

Hear & Now

Special Notice 2018



Important Industry and Profession Changes

Changes to Medical Regulation pertaining to Hearing Instruments

During 2017 there had been a lot of regulatory activity around medical devices and recently amendments have been introduced to the Medicines Act relating specifically to the purchasing, selling and fitting of hearing instruments as medical devices.

All legitimate hearing aid suppliers now need to register their products as medical devices in accordance with the new definitions and thus need to be compliant to the new Medicines Act. This has both a positive and negative impact on our practices in the way in which we buy, sell and supply hearing aids to the public.

The motivation behind the new regulations was brought on by a sudden increase in medical aid fraud and unprofessional conduct around the supply of hearing aids. Incidents of irregular claiming, unethical charging, the fitting of hearing aids by people not appropriately trained or qualified, "pop-up" shops and mobile suppliers, wholesalers selling directly to the public, online sales and the provision of personal listening devices as medical devices, has necessitated a long overdue rewrite of the Medicines Act, many of the previous amendments dating back to 1965. The new Act aims to address issues around licencing, incentivising, bonusing, price fixing, sampling and marketing.

How does it affect us?

We adhere to regulations set out by the HPCSA, guidelines issued by SAAA, processes stipulated by the POPI Act, the CPA and the PAIA Act so most of the amendments will not affect us, but there are a few things that we will have to change.

Reliable, consistent and stable relationships with our suppliers over the past 25 years have allowed us freedom to negotiate better pricing, discounts, special offers and value-added services for our clients. As of 1 January 2018, we will no longer have that benefit.

This means that we are no longer allowed to accept or offer discounts to our clients. We are not even allowed to do pro-bono work or offer donations as we've done in the past unless we are registered as an NPO. We must charge for costs that we had in the past absorbed or bundled in as part of our service to our clients and we will no longer be allowed to run promotions on hearing aids or accessories.

A major impact is the new regulation around sampling. Sampling is the provision of free trial devices by our suppliers to ourselves, as well as the provision of these trial devices to the public for free. This means we are no longer allowed to do free hearing aid trials.

We believe that without a trial, most first-time wearers struggle to make informed decisions around their hearing health, and it is important to understand that there is a choice as to brands, models and technologies available.

We may continue to run trials as long as it's done on a "Rental" or "Consignment" basis. "Rental" would involve utilizing practice property as demonstration devices where "Consignment" is where you are charged for real stock and credited if needed within a 3 week trial period. Not all models are kept in house as "rental" stock and these are of course not new, but used products. All consumables and time spent must be charged for. The rental fee will include all costs incurred in the process of fitting and trying such as our time, administrative costs and consumables used during the trial. Depending on the brand and model, these trials could cost between R300 and R700 per ear and per model, so we will advise cautiously as to not do excessive trialling of unnecessary products. The trial assumes the necessity of at least 2 visits which are covered by the trial fees, but additional, extensive visits will have to be charged for at normal medical aid rates. Trial fees will only be charged at rejection, so only if the fitting is not successful.

Incentives, Marketing and Pricing

It is the intent of the Act to protect the consumer by doing away with incentives which may introduce bias around the choice of product or service provider. Consumers are reliant on the advice and recommendations received from health professionals but it is based on a trust relationship between them.

Advertising discounts and special offers or claiming that one may provide better services or products than another practice, is considered unethical and in contravention of the Act.

Again, these changes will not impact on us. We do not accept any incentives, we don't pay/earn commissions and we do not entertain any offers of bonusing. We do not advertise for services we can't offer and we do not "bribe" clients to choose us over another. We are an autonomous practice and fit a variety of registered, internationally recognized brands.

As such we are not at risk of ill advising our clients for personal financial gain. We use a pricing guide which is recommended by our professional bodies and therefore do not profit more for selling one brand vs another. This will affect companies who provide one brand of hearing aid only and who do not disclose to their clients that there are other, sometimes more suitable, products available. It is also a concern where wholesalers posing as retailers are selling to the public and where incentives, commissions and bonuses are the norm.

Charging for Services Rendered

In the past, consumables used in office for hearing aid services, such as cleaning equipment, domes, tubes, batteries, couriers, insurance and administrative / professional services provided in the process were not charged for. According to the new Act, this is now considered a form of incentivising clients and is no longer allowed. If audited, we have to show that any costs incurred on behalf of a client, was passed on to the client.

As of 1 January 2018 we may not provide free services of any kind, including hearing aid repair/servicing, even those under warranty. We have to charge for all in-house costs in handling, posting, receiving etc of those products. We are going to keep costs as low as possible but there will be a service fee on all repairs. For hearing aids which are under warranty, we will charge R150 per hearing aid serviced. For hearing aids that are out of warranty, we will charge R250 over and above the charges levied by the suppliers.

Previously these costs were either absorbed by us or bundled into our charges to you, so it will not cost you more to service your aids, it will just be itemized separately for complete transparency. We will also charge for any visits that may be needed as a result of hearing aid servicing - the minimum being a 15 min appointment which costs around R115. Remember, we do charge medical aid rates and should you have medical aid benefits available for audiology and hearing aids, the charges will be paid by your medical aid directly to us.

We recommend that you service both your aids simultaneously to reduce the need for a post-service appointment. We still offer loan hearing aids on request for the duration of your own hearing aids' service time, but the use of those will be charged at R100 each to cover the in-house set-up, maintenance and consumables. Best that you just get one loan aid for the few days it takes to have your hearing aids serviced. That is typically 4-5 days.

Frustrations

These changes will cause some frustration and we assure you that we will try our best to keep all charges at a minimum and advise you up front of any costs that may be incurred.

These are regulations issued by the Department of Health and any variation from the Act or non-compliance to the Act is considered a criminal offence.

As members of HPCSA, SAAA, Profnet and Healthman we have a team of lawyers working on a lawsuit against the Department of Health to amend the Act in line with the best practice guidelines that we already follow, but at this stage, the profession has been advised to adhere to the Act as it stands seeing as non-compliance can be criminally charged and random audits will be done. We will keep you posted with any further changes.

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