility for the quality and safety of care. *CQC*

**Promoting professionalism, reforming regulation**
The Department of Health has published a consultation paper which seeks views on what needs to be done to protect the public as much as possible and at the same time support the development of the workforce. The consultation is part of the commitment to reform the system of regulation of healthcare professions. The proposed model of professional regulation will:

- Secure public trust;
- Improve clinical practice; and
- Adapt to developments in healthcare. *Department of Health*

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## Canada

**Canada–Newfoundland and Labrador bilateral agreement to improve health care services**
The governments of Canada, Newfoundland and Labrador have signed a bilateral agreement. According to the agreement it has been planned to invest 72 million CAD in targeted federal funding. The funding will be provided over a stretch of five years in order to improve access to home and community care and mental health and addiction services. This agreement will be renewed in the year 2021 for the remaining five years of the ten-year commitment. The government has set out the following priorities in the bilateral agreement:

- Develop a home first integrated network and implement a home first approach;
- Invest in palliative care and end-of-life improvements;
- Expand supports for persons with dementia;
- Implementing a provincially-integrated mental health service delivery model;
- Expanding existing and introducing new e-mental health initiatives;
- Improving access to addictions services; and
- Improving community-based services to replace hospital care. *Health Canada*

**Health Canada welcomes comments on release of clinical information on drugs and medical devices**

Health Canada has published a draft that proposes to make clinical information in drug and medical device submissions publicly available after the Department has completed its regulatory review process. Increasing access to clinical data can have widespread benefits for patients and the health care system, for example:

- Providing more detailed information about drugs and medical devices enables independent analysis that could help health professionals make more informed decisions about their appropriate use; and
- Sharing these data could also help reduce inappropriate use of drugs and medical devices. *Health Canada*

**Consultation on proposed regulations for monitoring Medical Assistance In Dying (MAID)**

The Government of Canada has published draft regulations which is a key step in creating a federal, pan-Canadian monitoring system on medical assistance in dying. The draft regulations set out reporting requirements for those who are authorised to provide medical assistance in dying—physicians, nurse practitioners and pharmacists who dispense medication for assisted dying. Key features of the proposed regulatory regime include:

- Requirements to file information for physicians and nurse practitioners who receive written requests for MAID, and pharmacists who dispense medications for the purpose of assisted dying;
- Voluntary provision of information by coroners and medical examiners;
- Identification of the designated recipient for information related to MAID;
- Requirement to publish a report at least once per year on MAID in Canada on the Government of Canada website; and
- Provision for making data available to qualified researchers for the purpose of independent analysis and research. *Health Canada*

**Message by the Minister of Health on Alzheimer's Awareness Month**

The Government of Canada will be leading the development of a national dementia strategy. The Government will also create an advisory board to advise on the health care needs and gaps for people living with dementia and to provide valuable input into the development of the national dementia strategy. The Government will be hosting a national conference that will include a broad range of stakeholders and partners from across the country to facilitate effective and inclusive conversations about the national strategy. *Health Canada*

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## South Africa

**Industry performance newsletter 2016-2017**

The Council for Medical Schemes (CMS) published the second issue of the medical newsletter. The second issue talks about the following updates from the financial year 2017:

- Fundamental principles of the CMS on medical schemes cost increase assumptions;
- Trends on the utilisation of health services for the financial year 2017;
- Contribution income and healthcare expenditure for the financial year 2017;
- CMS views on risk pooling in pursuit of Universal Health Coverage;
- Progress on ensuring compliance with the Demarcation Regulations since April 2017. *CMS*

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## UK

**Introducing opt-out consent for organ and tissue donation**

The Department of Health launched a consultation about organ and tissue donation. The UK government wants to know what people think about proposed changes in which people are considered willing to be an organ donor after their death, unless they have 'opted out'. The defining issues of the new system are:

How much say families have in their deceased relative's decision to donate their organs;

When exemptions to 'opt-out' would be needed, and what safeguards would be necessary; and

How a new system might affect certain groups depending on age, disability, race or faith. *Department of Health*

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## Australia

**110 Million AUD additional investment in child and youth mental health**
The Government will provide 110 million AUD to extend and expand mental health programs for young Australians. *Department of Health*

**Expert committee to consider out-of-pocket medical costs**
The Australian Government will work with the medical profession to address the large and sometimes unanticipated out-of-pocket medical fees some patients face. A new expert committee chaired by the Commonwealth Chief Medical Officer, will investigate out-of-pocket costs and options to ensure that consumers are better informed of fees before agreeing to treatment. It will identify why some doctors are charging large fees, and explore strategies to ensure that consumers and referring General Practitioners can compare fees and out-of-pocket costs when choosing a doctor. The committee will consult with the medical profession, hospital sector, private health insurers and consumers. *Department of Health*

**Private patients in public hospitals remains a growing concern**
The Australian Government has expressed its concern about the growing practice of private health insurance being charged by public hospitals for treatments that should be free. Figures released by the Australian Institute of Health and Welfare (AIHW) show that state governments and hospitals are continuing to actively encourage patients to use their private health insurance to boost hospital revenue. The Australian Government wants to ensure a sustainable balance between public and private health systems and will consider further actions in the broader National Health Agreement context. *Department of Health*

**8 Million AUD boost for cancer research projects**
The Australian Government has announced more support for cancer research with 8 million AUD in grants. The 24 successful grant recipients lead projects focus on prevention, diagnosis and treatment of a range of cancer types. There is also a strong focus on defeating and improving the outcomes of childhood brain cancers and other cancers. Sixty per cent of the grant funding will go to projects that focus on rare and less common cancers and cancers with low survival rates. *Department of Health*

**Hearing services review aims to improve client care**
The Minister responsible for hearing services, released the findings of the Review of Services and Technology Supply under the Government's Hearing Services Program (HSP). The report contains 12 findings and 13 recommendations aimed at ensuring a sustainable, client-focused delivery model that provides quality outcomes and meets the needs of Australians who require hearing support. The Government is continuing its focus on ensuring all Australians in need of hearing help can access appropriate care and support, when and where they need it. *Department of Health*

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## US

**New steps to facilitate efficient generic drug review to enhance competition, promote access and lower drug prices**
The Food and Drug Administration (FDA) has introduced additional steps to encourage generic competition, in order to implement the Drug Competition Action Plan. The additional steps aim toward achievement of improving the efficiency and predictability of the FDA's generic review process to reduce the time it takes to get a new generic drug approved and lessen the number of review cycles undergone by generic applications before they can be approved. The first draft guidance published by FDA highlights common, recurring deficiencies seen in generic drug applications that may lead to a delay in their approval. *FDA*

**FDA permits marketing of device to treat diabetic foot ulcers**
The Food and Drug Administration (FDA) has allowed the marketing of the first shock wave device intended to treat diabetic foot ulcers. The FDA is dedicated to making technologies available that can help improve the quality of life for those with chronic diseases. *FDA*

**Failure to protect the health records of millions of persons costs entity millions of**

**dollars**
A radiation therapy and integrated cancer treatments provider has agreed to pay 2.3 million USD in lieu of potential civil money penalties to the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) and adopt a comprehensive corrective action plan to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules. *HHS*

**FDA approves the first short-acting insulin product to treat diabetes**
The Food and Drug Administration has approved an insulin lispro injection, a short-acting insulin indicated to improve control in blood sugar levels in adults and pediatric patients aged 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus. *FDA*

**FDA approves first drug for Eosinophilic Granulomatosis with Polyangiitis**
The Food and Drug Administration (FDA) expanded the approved use of Nucala to treat adult patients with a rare autoimmune disease that causes vasculitis, an inflammation in the wall of blood vessels of the body. *FDA*

**High-Level opioids meeting**

The Health and Human Services (HHS) Acting Secretary held a meeting to discuss strategies for addressing America's opioid crisis. The discussion was organized around HHS's comprehensive five-point strategy to combat the opioid crisis:

- Better prevention, treatment, and recovery services;
- Better targeting of overdose-reversing drugs;
- Better data on the epidemic;
- Better research on pain and addiction; and
- Better pain management. *HHS*

**New tool for sharing information that allows doctors to better manage antibiotic use; improve patient care**
The Food and Drug Administration (FDA) has announced a new approach to get critical updates regarding antibiotics and antifungal drugs to health care professionals as part of an overall effort to combat antimicrobial resistance. The FDA created a website that will provide direct and timely access to information about when bacterial or fungal infections are likely to respond to a specific drug. This approach is intended to aid health care professionals in making more informed prescribing decisions that will both benefit their patients and prevent the spread of resistant bacteria. *FDA*

**HHS highlights Office for Civil Rights' ongoing response to the opioid crisis**
The Health and Human Services (HHS), Office for Civil Rights (OCR) has launched an array of new tools and initiatives in response to the opioid crisis, while implementing the 21st Century Cures Act. These tools and initiatives also fulfill requirements of the 21st Century Cures Act to ensure that the healthcare sector, researchers, patients, and their families understand how the Health Insurance Portability and Accountability Act (HIPAA) protects privacy and helps improve health and healthcare nationwide. *HHS*

**FDA approves drug to treat dangerously low blood pressure**
The Food and Drug Administration has approved an injection for intravenous infusion to increase blood pressure in adults with septic or other distributive shock. There is a need for treatment options for critically ill hypotensive patients who do not adequately respond to available therapies. *FDA*

**CMS updates website to compare hospital quality**
The Centers for Medicare & Medicaid Services (CMS) updated data on the Hospital Compare website and on data.medicare.gov to provide patients, families and all stakeholders with the information they need to compare the performance of hospitals where they seek medical care. Along with data on quality measures, CMS will also update the Overall Hospital Star Rating. *CMS*

**FDA approves new treatment for certain digestive tract cancers**
The Food and Drug Administration approved Lutathera drug for the treatment of a type of cancer that affects the pancreas or gastrointestinal tract called gastroenteropancreatic neuroendocrine tumors (GEP-NETs). This is the first time a radioactive drug, or radiopharmaceutical, has been approved for the treatment of GEP-NETs. This approval provides another treatment choice for patients with these rare cancers.. *FDA*

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## WHO

**Setting up an efficient cholera treatment hospital and for scaling up preventive interventions in the community**
The United Nations in Zambia, the Centres for Disease Prevention and Control (CDC) and the UK's Department for International Development (DFID) described the Cholera Treatment Hospital set up by the government of Zambia as a good initiative and a massive asset in the on-going cholera response. The bodies also commended government for scaling-up preventive interventions in the community. *WHO Afro*

**Uganda ends Marburg virus disease outbreak**
In a press release, the World Health Organization (WHO) stated that Uganda successfully controlled and prevented the spread only weeks after it was first detected, of an outbreak of Marburg virus disease (MVD). The Ugandan Ministry of Health notified WHO of the outbreak on October 17, after laboratory tests confirmed that the death of a 50-year-old woman was due to infection with the Marburg virus. A Public Health Emergency Operations Centre was immediately activated and a national taskforce led the response. Surveillance and contact tracing on the Kenyan side of the border by the Kenyan Ministry of Health and partners also prevented cross-border spread of the disease. *WHO Afro*

**WHO identifies avenues for Digital Health Technologies in Africa**
At the Global Digital Health Forum a joint session was conducted by WHO and the International Telecommunications Union (ITU) on using digital health services to accelerate Sustainable Development Goals (SDGs) in the Africa Region. Salient features relating to data exchange platforms, capacity building, partnerships and integrated electronic medical devices of the recently launched digital health effort for Africa between WHO AFRO and ITU were tabled discussed. The presentation centred on how technology can be adopted in the health sector to promote Universal Health Coverage and the SGDs. *WHO*

**UN Environment and WHO agree to major collaboration on environmental health risks**
The UN Environment has agreed with the WHO on a new collaboration to accelerate action to curb environmental health risks that cause an estimated 12.6 million deaths a year. The Head of UN Environment and the Director-General of WHO has signed an agreement to step up joint actions to combat air pollution, climate change and antimicrobial resistance, as well as improve coordination on waste and chemicals management, water quality, and food and nutrition issues. The two agencies will develop a joint work programme and hold an annual high-level meeting to evaluate progress and make recommendations for continued collaboration. *WHO*

**WHO supports the immunization of 1 million people against cholera in Zambia**
With support from World Health Organization (WHO), the Government of Zambia launched a campaign to vaccinate residents against cholera. The campaign will bring the life-saving oral cholera vaccine to the people who are in need of it. *WHO*

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