EXPLANATORY MEMORANDUM TO

THE HEALTH PROFESSIONS (HEARING AID DISPENSERS) ORDER 2009

2009 No. [XXXX]

1. This Explanatory Memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This Order makes provision in respect of the abolition of the Hearing Aid Council (HAC) which was established by the Hearing Aid Council Act 1968 ("the 1968 Act") and provides for the regulation of hearing aid dispensers operating in the private sector, currently undertaken by the HAC, to be taken over by the Health Professions Council (HPC).

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 Section 123 of the Health and Social Care Act 2008 ("the 2008 Act") provides both for the repeal of the 1968 Act and for the abolition of the HAC. The 2008 Act also amended section 60 of the Health Act 1999 to allow an order to be made under section 60 relating to the regulation by a health regulatory body of the profession currently regulated by the HAC (namely hearing aid dispensers operating in the private sector).

4.2 This Order makes provision for the regulation of such hearing aid dispensers by the HPC under the Health Professions Order 2001 (SI 2002/254) ("the HP Order") by including them as a "relevant profession" in Schedule 3 to the HP Order.

Amendments to the HP Order ensure that "grandparenting" will not apply to hearing aid dispensers who are liable to be registered by the HPC-that is to say that they will all be required to be registered as soon as the relevant provisions come into force in order to avoid committing any offences under the HP Order.

Those amendments also include a criminal offence prohibiting the retail sale or supply of hearing aids by unregistered persons subject to certain exemptions for persons studying to be hearing aid dispensers and for ENT specialists.

The Order also makes transitional arrangements connected with the changeover from regulation by HAC to regulation by HPC.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom .

6. European Convention on Human Rights

6.1 The Secretary of State has made the following statement regarding human rights:

6.2 In my view, the provisions of the Health Professions (Hearing Aid Dispensers) Order 2009 are compatible with the Convention rights.

7. Policy background

- ***What is being done and why***

7.1 The Hampton Report on Regulatory Inspections and Enforcement recommended in 2005 that the overall number of regulating authorities be rationalised. As part of its recommendations, it called for the merger of the HAC into a new body, the Consumer and Trading Standards Agency (CTSA). The plan to set up the CTSA was later amended in order to create the Local Better Regulation Office. Further consideration was then given as to what should happen to the HAC and how hearing aid dispensers should be regulated.

7.2 After deliberations, the Government decided that the HPC should regulate hearing aid dispensers operating in the private sector. At the same time, it also decided that the requirement for employers of private hearing aid dispensers to be registered would cease as their activities could be regulated under consumer protection legislation.

7.3 The HPC currently regulates 14 different health professions. It has developed systems and processes to handle the complexities that this brings to statutory regulation. It sets standards of education, training, performance and conduct. In particular, it is able to investigate and take action against a registrant (e.g. remove from the register) before harm is caused. This is in contrast to the position where the HAC had to wait until the harm has been done and the matter has been drawn to its attention before it could take any action.

7.4 Regulation of private hearing aid dispensers by the HPC is the first step towards bringing together the regulation of dispensing of hearing aids in both the private sector and the NHS by one body.

- ***Consolidation***

7.5 None required.

8. Consultation outcome

8.1 In line with the code of practice for consultations laid down by the Cabinet Office and as required by paragraph 9 of Schedule 3 to the Health Act 1999, the Department of Health (England) carried out a formal public consultation. "The regulation of private hearing aid dispensers by the Health Professions Council – A paper for consultation" was published on 7th April 2009 electronically on the Department of Health website. The consultation closed on 7th July 2009. Interested parties, including organisations in Scotland, Wales and Northern Ireland, were notified of the consultation by the Department of Health.

8.2 The Department received thirty-two responses to the consultation from a mixture of organisations, employers of hearing aid dispensers and healthcare professionals in the field of audiology practice. There were also a number of public meetings organised by the HAC with its registered members and employers and professional bodies. All thirty- two responses were reviewed as part of the consultation.

8.3 Generally speaking, the package was welcomed. However, a few concerns were raised that the Order does not make provision for the possibility that assistants could provide services in the future. The Government will consider the regulation of hearing aid assistants in line with the recommendations of the working group on Extending Professional and Operational Regulation.

8.4 Moreover, whilst the majority of respondents supported the Government's proposals on the criminal offence, some concerns were also raised around who would be exempted from committing the offence. In particular, some respondents asked why its was proposed that some medical professionals were exempt. The Department is satisfied that public safety will be

maintained without requiring registered medical practitioners to register additionally with the HPC as they would necessarily be registered with the General Medical Council.

8.5 The Department agreed with two respondents who suggested an alternative definition of "hearing aid" from that contained in the 1968 Act. The definition incorporated into the HP Order by this Order has been proposed as a European standard.

9. Guidance

9.1 Guidance for hearing aid dispensers operating in the private sector is currently available on the HAC's website and will also be available on HPC's website shortly..

10. Impact

10.1 As mentioned in paragraph 7.2 above, employers of private hearing aid dispensers will no longer be required to register with the regulatory body.

10.2 Private hearing aid dispensers will pay a reduced fee than they currently do under the Hearing Aid Council when they apply to be registered with the Health Professions Council.

10.3 An Impact Assessment is attached to this memorandum .

11. Regulating small businesses

11.1 The legislation does not apply to small businesses.

12. Monitoring & review

12.1 The Council for Healthcare Regulatory Excellence (CHRE) will consider the regulation of private hearing aid dispensers as part of its annual performance review of the HPC. CHRE publishes its annual reviews and is required to report its findings to Parliament.

13. Contact

13.1 Keith Baggs at the Department of Health Tel: 0113 254 5791 or email: keith.baggs@dh.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options		
Department /Agency: Department of Health	**Title: Impact Assessment of the abolition of the Hearing Aid Council and the transfer of responsibilities to the Health Professions Council**	
Stage: Final	**Version: one**	**Date: 17/08/2009**
Related Publications: Health and Social Care Act 2008 http://www.opsi.gov.uk/acts/acts2008/pdf/ukpga_20080014_en.pdf		

Available to view or download at: Hampton review http://www.hm-treasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cfm

Contact for enquiries: Keith Baggs **Telephone:** 0113 254 5791

What is the problem under consideration? Why is government intervention necessary?

The Hampton Report on Regulatory Inspections and Enforcement recommended in 2005 that the overall number of regulating authorities be rationalised. As part of its recommendations, it called for the merger of the Hearing Aid Council (HAC) with a new body, the Consumer and Trading Standards Agency (CTSA), by April 2009. The plan to set up the CTSA was later amended in order to create the Local Better Regulation Office and further consideration was given at that time to what should happen.

What are the policy objectives and the intended effects?

There are a number of positive benefits from the regulation of private hearing aid dispensers by the Health Professions Council. This change will:

- reduce the cost of regulation and reduce the number of regulatory authorities;
- modernise and improve the regulation of private sector dispensers;
- pave the way for regulation of public and private dispensers;
- improve the protection of consumers as the Health Professions Council have wider powers;
- improve the transparency of regulation for consumers.

What policy options have been considered? Please justify any preferred option.

Option A. is do nothing effectively meaning no change. This has already been ruled out by the Government and is therefore closed.

Option B. Given that the Westminster Government accepted in full the Hampton recommendations (Budget Report 2005), and the UK Parliament has passed primary legislation allowing for the abolition of the Hearing Aid Council on the presumption that the register would be transferred to the Health Professions Council, this is the option that the Government has accepted and are implementing in these draft regulations.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The Health Professions Council will monitor the regulation of private hearing aid dispensers and will report on the transfer through its own accounting and reporting procedures. The Hearing Aid Council will publish final accounts detailing the costs of the transfer and close down.

Ministerial Sign-off For final stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Ann Keen .....Date: ***12th October 2009***

Summary: Analysis & Evidence

Policy Option:	Description: abolition of the Hearing Aid Council and the transfer of its responsibilities to the Health Professions Council

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ £241K	
Average Annual Cost	
£	

Description and scale of **key monetised costs** by 'main affected groups'

The main group affected is the HAC which is funding transfer as a one off transitional cost through the retention fee levied against its registrants.

Total Cost (PV)	£ 241K

Other **key non-monetised costs** by 'main affected groups'

The main group with non-monetised costs is the HAC registrant body. Registrants may incur transition costs from adjusting to the regulatory change. There will be an additional average annual cost for companies to comply with HPC fitness to practise requirements.

BENEFITS

ANNUAL BENEFITS		
One-off	**Yrs**	
£ **0**		
Average Annual Benefit (excluding one-off)		
£ 1,100K	1	

Description and scale of **key monetised benefits** by 'main affected groups'

Lower retention fee for dispensers and no retention fee for employers.

Total Benefit (PV)	£8,370K

Other **key non-monetised benefits** by 'main affected groups'

Improved regulatory environment for dispensers. Lower compliance costs for dispensers and employers. Improved consumer protection and clarity through improvements to the regulatory environment. Will pave the way for regulation of public and private dispensers under a single regulator with a single set of standards. Lower costs to industry should lower consumer prices and improve access to services. The average annual benefit is compared to status quo though limited to five years.

Key Assumptions/Sensitivities/Risk

It is conservatively assumed that the number of registrants will remain constant at January 2009 levels. If the number of dispensers continues to rise then the benefit of transfer will be greater. It is assumed that were it not abolished the HAC registration fee would remain at its current level minus the portion of the fee funding transfer costs. The HPC fee is assumed to remain at its current level.

Price Base Year 2008	Time Period Years 1	**Net Benefit Range** (NPV) £ **N/A**	**NET BENEFIT** (NPV Best estimate) £ 8,130K

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			April 2010	
Which organisation(s) will enforce the policy?			HPC	
What is the total annual cost of enforcement for these organisations?			£111,744	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			N/A	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ N/A	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro **N/A**	Small **N/A**	Medium N/A	Large N/A
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key **Annual costs and** (Net)

Evidence Base (for summary sheets)

Background

The Hearing Aid Council (HAC) was set up by the Hearing Aid Council Act 1968. The Act was extended to Northern Ireland by the Hearing Aid Council (Extension) Act 1975 and amended by the Hearing Aid Council (Amendment) Act 1989. In order both to abolish the Hearing Aid Council and enable the Health Professions Council to take over the regulation of private hearing aid dispensers, primary legislation was needed to allow for this abolition and transfer.

The Hearing Aid Council is a high overhead body that results in significant annual fees of more than £600 for its registrants. Over time, the HAC's powers have become insufficiently flexible to allow for the most effective enforcement; for example the HAC has no powers to remove registrants from the register on fitness to practise grounds and its registrants are not classed as a notifiable profession with the police.

The Health Professions Council was set up by the Health Professions Order 2001 which was made under powers in the Health Act 1999. Adding new professions to be regulated by the Health Professions Council is usually achieved through amending the Health Professions Order. In the case of the Hearing Aid Council, however, this was not possible unless an amendment was first made to the 1999 Act removing certain restrictions which would prevent the Health Professions Council taking over this new regulatory role. These amendments were passed in the Heath and Social Care Act 2008 with full support from Parliament.

The Hampton Report on Regulatory Inspections and Enforcement recommended in 2005 that the overall number of regulating authorities be rationalised. As part of its recommendations, it called for the merger of the Hearing Aid Council into a new body, the Consumer and Trading Standards Agency (CTSA), by April 2009. The plan to set up the CTSA was later amended in order to create the Local Better Regulation Office and further consideration was given to what should happen to the Hearing Aid Council.

After discussions between the Cabinet Office and the Treasury, it was agreed that the Health Professions Council was the most appropriate body to take over regulation of private hearing aid dispensers. The Westminster Government then explored how best to achieve the transition given that primary legislation was required to repeal the Hearing Aid Council Acts.

After further deliberations, the Westminster Government (Cabinet Office, Treasury and BERR) decided that the register of private hearing aid dispensers should be transferred to the Health Professions Council while the registration requirement for employers should cease. At the point of transfer, employers of dispensers will be regulated in the same way as any other business. The regulations governing businesses: health and safety, employment, commercial practices etc – are well established with appropriate responsible statutory bodies.

Officials in the Cabinet Office contacted and had a meeting with DH officials in April 2006 and informed DH that they intended to use the Legislation and Regulatory Reform Bill which would allow a Regulatory Reform Order to be made re-writing other Acts of the UK Parliament. This would provide the basis of the primary legislation. However, legal advice received suggested that the legislation proposed could not be used and therefore it was not until February 2008 that BERR formally made a request to DH to use the Health and Social Care Bill to make the primary legislation amendments needed.

The Health Professions Council; currently regulates 13 different health professions and it has developed systems and processes to handle the complexities that this brings to statutory regulation. Like the Hearing Aid Council, the Health Professions Council sets standards of education, training, performance and conduct for its registrants. However, it has more complete public protection powers than the Hearing Aid Council and is able to able to charge significantly lower fees. The transfer of the Hearing Aid Council's register to the Health Professions Council will serve to simplify regulation of that sector.

Following agreement by Health Ministers, an amendment to the Health and Social Care Bill was moved in the House of Lords which would have effect of dissolving the Hearing Aid Council and amending Section 60 of the Health Act 1999 to allow for the transfer of the register of hearing aid dispensers to a health regulatory body. The amendment had wide support and was accepted and became part of the Act when it received Royal Assent..

The provisions which abolish the Hearing Aid Council and the repeal of the Hearing Aid Council Act 1968, and the Hearing Aid Council (Extension) Act 1975 are contained in sections 123(1) and (2) of the Health and Social Care Act 2008. The Hearing Aid Council (Amendment) Act 1989 is also repealed by the Health and Social Care Act 2008.

Options

Given that the Westminster Government accepted in full the Hampton recommendations (Budget Report 2005), and the UK Parliament has passed legislation allowing for the abolition of the Hearing Aid Council on the presumption that the register would be transferred to the Health Professions Council, there are limited policy options at this stage. We are basing this Impact Assessment therefore on two options; the status quo where the Hearing Aid Council continues to operate as it does now. (Option A) and the transfer of the register to the Health Professions Council (Option B).

Option B is the preferred option in order to ensure that there is a modern regulatory regime for private hearing aid dispensers. The Health Professions Council has more complete public protection powers than the Hearing Aid Council and is able to able to charge significantly lower fees. The transfer of the Hearing Aid Council's register to the Health Professions Council will also simplify regulation and remove barriers between the public and private sectors.

Option A: Status quo – the HAC continues to exist and carry out its functions

The HAC is entirely funded by its registrants. Each registered dispenser and registered employer must pay an annual retention fee. For the year 2009-10, the fee levied was £695, of which £635 was to cover the HAC's running costs for 12 months and £60 was to cover the cost of a one-off post-transfer closedown period of 4 months. As of January 2009, there are 1552 dispensers registered and 321 employers.

Conservatively assuming that the fee did not increase in 2010-11 and that there was no growth in the number of dispensers or employers registered, then the cost of option A in 2010-11 would be equal to the number of registrants multiplied by the fee levied to cover 12 months of operating costs (£635). This is equal to £1,185,355. Were the fee or number of registrants to increase then the costs would also rise.

There may be further non-monetised costs, particularly adjustment costs for employers and other stakeholder bodies whose business plans anticipate an imminent change in the regulatory environment.

In February 2008, the BERR Minister Gareth Thomas wrote to the DH Minister Ben Bradshaw to request that DH use the Health and Social Care Bill which was progressing through the UK Parliament to abolish the Hearing Aid Council and transfer the register of dispensers to the HPC. The Minister of State for Health Services accepted the proposal and arranged for the appropriate amendment to the Bill. The amendments are now contained within the Health and Social Care 2008 which support option B and therefore effectively ending option A.

Option B: The transfer of the HAC's register to the Health Professions Council

The Health Professions Council is funded by its registrants. It currently charges an annual retention fee of £72. Were the transfer to proceed, the Health Professions Council would only register individual dispensers. Employers would not be registered and would not pay a retention fee. Assuming no growth in the number of dispensers registered or the fee charged by Health Professions Council then the cost of registering 1552 dispensers at £76 each would equal £117,952.

Assuming conservatively that the fees levied by the HAC and Health Professions Council did not increase in 2010-11 and that there was no growth in the number of dispensers or employers registered, then the annual saving from reduced retention fees would be equal to £1,077,611. Were the fees of both organisations to increase at the rate of inflation or the number of registrants to rise then the saving would be greater.

The benefits of option B are:-

- Improved regulatory environment for dispensers;
- Lower compliance costs for dispensers and employers;
- Improved consumer protection and clarity through improvements to the regulatory environment;
- Will pave the way for regulation of public and private dispensers under a single regulator with a single set of standards;.
- Lower costs to industry should lower consumer prices and improve access to services;
- The average annual benefit is compared to status quo though limited to five years.

Risks identified with option B are:-

- That agreement cannot be reached with the Devolved Administrations and this is being managed by close liaison;
- good working relationship was needed and maintained between the HAC and the Health Professions Council;
- Support for the transfer required from key stakeholders.

Competition assessment

There are no competition specific issues involved in any of these proposals but it is possible, given the higher fees and compliance costs of continuing with the HAC that the lower cost of registration will reduce barriers to entry for practitioners.

Small firms test

'Think small first' principles have been applied to this impact assessment. In terms of practitioners, most will be self employed or in small practices and most companies trading in the area could be described as small-medium size enterprises. All practitioner industry bodies are supportive of the transfer taking place as soon as practicable and state serious concerns that there would be any kind of delay. These concerns are based around the cost of registration with the HAC and the lower compliance costs of the HPC. A further benefit of the transfer of particular relevance to small firms is that the relatively large HAC fee must be paid in a single amount whereas the Health Professions Council's fee can be paid by instalments.

Equality impact assessment

In line with better regulation best practice and the Equalities Duties we have considered the impact of the three options on minority groups. There are no obvious differential impacts in terms of race or gender to consider. Given the area in question there is potentially an impact on disabled users, as explored below.

Disability Impact Assessment

It is important to differentiate between the 'culturally deaf' and people who are hard of hearing. The culturally deaf are those who are pre-lingually deaf (deaf from early childhood) and use British Sign Language as their first language. 'Culturally deaf' people will have typically accessed audiology services through the NHS from an early age and are much less likely to engage with private hearing aid dispensers, and consequently, the HAC. Hard of hearing people typically have a deteriorating or acquired hearing loss that worsens with age. Hard of hearing people are far more likely to engage with private hearing aid dispensers, the sector which the HAC currently regulates.

The abolition of the HAC is viewed as minor both in terms of scale and significance. While the impact is clearly on a minority group, the numbers of people affected are very small and stakeholder groups agree that any impact would be positive.

The HAC deals with a range of consumers and their families; only the most vulnerable are those who will be most affected by a transfer to the HPC. This will typically be a female, living alone without dependents, in her early eighties. Her principle disability would not be related to hearing. For example, it is presumed the complainant would be suffering from the physical and mental difficulties often associated with people of that age. This could include dementia, chronic conditions, confusion, memory loss and frailty.

Currently complaints to the HAC are split into two distinct areas: consumer protection (overcharging, refunds, contracts of sale etc.) and fitness to practise (complaints regarding the competence of the audiologist). Following the transfer, complaints strictly in the consumer protection area will be dealt with by other competent bodies (e.g. the Office of Fair Trading and Trading Standards) under the general consumer protection legislation. The Health Professions Council will deal with complaints in respect of fitness to practice, standards etc. However, the Health Professions Council will take an interest in consumer protection complaints where they suggest a breach of the Health Professions Council's Standards of Conduct, Performance and Ethics.

Given that the Health Professions Council already deal with vulnerable consumers in respect of their other areas of regulation, they have experience, procedures and technical equipment that a consumer from the HAC may require. Both organisations provide support at hearings which can include British Sign Language translators, lip readers, palantypists and visual support, use of premises with specialised disabled access and hearings can be moved closer to vulnerable people. The Health Professions Council also offer their publications in alternative formats including larger text and Braille.

As part of an orderly transition, the Health Professions Council are working closely with the HAC to benefit from their experience is dealing with their particular consumers and registrants. To ensure they continue to meet people's needs the Health Professions Council review their policies annually and will seek guidance from consumers groups where appropriate.

Likely number of people affected

According to the Office for National Statistics figures show that as at March 2007, 54,500 people were recorded on the register of the deaf and 164,600 people were registered as hard of hearing. These will be divided between the public (NHS) and the private sector. The Hearing Aid Council regulates only the private hearing aid industry.

Information and reconsideration following the results of the public consultation exercise

The public consultation exercise which covered the Government's proposals (see separate document on the Government's response to the consultation: The Health Professions (Hearing Aid Dispensers) Order 2009) to transfer the private hearing aid dispensers to the Health Profession Councils took place between 7th April and 7th July 2009. There were thirty-two responses to the consultation from a wide range of bodies/organisations and healthcare professionals in the field of audiology practice.

Support for the Government's proposals was overwhelming. Of the seven specific questions 97% of respondents supported the Government's proposals in four of them. The other three questions received support of 82%, 78% and 72%.

All thirty-two questions were analysed. Their was four issues that arose, the possibility of employing hearing aid assistants in the future, the definition of "hearing aid", exemption for students on non-approved courses, and whether the Government's proposal to exempt some medical staff from the requirement to register with the HPC was correct.

The possibility of employing assistants in the future: The Department is aware that the profession has begun to debate the possible use of dispensing assistants to help dispense hearing aids. The Order as drafted does not allow unregistered assistants to deliver such services and only those practitioners who are qualified and registered with the HPC will be able to assess, test and dispense a hearing aid to a private patient. This reflects the current position under the HAC. The issue of using assistants is currently under consideration. In its recent report the Extending Professional Regulation Working Group highlighted the potential benefits of licensing/licensure regimes which may be applicable to health roles. In their response to the Report the four Health Administrations of England, Northern Ireland, Scotland and Wales noted that they would review, in particular, the recent Scottish Health Care Support Workers Pilot and the licensing proposals made by the HPC concerning assistants within the Report, to assess their applicability within their jurisdictions.

The definition of a hearing aid: The Department has also re-considered the definition of "hearing aid" following comments received from 2 respondents. The respondents' proposal was that the definition should be the definition drafted by the European Committee for Standardisation Technical Committee on Hearing Aid Specialists Services because it reflected the latest technology. The Department has accepted this proposal and has amended the draft Order accordingly. The revised definition applies to both analogue and digital devices. The change in the definition does not change the position of any

individual practitioner currently registered with the HAC or any student undergoing training to become a dispenser.

Exemption of students on approved courses: The issues of exemption for students on non-approved courses was raised in the consultation. The Department has considered the issue of students . The Order allows exemption for students on courses approved by the HPC. Also exempt are students on non-approved courses where the clinical placement is undertaken in the NHS. Therefore no exemption is needed for these students. The HPC is currently in discussion with the Higher Education Institutes to ensure approval which will avoid disruption to students and their education prior to the transfer.

Exemption of some medical staff:- The exemption applies to a very small number of medical staff and is necessary to allow them to carry out their current duties which can include private work, particularly for overseas patients. Any work for the NHS falls outside the Government's proposals and therefore it is only private work that needs either registration with the Health Professions Council or exemption from the need to do so. The Government has considered the consultation responses and has concluded that its proposed exemption should be retained. However, it does not mean that these medical staff are unregulated. They are regulated by the General Medical Council and as such are required to work to the standards set by that body. The Government does not think it could be justified to require these group of people to register with the Health Professions Council as well as maintaining registration with the General Medical Council.

Conclusion from the consultation

The consultation exercise raised no issues of equality or regulatory burden on the practitioners, business or for patients and the public. The HPC will take over as regulator from the HAC have an equality and diversity policy which is published in full on their website. The HPC policy covers:-

- setting standards;
- approving programmes of education and training;
- registering health professionals; and investigating and adjudicating allegations about their fitness to practise.

In so the HPC interact's with a diverse range of people, including:-

- the public, especially complainants or witnesses in fitness to practise proceedings;
- registrants and potential registrants;
- education and training providers;
- health care providers, professional bodies, consumer groups and other partner organisations; d
- their employees and the "partners" who carry out tasks on their behalf.

The HPC is required to meet the general duties under relevant equality legislation, including: the Race Relations Act 1976 and the Disability Discrimination Act 1995.

No issues were identified that would lead to changing the benefits or costs analysis. The draft Order has been amended to include a new, more modern definition of a hearing aid and by other minor drafting issues.

Following the overwhelming support for the Government's proposals, Ministers have agreed that the Order should be laid taking account of the amendment concerning the definition of an hearing aid.

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	N/A	No
Small Firms Impact Test	Yes	No
Legal Aid	N/A	No
Sustainable Development	N/A	No
Carbon Assessment	N/A	No
Other Environment	N/A	No
Health Impact Assessment	N/A	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	N/A	No
Rural Proofing	N/A	No

The Health Professions (Hearing Aid Dispensers) Order 2009

Consultation Report: September 2009

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

Document Purpose	For Information
Gateway Reference	12495
Title	The Health Professions (Hearing Aids Dispensers) Order 2009 Consultation Report
Author	Department of Health Workforce Professional Standards
Publication Date	22 Oct 2009
Target Audience	Regulatory Bodies, Council for Healthcare Regulatory Excellence, Employers of Hearing Aid Dispenseras and the Dispensers
Circulation List	PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs , Directors of HR, Communications Leads, Voluntary Organisations/NDPBs,
Description	The draft Order has been laid in Parliament and subject to Parliamentary approval will come into force on I April 2010.
Cross Ref	The Regulation of private hearing aid dispensers by the Health Professions Council
Superseded Docs	N/A
Action Required	N/A
Timing	**N/A**
Contact Details	Keith Baggs Workforce Professional Standards Room 2N09 Quarry House Quarry Hill Leeds LS2 7UE 0113 254 5791 http://www.dh.gsi.gov.uk/en/consultations/responsestoconsultations/index.htm
For Recipient's Use	

© Crown copyright 2008
First published October 2008
Published to DH website, in electronic PDF format only.
http://www.dh.gov.uk/publications

The Health Professions (Hearing Aid Dispensers) Order 2009

Consultation Report: September 2009

Prepared by: Keith Baggs

Contents

Executive summary 6
Introduction 7
Background 8
Consultation process 9
Conclusion 16
Annex A 17
Annex B 19

Executive summary

On 7th April 2009, the Department of Health published a consultation paper *"The regulation of private hearing aid dispensers by the Health Professions Council – A paper for consultation"* accompanied by a draft order setting out the legislative arrangements relating to the proposed transfer of the register of Hearing Aid Dispensers administered currently by the Hearing Aid Council (HAC) to the Health Professions Council (HPC).

The draft Health Professions (Hearing Aid Dispensers) Order 2009" ("the draft Order") will, once enacted:

- make the necessary legislative arrangements for effecting the transfer of the register of private hearing aid dispensers kept by the HAC to the HPC's register;
- create a new offence relating to the dispensing of hearing aids by unregistered persons;
- make the necessary legislative arrangements relating to the abolition of the HAC;
- make transitional arrangements in respect of uncleared HAC casework at the point of transfer.

Introduction

This paper sets out the outcome of the consultation on the draft Order.

The consultation took place over a 13-week period between 7th April and 7th July 2009, and was published on the Department of Health website. The Department emailed a weblink of the consultation paper to interested professional bodies, patient groups and professionals. This included organisations in Scotland, Wales and Northern Ireland that were identified by officials in those countries.

The Department has received thirty-two responses to the consultation and this analysis takes account of all the replies.

Background

The Hearing Aid Council (HAC) was established by the Hearing Aid Council Act 1968 ("the 1968 Act"). Since 2003, the HAC has been operating as an Executive Non-Departmental Public Body (NDPB).

The 1968 Act makes it an offence, both to act as a private dispenser of hearing aids and to employ someone to act as a private dispenser of hearing aids, unless registered with the HAC. The HAC therefore currently has two registers; a register of hearing aid dispensers operating outside the NHS and a register of employers of such persons. The HAC also regulates the profession with the 1968 Act allowing hearing aid dispensers to be removed from its register in the event of misconduct etc.

The Hampton Report on Regulatory Inspections and Enforcement **http://www.hm-treasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cfm** recommended in 2005 that the overall number of regulating authorities be rationalised. As part of its recommendations, it called for the merger of the HAC into a new body, the Consumer and Trading Standards Agency (CTSA), by April 2009. The plan to set up the CTSA was later amended in order to create the Local Better Regulation Office and further consideration was given to what should happen to the HAC and the regulation of its hearing aid dispensers.

After deliberations, the Department decided that private hearing aid dispensers should be regulated by the Health Professions Council (HPC). At the same time, the requirement for employers of private hearing aid dispensers to be registered will cease so that they will be regulated in the same way as any other business.

Health Ministers moved an amendment to the Health and Social Care Bill in the House of Lords, to allow both for the abolition of the HAC and for section 60 of the Health Act 1999 to be amended to allow an order under that section to effect the transfer of the register of Hearing Aid Dispensers to a body regulating a health profession. The amendment had wide support and was inserted into the Bill.

Both the abolition of the HAC and the repeal of the Hearing Aid Council Act 1968 and associated legislation are effected by in section 123(1) and (2) of the Health and Social Care Act 2008. These provisions will be commenced when the section 60 order relating to the regulation of private hearing aid dispensers has been passed into law.

Consultation process

The consultation took place over a three-month period between 7th April and 7th July 2009.

Respondents were requested to fill in a questionnaire response form and return either electronically, or by post to the Department. In total, thirty-two responses were received by the closing date. All thirty-two responses were reviewed as part of the consultation process. The Department has also been involved in discussions with the HPC, the HAC and the Department for Business, Innovation and Skills (formerly the Department for Business, Enterprise and Regulatory Reform) throughout the process of producing the Order.

The HAC have also undertaken a number of public meetings to discuss the transfer of its register to the HPC with its registrant members, professional bodies and employers of hearing aid dispensers.

The responses to the consultation received by the Department represented a mix of responses from bodies/organisations and healthcare professionals in the field of audiology practice.

Annex A shows a breakdown of the number of responses to each of the questions in the consultation document. Below is a summary of consultation responses received in response to the questions and the Department's position on these.

Annex B identifies those who responded to the consultation, all of whom were happy for their names to be included.

Q1: Do you agree that the HPC is the most appropriate regulatory body to replace the HAC as the regulator of private hearing aid dispensers? If not, why not and who instead should regulate private hearing aid dispensers?

- 31 respondents (97%) supported the proposal that the HPC was the most appropriate regulatory body to regulate private hearing aid dispensers instead of the Hearing Aid Council.

.

- In view of the level of support for the proposal, the Department has decided that the HPC should be the regulator for the private hearing aid dispensers following the transfer.

- One of the respondents who supported the proposal raised the issue of those on the Registration Council for Clinical Physiologists' register also being allowed to join the HPC. The Department believes that only those dispensers who are on the HAC register at the point of transfer should be automatically transferred to the register of the HPC. From the date of transfer, it would be for the HPC to consider applications to join its register in the normal way. All those who wish to transfer automatically to the HPC register should apply to the HAC for inclusion on their register prior to the date of transfer.

- No change is therefore necessary to the draft Order in this respect.

Q2: Do you agree that there should be no "grandparenting" period when the register of dispensers is transferred from the HAC to the HPC?

- 31 respondents (97%) supported this proposal.

- The one respondent who did not support the proposal commented that there are experienced, qualified audiologists who are competent to assess and fit hearing aids. Many work in the NHS and some clinical scientists (audiology) are already registered with the HPC. The respondent is concerned that an experienced NHS audiologist registered with the HPC as a clinical scientist would be prevented from dispensing private hearing aids.

- Some respondents raised the issue of protecting the title of Hearing Aid Audiologist as well as Hearing Aid Dispenser. However, these titles are also used by practitioners working in the NHS, and, if protected then if the NHS staff would be unable to continue to use the titles leading to confusion for both staff and patients.

- The draft Order excludes those solely dispensing hearing aids within the NHS from the need to register with the HPC as they would not be doing so by way of retail sale. Therefore, NHS staff will not be prevented from dispensing hearing aids unless they are doing so in a private capacity. In view of the overwhelming support received for the Department's proposal, the Department has decided that there will be no "grandparenting period".

- However, after having sought further legal advice on the issue, the Department formed the opinion that a technical legal amendment to the draft Order was nevertheless required to ensure that the policy intention not to have a grandparenting

- period was legally sound.

- The Department is aware that some dispensers call themselves audiologists or hearing aid audiologist. However, the title "Hearing Aid Dispenser" is the registered title currently recognised by the HAC and we believe therefore, is the appropriate title to be regulated by the HPC. It would not be appropriate to protect the title of "Hearing Aid Audiologist" at this time, as this would lead to confusion for NHS staff about whether or not they can use this title. It would be possible to do so in the future if the NHS staff become regulated and it was felt appropriate by the Department to do so.

Q3: Do you agree that all those dispensers on the HAC register the day before transfer to the Health Professions Council should be automatically transferred to the Health Professions Council's register? If not, why not?

- 31 respondents (97%) supported this proposal.

- 1 respondent (3%) was unsure whether to support the proposal or not. The respondent raised concerns about arrangements for those

temporarily removing themselves from the HAC register. The respondent believes that the HPC should continue the HAC policy of allowing re-instatement within three years. The Health Professions Council's rules allow reinstatement within a two year period Individuals applying for reinstatement having been out of practice for between 2 and 5 years are required to undertake a period of 30 days supervised practice before re-admittance. After being out of practice for 5 years or more, the 30 day supervised practice period rises to 60 days.

- Another respondent raised the issue of many dispensers being remunerated by their employers on a commission for sale basis. In future the respondent would like to see it made a condition for HPC registration that dispensers are not paid on a commission basis.

- The Department believes that all dispensers on the HAC register the day prior to the transfer to the HPC should automatically transfer to the HPC's register. No change is therefore necessary to the draft Order in this respect.

- The HAC has however agreed to write to everyone who has removed themselves voluntarily from their register within the last three years to explain that they may either re-register with the HAC prior to the transfer to the HPC, or apply subsequently to the HPC. If they choose the latter course of action their application would be determined under the HPC's rules.

- Issues relating to commission for sale would be covered by the HPC's fitness to practise procedures, i.e. registrants would be expected to abide by professional ethics (promoting and protecting acting in the best interests of patients rather than being influenced by commercial considerations).

Q4: As outlined in article 5 of the draft Order, do you agree that outstanding HAC fitness to practise cases at the time of transfer should be investigated and determined by the HPC and the HPC's rules? If not, why not?

- 31 respondents (97%) supported this proposal.

- 1 respondent was unsure whether to support or not. The unsure respondent commented that while he agrees with the proposal there might be cases where the HPC will need to consult the professional bodies.

- Another respondent suggested that as elements of the HAC code of practice are not covered by the HPC standards, the HPC might not be able to resolve a case but would need to be referred elsewhere eg to trading standards.

- In view of the high level of support shown, the Department has decided that the proposed transitional arrangements concerning outstanding cases at the time of transfer should remain as set out in the draft Order. The HPC will therefore consider

outstanding cases under the rules applicable to the individual practitioner at the time the event giving rise to the complaint took place.

Q5: Do you agree that any person who is not registered as a hearing aid dispenser with the HPC and who is not exempt from registration, who assesses, tests or prescribes a hearing aid for an individual with a view to supplying a hearing aid to, or for the use of, that person, should be considered to have committed a criminal offence?

- 25 respondents (78%) supported the proposal.

- 4 respondents (13%) did not support the proposal while the remaining 3 (9%) of the respondents were unsure

- Those who disagreed with the proposal queried the need to exempt staff on the specialist register of otolaryngology, oto rhino largngology or ENT surgery from the requirement to register with the HPC because they will not be acting with a view to supplying a hearing aid by way of retail sale.

- It was also suggested that BSC audiology students who are unable to register with the HPC would not be able to dispense.

- There is a need to consider the position of trained assistants who were not registered. These assistants undertake testing under supervision of registered personnel.

- 2 respondents suggested that the definition of "hearing aid" in the draft Order was archaic and provided an alternative definition.

- One respondent suggested that the HPC should protect only by title and that there should be no criminal offence relating to function. In other words any person, whether registered with the HPC or not, could test or assess hearing, prescribe and supply (sell) hearing aids to members of the public. The respondent felt this would allow greater consumer choice and would keep prices down.

- Another issue raised was that there is a need to ensure that the title Hearing Aid Dispenser is embedded in the Heath Professions Order 2001.

- There were also concerns about whether audiologists who undertake private hearing tests and then refer to a dispenser would be committing an offence or not.

- It was also suggested that there was a need to further explain "supplying by way of retail sale" and consideration should be given to redrafting the definition in the Order to provide further clarity.

- There does appear to be some confusion concerning both the proposed offence, which relates to the function and not just title, and the proposal to exempt certain groups of staff. Under the proposal, unregistered NHS audiology staff cannot commit the offence while doing NHS work because they are not supplying with a view to selling or hiring. Any persons who undertake assessing, testing or prescribing hearing aids in a private capacity, with a view

to selling or hiring it, would need to register with the HPC or they would be committing an offence.

- The exemption for specialist doctors such as ENT surgeons is necessary to allow them to carry out their current duties which can include private work, particularly for overseas patients. However it does not mean that such work is unregulated. Many ENT surgeons carry out medical procedures that involve fitting a device which improves patients' hearing. For example, undertaking private work such as fitting a child with profound hearing loss with a cochlear implant or fitting a person with a bone anchored hearing aid. The exemption proposed in the draft Order allows such doctors to carry out these procedures without having to register with the Health Professions Council as Hearing Aid Dispensers. This does not however mean that they are unregulated. Doctors must adhere at all times to the standards of the General Medical Council. They must only carry out tasks for which they are qualified and able to deliver safely and effectively. An ENT surgeon (for example) who is not qualified to dispense hearing aids will not therefore be able to dispense whether in the public or private sector. The Department does not believe there is a case to force such doctors who dispense hearing aids to register with the Health Professions Council in addition to their registration with the General Medical Council.

- The Department has considered the issue of audiology students, assistants, and other non-registered personnel. The draft Order allows for students on courses approved by the HPC to be exempt from the criminal offence. Also exempt are students on non-approved courses where the clinical placement is under taken in the NHS. The HPC is currently in discussion with Higher Education Institutes to ensure disruption to students and their education is avoided prior to the transfer.

- The Department is aware that the profession has begun to debate the possible use of dispensing assistants to help dispense hearing aids. The draft Order as currently drafted does not allow unregistered assistants to deliver such services. Only those practitioners who are qualified and registered with the HPC will be able to assess, test and dispense a hearing aid to a private patient. This reflects the current position under the HAC. The issue of the regulation of assistants is also subject to debate by all the healthcare regulators and was recently considered in *"Extending professional and occupational regulation: the report of the Working Group on Extending Professional Regulation*".The Extending Professional Regulation Working Group highlighted the potential benefits of licensing/licensure regimes which may be applicable to health roles. In their response to the Report the four Health Administrations of England, Northern Ireland, Scotland and Wales noted that they would review, in particular, the recent Scottish Health Care Support Workers Pilot and the licensing proposals made by the HPC concerning assistants within the Report, to assess their applicability within their jurisdictions.

- Audiologists who undertake private hearing tests and then refer to a dispenser would be committing an offence under current Hearing Aid Council rules. The Health professions Council would need to consider the circumstances including whether there had been a commercial motivation that had led to the action of the audiologist.

- The Department has also reconsidered the definition of "hearing aid" following comments received from 2 respondents. The respondents' proposal was that the definition used should be the definition drafted by the European Committee for Standardisation's Technical Committee on Hearing Aid Specialists Services because it reflected the latest technology. The Department has accepted this

proposal and has amended the draft Order accordingly. The revised definition applies to both analogue and digital devices.

- The Department takes the view that it is entirely appropriate to regulate by function. In this case, the functions are concerned with supplying a hearing aid by way of retail sale or hire: this accords with what the HAC have been regulating up to now. Therefore, it does not apply to state funded supply of hearing aids through the NHS. To regulate by title only would only lead to confusion for those dispensers working in the NHS, as to whether or not they needed to register. It would also allow unregistered staff to continue working but using a different title. This, in the Department's opinion, would compromise public protection and safety.

- The Department believes that there is a need for a sanction that can be used to deter unregistered individuals from practicing as a dispenser. The deterrent supports patient and public safety as only appropriately qualified people will be able to register with the HPC.

- In response to the comment relating to embedding the protected title of "hearing aid dispenser" in the HPC Order 2001, the draft Order does this in article 10.

Q6: Do you agree with the scope of the definition of "supplying"? If not, why not?

- 26 respondents (82%) supported the proposal.

- 3 respondents (9%) did not support the proposal and 3 respondents were unsure.

- The main issues raised were concerning the need for clarification of the definition and whether it needs revision.

- Having considered the responses to the consultation on this question, the Department has taken the view that the definition of "supplying" in the draft Order reflects both the existing definition and the intended scope of the activities to be regulated. We accept that the HPC will need to provide guidance to its registrants, employers, patients and the public on this issue.

- **Q7: Are you content with the administrative arrangements for dealing with the closure of the HAC? If not, why not.**

- 23 respondents (72%) supported the proposal.

- 1 respondent (3%) did not support the proposal and 2 respondents (6%) were unsure. 6 respondents (`19%) failed to answer the question.

- The 1 respondent who did not support the proposal commented that the HAC's code of practice states that they will run two examinations per year, but are not doing so in 2009.

- Other respondents raised the issue of the need for costs to be reasonable and relevant and asked what would happen to residual HAC funds on closure. It was suggested that any unspent HAC funds should be given to research in the audiology field.

- The Department believes that there needs to be a period after the transfer of the register of hearing aid dispensers from the HAC to the HPC to enable the HAC to finalise its business and notes that there was no opposition to this specific proposal. Therefore, the Department intends that the HAC will be abolished on 31st July 2010.

- In the period immediately after the transfer and before the date of abolition, the HAC will be finalising its affairs. The HAC's accounts for the year ending 31st March 2010 will be prepared, audited and presented to Parliament along with an annual report in the usual way .A further set of audited accounts will however have to be prepared and audited and presented to Parliament in respect of the period 1st April 2010 to 31st July 2010.

- In response to the code of practice issue which has been raised, the HAC has pointed out that the document concerned is the standards of competence not the code of practice. However, the HAC will still run two examinations in 2009 .

- On the question of what will happen to any residual funds, the Department for Business, Innovation and Skills (BIS) which sponsors the HAC have confirmed that any residual monies will be returned to them. Likewise, if there are any outstanding liabilities of the HAC at the date of abolition, these would have to be settled by BIS.

Conclusion

We are grateful to those who took the time to respond to the consultation. Overall, the response has been very positive. However, a very small number of responses to questions 5, 6 and 7 were less positive.

There was widespread support for the HPC being the appropriate regulatory body to register hearing aid dispensers operating in the private sector. HPC already regulate some audiologists as clinical scientists and so would be likely to become the regulatory body for NHS audiologists once they become a regulated profession. Therefore, allowing HPC to regulate those hearing aid dispensers will enable the development of joint approaches in the future for those dispensing hearing aids, both in the NHS and the private sector.

Questions 5 and 6 have raised a number of issues concerning the offence and regulation by function, not just by title. The Department welcomes these responses as a contribution to the debate. The Department believes that it is correct to regulate by function, as it is the best way to avoid NHS staff being caught unintentionally by the provision. An offence will be committed if an unregistered person performs the functions of a dispenser of hearing aids. That is, if he/she tests or assesses a person's hearing with a view to the retail supply of the hearing aid. The Department acknowledges that further guidance needs to be issued in this area and looks to the HPC as the regulator to provide and publish such guidance.

The Department believes that the draft Order will both enhance public protection and help further develop the profession by bringing it into the mainstream health field. Clearly, there is widespread support for the transfer of the regulation of private hearing aid dispensers to the HPC and this has been apparent since the Department moved the amendment to the Health and Social Care Bill in the House of Lords. The Department is grateful for the support received which has been borne out by the responses to this consultation.

As a result of this consultation exercise, we have agreed to modify the definition of “hearing aid” as suggested by two respondents, as well as making a number of small drafting changes to better reflect the policy intention. We have not made provision exempting assistants or students undertaking non-approved courses who dispense hearing aids in the private sector. Therefore, this group of people will commit a criminal offence if, whilst being unregistered, they test or assess a person’s hearing or prescribe a hearing aid for a person, with a view to supplying it to that person by way of retail sale or hire.

The Department has therefore decided to proceed with its proposals as amended and the draft Order has been laid in Parliament.

Annex A

Set out below are the questions included in the consultation on the regulation of private hearing aid dispensers by the Health Professions Council together with a summary of the responses

Q1: Do you agree that the Health Professions Council is the most appropriate regulatory body to replace the Hearing Aid Council as the regulator of private hearing aid dispensers? If not, why not and who instead should regulate private hearing aid dispensers?

	Support	Not Support	Unsure	Not Answered
Number	31	0	1	0
%	97%	0%	3%	0%

Q2: Do you agree that there should be no "grandparenting" period when the register of dispensers is transferred from the HAC to the Health Professions Council?

	Support	Not Support	Unsure	Not Answered
Number	31	1	0	0
%	97%	3%	0%	0%

Q3: Do you agree that all those dispensers on the HAC register the day before transfer to the Health Professions Council should be automatically transferred to the Health Professions Council's register? If not, why not?

	Support	Not Support	Unsure	Not Answered
Number	31	0	1	0
%	97%	0%	3%	0%

Q4: As outlined in article 5 of the draft Order, do you agree that outstanding Hearing Aid Council fitness to practise cases at the time of transfer should be investigated and determined by the Health Professions Council and the Health Professions Council's rules? If not, why not?

	Support	Not Support	Unsure	Not Answered
Number	31	0	1	0
%	97%	0%	3%	0%

Q5: Do you agree that any person who is not registered as a hearing aid dispenser with the Health Professions Council and who is not exempt from registration, who assesses, tests or prescribes a hearing aid for an individual with a view to supplying a hearing aid to, or for the use of, that person, should be considered to have committed a criminal offence?

	Support	Not Support	Unsure	Not Answered
Number	25	4	3	0
%	78%	13%	9%	0%

Q6: Do you agree with the scope of the definition of "supplying"? If not, why not?

	Support	Not Support	Unsure	Not Answered
Number	26	3	3	0
%	82%	9%	9%	0%

Q7: Are you content with the administrative arrangements for dealing with the closure of the HAC? If not, why not.

	Support	Not Support	Unsure	Not Answered
Number	23	1	2	6
%	72%	3%	6%	19%

Annex B

Responses Received from

Alan Torbet, BSHAA
Amplifon Ltd
Anthony Gunnel, Starkey
Brian Crellin
British Association for Counselling & Psychotherapy
British Hearing Aid Manufacturers Association (BHAMA)
Curtis Alcock
David Ormerod
Federation of Ophthalmic & Dispensing Opticians
General Optical Council
Gillian Timmius
Graham Frost British Society of Audiology
Health Professions Council
Hearing Aid Council
Hidden Hearing (NI) Ltd
Janet Brown
John Irwin
Jonathan Parson, British Academy of Audiology
Kevin Allfort
Lancashire County Council
Mark Begley
National Deaf Children's Society
Paul Shaw, Leeds University
Rita Ray
Rosie Hayes
Royal National Institute for the Deaf
School of Health Science, Swansea University
Siemans Hearing Instruments Ltd
Sonetik Ltd
Specsavers Healthcare Group Ltd
The Hearing Company
Tony Corcoran