7 November 2012

Australian Healthcare & Hospitals Association
Submission to

Standing Committee on Finance and Public Administration References Committee
Inquiry into Medicare funding for Hyperbaric Oxygen Treatment

1. Terms of Reference

On 1 November 2012, the Senate referred the following matters to the Finance and Public Administration References Committee for inquiry and report by the first sitting day of 2013:

(a) the withdrawal of Medicare funding for Hyperbaric Oxygen Treatment (HBOT) of problem wounds and ulcers in non-diabetics (MBS Item number 13015), which will commence on 1 November 2012;

(b) the Medical Services Advisory Committee (MSAC) process regarding this withdrawal, and other changes to the Medicare Benefits Schedule;

(c) the costs/benefits of this withdrawal in relation to associated treatments for these medical conditions; and

(d) any related matters.

2. Introduction

2.1 The Australian Healthcare & Hospitals Association (AHHA) welcomes the opportunity to provide the following submission to the Standing Committee on Finance and Public Administration References Committee in relation to its Inquiry into Commonwealth Medicare Benefits Schedule (CMBS) funding for Hyperbaric Oxygen Treatment (HBOT).

2.2 The AHHA is the peak body and advocate for the Australian public healthcare and not-for-profit sectors. Our membership includes state health departments, Local Hospital Networks and public hospitals, community health services, Medicare Locals and primary healthcare providers, universities, and individual health professionals and academics. We are uniquely placed to be an independent, national voice for universally accessible, high quality healthcare.

2.3 There are nine hyperbaric facilities located Australian public hospitals (most of them provide comprehensive services) as follows: WA – Fremantle and Broome Hospitals; NT - Royal Darwin Hospital;
QLD – Townsville and Royal Brisbane Hospitals; NSW - Prince of Wales Hospital;
Victoria - The Alfred Hospital; TAS - Royal Hobart Hospital; SA - Royal Adelaide Hospital.
There are an additional four centres operating in the private sector as follows: The Wesley Centre for Hyperbaric Medicine in Brisbane, the Hyperbaric Health facilities at Vaucluse and Berwick in Victoria and the Hyperbaric Health Facility at Mascot in Sydney. The Medical Directors of these facilities constitute the Australian and New Zealand Hyperbaric Medicine Group (ANZHMG).

2.4 The AHHA has worked with the ANZHMG since 2004 to ensure ongoing availability of HBOT through the Medicare Benefits Schedule including many representations to Ministers, the Department of health and Ageing and other stakeholders. Copies of letters to Minister Plibersek on 13 July and 19 August 2012 are attached. (attachments 1 & 2) The AHHA and the ANZHMG are seeking reversal of the Government decision, announced in the 2012-13 Commonwealth Budget, to withdraw CMBS funding (effective 1 November 2012) for

patients undergoing the treatment of chronic non-diabetic wounds (MBS 13015) on the recommendation of Medical Services Advisory Committee (MSAC).

2.5 This submission details the concerns held by AHHA and ANZHMG members in respect of this decision.

2.6 The decision to withdraw CMBS funding for the HBOT of chronic non-diabetic wounds (CMBS 13015) in the 2012-13 Commonwealth Budget was made, in the view of AHHA, on the basis of flawed decisions by the MSAC. Its Assessment Report 1054.1 (November 2011) and subsequent Reconsideration (2 August 2012) were wrong in both principle and practice and inconsistent with Medicare principles as is explained in this submission. The result is that the MSAC has recommended withdrawal of public funding from existing funded treatment, but has provided no evidence that any alternative treatment is effective.

3. Executive Summary

Quality of life

3.1 Chronic non-diabetic wounds are painful and significantly reduce quality of life for the patient. There is the potential for serious adverse outcomes if not successfully treated. This submission seeks to show that HBOT is a positive adjunct to standard care for patients with these wounds. The advantage for patients is that standard wound care can i) be covered by the relevant HBOT item number during the period of HBOT and ii) ceased altogether for the many wounds where HBOT has led to healing.

3.2 It is critical to note that the MSAC Assessment Report 1054.1 states: *analysis does not take into account improvements in quality of life following successful treatment or any reduction in quality of life following surgery or due to unsuccessful treatment. Evidence suggests that the impact on patient's quality of life may be substantial. Consequently the actual benefit to the patient of providing HBOT is likely to be underestimated*. (MSAC 1054.1 page 95)

3.3 Furthermore, HBOT has been funded since the CMBS started in 1984 (originally item number 13012) and, until 2001, the use of the treatment was at the discretion of the specialists who work in the field. With self-regulation, the utilisation of HBOT in Australia, has been static for a decade providing a real cost saving for the Federal Government.

3.4 These specialists exercise considerable self-regulation by adhering to treatment for cases where clinical opinion considered the evidence to be high enough for efficacy. For example, in comprehensive facilities, treatment is not offered for multiple sclerosis, sports injuries, cerebral palsy, autism, and many other conditions. The ANZHMG has always been at the forefront of applying evidence-based principles in treatment of patients.

MSAC failed to reach an evidence-based conclusion

3.5 The MSAC failed to reach an evidence-based conclusion that would underpin its decision to defund HBOT. The MSAC based its decision on a very rigid interpretation of data quality and appears to be more focused on cost than quality of care: "*The results indicate that usual care is a less expensive option for the treatment of chronic wounds, ceteris paribus. There is uncertainty around the comparative effectiveness of HBOT and usual care. While the available evidence tentatively indicates a benefit for the use of HBOT, the overall body of evidence is currently insufficient to determine whether clinical management with HBOT is more effective than clinical management without HBOT"*. (MSAC Assessment Report 1054.1 Nov 2011 page 13)

3.6 The MSAC took into account only one small (16 patient) Randomized Control Study published by Hammarland and Sundberg undertaken in 1994. Five case series reports, three of which came from the Australian work requested by the MSAC in 2004, were dismissed as uncontrolled and of too poor a quality to be included, as was the bulk of expert opinion

sought by the MSAC. The whole effectiveness review thus rested on a single 18 year-old study, the small size of which required a considerable difference in outcomes to reach statistical significance.

3.7 The results of one small RCT study that failed to demonstrate the benefits of HBOT statistically do not justify withdrawing public funding for an established therapy. That does NOT mean that it is less effective; only that, in strictly scientific terms, it is impossible to make any definitive comparison of relative effectiveness.

3.8 This is particularly pertinent when it is noted that the MSAC Assessment Report did acknowledge the effectiveness of HBOT using lower level evidence.

3.9 Of greater concern, data from Gordon et al 2006 show that only 8.9% of problem wounds heal with standard care in the initial 3 to 6 month period (ie less than one sixth of the success rate quoted in the MSAC report). This data was available to the MSAC but they declined to use it. Accordingly, the MSAC rejected the data from the Australasian Wound Study that was set up following the MSAC's own recommendations in 2003/4 (see 5.14-5.18 below).

MSAC made an incorrect assumption in relation to the 'clinical pathway' for HBOT

3.10 The MSAC made an incorrect assumption in relation to the 'clinical pathway' for HBOT leading to serious error in its analysis of the projected costs of treatment. HBOT has always been used as a secondary treatment after failure of standard measures. However, the MSAC used an incorrect clinical pathway when costing the treatment for chronic non-diabetic wounds as if HBOT was a first line primary treatment resulting in an inflated estimate of cost.

3.11 On the basis of this cost modeling which is, at best, dubious, a recommendation to cease existing Medicare funding was made. The correct calculations show that there is very little cost difference between the alternatives; in fact, the HBOT option may even be cheaper.

Questions arise about how MSAC obtains its information and conducts its reviews

3.12 This raises questions about how the MSAC obtains its information and conducts its reviews. Its main assessment role relates to new technologies for which there are, by definition, no Australian data. Applications for approval come from the originators or users of the technology and the assessment process rightly includes ensuring that the information provided was collected and analysed independently and in accordance with the relevant scientific standards. The onus is on those seeking approval, on either commercial or professional grounds, to demonstrate its clinical value and cost-effectiveness.

3.13 But this was a review of an established therapy supported by the CMBS since 1984. The MSAC Assessment Report included expert clinical comments that queried whether the standard MSAC assessment process was suitable for such a review and the AHHA's request for reconsideration made similar comments. The MSAC was wrong in rejecting this argument.

3.14 Unsurprisingly, the processes created to assess new technologies have proved inappropriate and misleading when applied to existing technologies. This is most apparent in the requirement for a very high level of evidence for the treatment of interest and no such requirement for the alternative funded therapies available. Once again, very few existing therapies would pass such an unbalanced assessment. The result is that the MSAC has recommended withdrawal of public funding from a funded treatment, but has provided no evidence that any alternative treatment is effective.

MSAC lacks independent appeals processes

3.15 The MSAC does not have enshrined in its terms of reference or processes any independent appeals process or scrutiny by another body when it has recommended withdrawal of public

funding. It is inappropriate when making decisions to withdraw funding from treatments that are already fully funded as this has an impact on the Australian community and is not accordance with best practice in administrative decision making.

3.16 On this occasion, probably due to representations, the Department of Health & Ageing asked the National Health & Medical Research Council to review the MSAC's most recent decision. This extraordinary step was made in haste and within a very narrow brief without consultation from the 1054.1 committee. There was however no structure to the review and no published report from the NH&MRC, confirming this was an ad-hoc process.

4. Term of Reference (a)

- the withdrawal of Medicare funding for Hyperbaric Oxygen Treatment (HBOT) of problem wounds and ulcers in non-diabetics (MBS Item number 13015), which will commence on 1 November 2012

MSAC wrong in principle and practice

4.1 The decision to withdraw CMBS funding for the HBOT of chronic non-diabetic wounds (CMBS 13015) in the 2012-13 Commonwealth Budget was made, in the view of AHHA, on the basis of flawed decisions by the MSAC. Its Assessment Report 1054.1 (November 2011) and subsequent Reconsideration (2 August 2012) were wrong in both principle and practice and inconsistent with Medicare principles as is explained below.

MSAC failed to reach an evidence-based conclusion

4.2 The MSAC's decisions imply that HBOT treatment of non-diabetic problem wounds provides no benefit and should therefore not be funded at all; but the MSAC did not conclude that HBOT was an inferior treatment to standard care.

4.3 On the contrary, the Assessment Report states that: "*HBOT offers a viable, safe and non-invasive treatment to promote healing in patients where conventional treatment therapies have been found to be ineffective. Indeed there may be a good argument to introduce HBOT earlier in the treatment pathway to potentially significantly improve patients' clinical outcomes and quality of life, and avoid the more radical and invasive treatment strategies otherwise used for these conditions*''. (MSAC 1054.1 Nov 2011 p 83)

4.4 The MSAC stated: "*While the available evidence tentatively indicates a benefit for the use of HBOT, the overall body of evidence is currently insufficient to determine whether clinical management with HBOT is more effective than clinical management without HBOT*". (MSAC 1054.1 Nov 2011 page 13) That does NOT mean that it is less effective; only that, in strictly scientific terms, it is impossible to make any definitive comparison of relative effectiveness.

4.5 The MSAC took into account only one small, (16 patient) Randomized Control Study published by Hammarland and Sundberg in 1994. Five case series reports, three of which came from the Australian work requested by the MSAC in 2004 were dismissed as uncontrolled and of too poor a quality to be included, as was the bulk of expert opinion sought by the MSAC. In this context, it is particularly pertinent to note that the MSAC Assessment Report did acknowledge lower level evidence and clinical support: "*Clinical expert opinion is that the evidence in support of the use of HBOT is at least as good as that available for alternative treatments and therapies*". (MSAC 1054.1 Nov 2011 p 81)

4.6 The whole effectiveness review thus rested on a single 18 year-old study, the small size of which required a considerable difference in outcomes to reach statistical significance. The results of one small RCT study that failed to demonstrate the benefits of HBOT statistically do not justify withdrawing public funding for an established therapy. Furthermore, Dr Christer Hammarlund found that HBOT did improve chronic wound healing: "*In the oxygen group there was an overall reduction in wound area after 30 HBO treatments of 36%*

compared with 3% in the control group". (C Hammarlund, Helsingborg Hospital, Sweden - Conference Ravenna Italy 27-28 October 2006)

4.7 Based on the existing treatment protocol (no access to HBOT until after 3 months of failed conventional treatment), the two options must therefore be treated as equally effective. There is no other conclusion.

MSAC made an incorrect assumption in relation to the 'clinical pathway'

4.8 The MSAC made an incorrect assumption in relation to the 'clinical pathway' for HBOT leading to serious error in its analysis of the projected costs of treatment. HBOT has always been used as a secondary treatment after failure of standard measures. However, the MSAC used an incorrect clinical pathway when costing the treatment for chronic non-diabetic wounds as if HBOT was a first line primary treatment, resulting in an inflated estimate.

4.9 Therefore, the AHHA disputes the expected savings from this measure ($4.9m over 4 years), and emphasises that even using the Assessment Report's own flawed costing, the total incremental cost of the item is likely to be less than $800,000 over 4 years ($2151 per patient).

4.10 Indeed calculations made by the ANZHMG indicate there will be cost savings by using HBOT as a secondary intervention because HBOT is less expensive than normal treatment when commenced after three months of failed standard care. Hence it could be anticipated that to withdraw funding for HBOT will actually lead to increased health care costs.

5. Term of Reference (b)

- the Medical Services Advisory Committee (MSAC) process regarding this withdrawal, and other changes to the Medicare Benefits Schedule

Cost of reviews exceeds annual budget for the MBS item number

5.1 Given the cost of the MSAC reviews, (approximately $300,000 each), the amount of money allocated for reviews of this treatment has now exceeded the annual budget for the item number in question and a withdrawal of funding from the Australian public for an existing treatment.

HBOT, as an existing technology funded under Medicare should not be reviewed by MSAC

5.2 Despite the MSAC's brief to review only new technologies, it has now conducted three reviews of HBOT since 1999, which is an existing service funded under Medicare.

5.3 This raises questions about how the MSAC obtains its information and conducts its reviews. Its main assessment role relates to new technologies for which there are, by definition, no Australian data. Applications for approval come from the originators or users of the technology and the assessment process rightly includes ensuring that the information provided was collected and analysed independently and in accordance with the relevant scientific standards. The onus is on those seeking approval, on either commercial or professional grounds, to demonstrate its clinical value and cost-effectiveness. Both the MSAC applications 1054 and 1054.1 were requested by the MSAC and were not initiated by the "applicants". The threat was that if applications did not occur, the funding for item number 13015 would be withdrawn.

5.4 But this was a review of an established therapy supported by the CMBS since 1984. The Assessment Report included expert clinical comments that queried whether the standard MSAC assessment process was suitable for such a review and the applicants' request for reconsideration apparently made similar comments. The MSAC was wrong in rejecting this argument.

5.5 Unsurprisingly, the processes created to assess new technologies have proved inappropriate and misleading when applied to existing technologies. This is most apparent in the requirement for a very high level of evidence for the treatment of interest and no such requirement for the alternative funded therapies available. Once again, very few existing therapies would pass such an unbalanced assessment. The MSAC has recommended withdrawal of public funding from a funded treatment but provided no evidence that alternative treatments (which continue to be funded), are effective.

5.6 The MSAC does not have enshrined in its terms of reference or processes any independent appeals process or scrutiny by another body when it has recommended withdrawal of public funding. This is appropriate when it is assessing NEW technology that will require NEW money to be allocated. It is completely inappropriate when it is making decisions to withdraw funding from treatments that are already fully funded.

5.7 On this occasion, probably due to representations, the Department of Health & Ageing asked the National Health & Medical Research Council to review the MSAC's most recent decision. This extraordinary step was made in haste and within a very narrow brief without consultation from the 1054.1 committee.

MSAC 1018-20 (2001)

5.8 These reviews started in 1999 when a manufacturer of monoplace (single person) hyperbaric chambers applied to have a separate Medicare item number added to the CMBS, via the MSAC. There was, of course, no difference in the treatment (monoplace versus multiplace), in a properly constituted hyperbaric treatment facility, but the MSAC decided to proceed with a review of HBOT in its entirety. This was contrary to the MSAC's brief that it was set up to review new technologies NOT existing funded technology.

5.9 In its 2001 report (1018-20), the MSAC placed severe restrictions on the medical conditions that could be treated by HBOT, citing "evidence" as its guiding principle. Seven conditions remained fully funded by Medicare which constituted a withdrawal of funding from the Australian public for an established treatment, and a major shift in the direction of the MSAC. Immediately after the release of the MSAC 1018-20 report, ANZHMG made further submissions to MSAC to restore full funding of HBOT of hypoxic non-diabetic problem wounds (and soft-tissue radiation injury and necrosis).

MSAC modified clinical specialist conclusions in MSAC 1054 (2004)

5.10 Subsequently, the second MSAC review was commenced. Despite positive recommendations from the supporting committee which included four HBOT specialists, the conclusions that were published in the final report (MSAC 1054 - 2004) were not the same as those of the supporting committee in April 2003 [attachment 3]. These conclusions had been modified by the MSAC, without further consultation, to a negative tone with only short-term funding provided.

5.11 The MSAC recommended that, "*in the absence of effective alternative therapies and in view of the progress of local data collections and an international trial, funding for HBOT should continue for existing MBS-listed indications at eligible sites for a further three years*". This recommendation was accepted by the Minister for Health and Ageing on 31 August 2004.

Background to MSAC 1054.1

5.12 In 2007, the ANZHMG was informed that CMBS funding for hypoxic non-diabetic problem wounds (and soft-tissue radiation injury and necrosis) would cease on 31 October 2010, and a further full submission would be required if funding was sought beyond that date. Since 2004, three-yearly funding only was maintained via Ministerial 3C funding determinations for the MBS Item number 13015. As a result of this directive the ANZHMG, in association with the AHHA, the Australian Society of Anaesthetists and the South Pacific Underwater

Medicine Society, made a full complying submission to the MSAC (January 2010). In February 2010, the applicants were informed that the MSAC had accepted the application and was commissioning another full review. Associate Professors Mike Bennett and David Smart from the ANZHMG were invited to join the MSAC Advisory panel 1054.1 as part of this review.

MSAC 1054.1 process lacked procedural fairness

5.13 The report from this review (1054) resulted in withdrawal of funding for chronic non-diabetic problem wounds. The way in which the MSAC process was conducted during this review lacked procedural fairness. The review was concluded with:

- excessive haste;
- relevant information was not taken into consideration;
- erroneous information was relied upon; and, from the perspective of the specialist advisers, the proceedings lacked transparency.

MSAC wrong in refusing to allow evidence from Australasian wound study

5.14 The MSAC was wrong in refusing to allow evidence, other than from the small Randomised Control Trial by Hammarlund and Sundberg (1994). In doing so, the MSAC declined to take into account data from the major Australasian wound study which was commenced in 2005, after *specifically* being requested by the MSAC in its 2004 1054 report. The requests for this data collection were reaffirmed and documented multiple times in the 1054.1 Assessment Report, for example: *that the profession develop guidelines and collect data regarding the outcomes of patients with non-diabetic problem wounds treated with HBOT*. References are on pages 9 and 10, page 17, page 64 and page 113.

5.15 The MSAC 1054.1 report even recognised Australasian wound study as "*a sizeable body of collective clinical data from Australian hyperbaric facilities, which measures the response of chronic problem wounds (those that have failed three months of standard treatment) to HBOT*". Despite this finding using Australian National Data, the MSAC rejected this evidence out of hand. It is inexplicable that results from this specifically requested national data collection (over 400 cases during a 7+ year period) were ignored.

5.16 This situation has resulted in a waste of ANZHMG's time and resources and potential loss of valuable patient data. The AHHA and ANZHMG have major concerns that in good faith a huge process of national data collection was started as requested by the MSAC (ethics, resources and time and effort by specialists to collect the data), only to be ignored by the MSAC in the 1054.1 report. This has wasted the time of all professionals in the field in Australia, and the MSAC needs to be accountable for its actions.

5.17 In relation to the evidence, the fact that the Australasian wound study is not yet complete and a multi-site Venous Ulcer Randomised controlled trial study has now commenced puts into question the MSAC statement in its latest report that 'opportunities to generate any more convincing comparative data was unlikely to be successful'. This incorrect conclusion seems to have led to the decision to cease interim funding of chronic non-diabetic problem wounds.

5.18 The MSAC did not publish a report by Associate Professors Smart and Bennett dissenting from its decision until it was forced to do so after a complaint was made. This dissenting report is now available on the MSAC website; however it has not been included in the 1054.1 report document, nor with the public summary document. As such it will not be apparent to anyone downloading these two documents that the clinical experts dissented from the report.

6. Term of Reference (c)

- the costs/benefits of this withdrawal in relation to associated treatments for these medical conditions

6.1 The MSAC costed HBOT as a first line treatment compared head to head with standard care. This resulted in flawed cost analysis, and a flawed conclusion that HBOT is more expensive than standard care. The critique of this analysis is presented in attachment 4, and costings have been supplied using the correct pathway that shows HBOT is cheaper that standard care – when used as a second-line intervention.

6.2 In addition, the MSAC used the outcome data from the ANZHMG wound study and assumed the outcomes for standard care would be the same as those for HBOT. There are no outcomes available for standard care after 6 months. The outcome after 3 months of standard care shows 57.6% of wounds healed. This is exactly the outcome that was determined when HBOT was added after 3 months of failed care and reflects HBOT data NOT standard care.

6.3 Of greater concern, data from Gordon et al 2006 show that only 8.9% of problem wounds heal with standard care in the initial 3 to 6 month period (ie less than one sixth of the success rate quoted in the MSAC report). This data was available to the MSAC but they declined to use it. The MSAC kept demanding randomised trial data, and rejected the data from the study that was set up following the MSAC's own recommendations in 2003/4.

6.4 Using this cost analysis, the MSAC 1054.1 calculated HBOT as first line treatment was $2151 per patient more expensive than standard care.

6.5 Applying HBOT as a second line treatment, (after 3 months failed standard care), AND using all of the data that the MSAC provided produces a completely different outcome for cost:

- average cost for all patients standard wound care to 6 months = $28,494 per patient percentage healed = 44.6%
- average cost for all patients 3 months standard care then HBOT course = $22,992 per patient percentage healed = 72.8%

Hence HBOT is a lower cost treatment by $5,502 per patient, with better outcomes when applied after usual care has failed

6.6 Conventional treatment (i.e. without HBOT) would be ongoing and long term, hence when unsuccessful, HBOT is considered. Successful HBOT removes the need for further conventional therapy. The importance of this is related to costs and efficacy of the treatment. Once HBOT is successful, it removes the need for longer term protracted treatment (and its costs), and a high degree or discomfort and pain for the patient.

6.7 Expected savings from revoking this item are $4.9m over 4 years, which contradicts the following quote from the MSAC Report:...*if direct replacement of usual care occurred for chronic non-diabetic wounds, the overall cost would be $3,752,327. If HBOT was used to treat 154 patients instead of usual care, there would be an incremental cost of $331,256 per annum*. (MSAC 1054.1 report Page 96)

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