Biotronik Australia Pty Ltd
Response to :

Private Health Insurance reforms – second wave

Introduction:

Biotronik Australia Pty Ltd is the wholly owned subsidiary of Biotronik SE & Co. KG. , a company headquartered in Berlin with key manufacturing facilities in Germany, Switzerland and USA. The Health Technology manufactured and marketed by Biotronik includes Active Implantable Devices and Passive Implanted Devices supporting Cardiac Applications and Combination Technology (Drug/Devices) which support the cardiac and peripheral vasculature. Common recognisable terminology for the devices marketed includes pacemakers, defibrillators, cardiac and peripheral stents where the company holds in the order of 10-15% worldwide market shares.

We respond to this consultation paper in good faith offering discussions and recommendations gained from experience across multiple developed and developing health care markets and also personnel who have worked many years in the current Australian system of reimbursement, reliant on the instrument called the Prostheses List (PL) as managed by the Commonwealth Department of Health. We have also sought feedback from other key industry stakeholders to stress test Biotronik's recommendations.

This response is contextualised around regulation mechanisms for the sustainability and growth of the privately funded health care market in Australia and which would be acceptable to an engaged multinational Health Technology stakeholder. We understanding the Commonwealth has its own stress testing processes (RIS Analysis) in ensuring regulation is necessary but not excessive, costly and limiting market operations and we would hope this report goes some way to informing that analysis.

The important basic premise is in setting a market environment that ensures appropriate investment by all stakeholders to utilise private capital and resource engagement in maintaining and innovating world's best healthcare practises in meeting the growing demand for health services into Australia's future.

Overview:
First Wave Reforms- Complexity and Value

We request through this consultation a detailed report accessing the success of Regulatory Actions directed at simplifying and enhancing the value of PHI Products and Services. This should be completed prior to proceeding with second wave reforms as it should be instrumental in informing what regulatory processes are effective and how they performed against the original accessed outcomes and RIC analysis.
Such an approach is the essence of good governance. The ongoing monitoring of key outcomes was originally planned to be included in the APRA Statistical datasets but is not readily accessible. E.g. switch to simplified product and potential inadvertent market risk transfer to consumers impacting on real vs perceived (premium costs) value of PHI.

Second Wave Reforms- Participation, Barriers and Integrity

Participation- Concern that discounting premiums through family aggregation will delay, not prevent, falling participation and does little to alleviate price pressures on premiums and therefor industry sustainability. The drop off in younger participants needs investigation as hitting it with increased discounts and payment deferrals has done little to arrest the dropping participation rate. It goes to the first wave reforms around perceived and actual value of the product offer and sadly reflects on the PHI's ability to understand and market the key components of its product offer to this cohort.

Barriers- Concern that regulation is pushing PHI to actively engage in the care management of patients which again hybridise their role in the market from payer to part provider, creating the obvious conflicts. Biotronik would comment that the health system, both public and private, have struggled with optimising care pathways due to the multi-siloed FFs approach to health. By expanding PHI involvement in the appropriate care environment while in principal needed, to ensure coverage, needs to be closely monitored, especially around potential conflicts of interest.

Integrity- Agreed that compliance rules may need review to minimise any bracket creep. There is no indication to the breadth and depth of the codding errors and if by gaming or true process errors. Again, an issue for all FSS reimbursement approaches based on cost rather than value creates. As there is a legislated requirement for contractual arrangements between the hospital and insurer, it would be more appropriate that regulation step back from this and allow commercial arrangements to function.

Detailed Response:

Consultation One – Increase the Family Age Bracket of Dependants/Disabled

Problem Definition

Segmenting membership based around age and family structure are two psycho-social determinants of health risk and hence raises questions around structuring product offers along less discriminative lines. Apart from the introduction of the MLS followed closely by the 30% rebate there has been little global impact on membership since 2000 where membership has drifted in the 40-50% of population band. Where the gradual decline from 47.3% in September 2015 to 43.8% in September 2020 as a percentage of population has been utilised by the PHA to drive regulatory engagement. In real terms membership has remained flat and therefore policy revenue has suffered. The premium revenue growth has declined below trend even with the number of policies growing slightly. The revenue drop being due to a marked shift to Exclusionary and Excess policies as funds attempt to lower the price point while keeping members engaged. The drop off in the younger cohort is real but has been presenting since 2015, the PHI response being to lower policy costs through risk transfer, which again lowers the value proposition when members do present to the health system. The general decline in membership over the last five years being driven primarily by a decline in the growth of average incomes which flow through to household expenditure on health (Figure 2.8).

A historic review of the regulatory levers around membership is reflected in the graphs below.

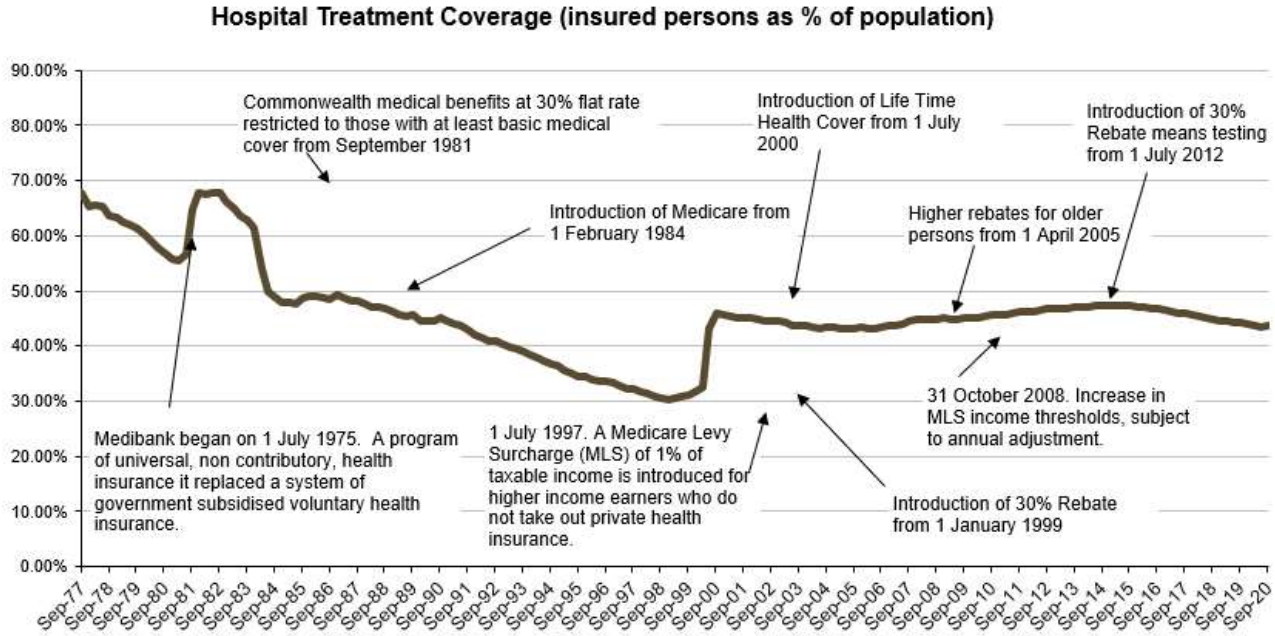
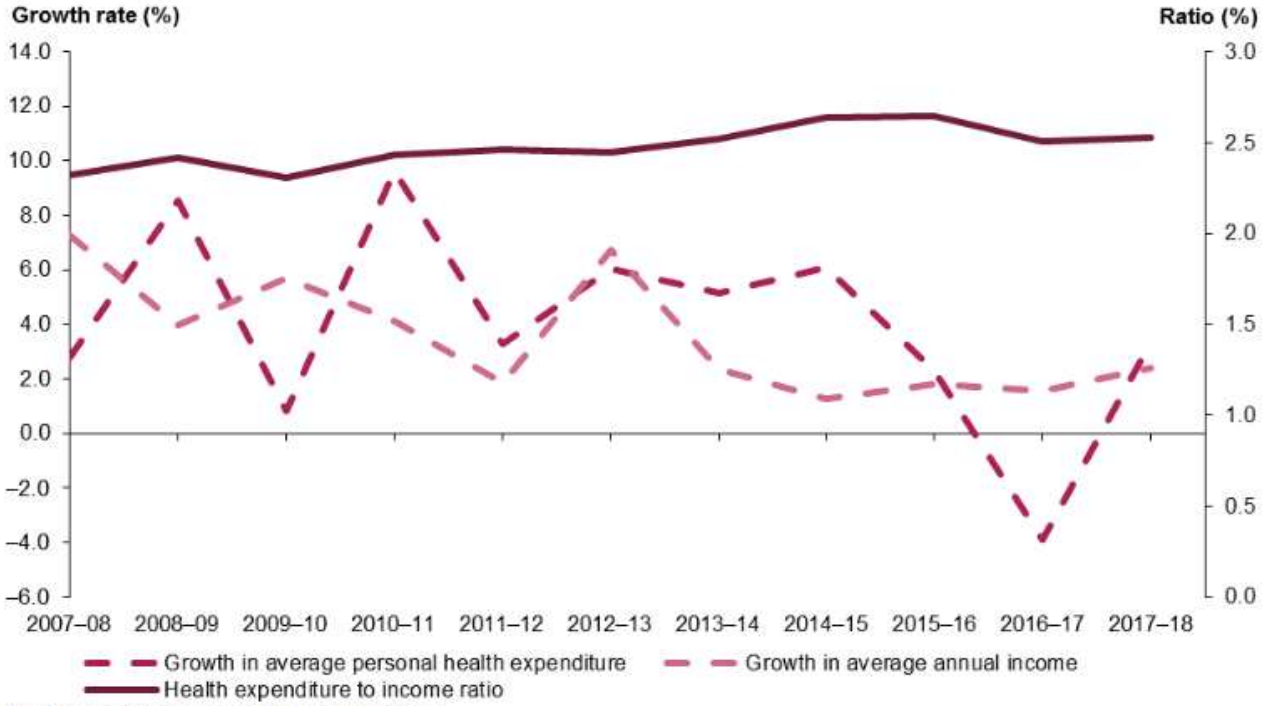


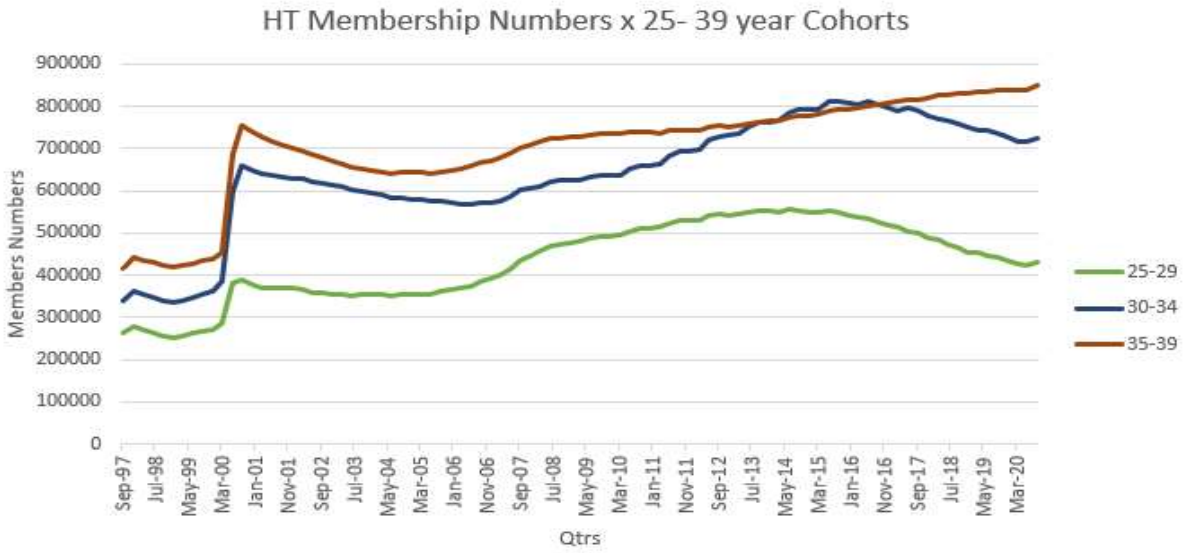
Figure 2.8: Growth in average income[(a)], average personal health expenses per person[(b)] and health expenditure to income ratio, current prices, 2007–08 to 2017–18



(a) Refers to annualised average weekly earnings.

(b) Based on ABS estimated resident population (see Table 5.1).

Sources: AIHW health expenditure database; Australian Bureau of Statistics (2018a, 2019a) (see Table 2.10).



Source: APRA Report – PHI Membership Trends Sept 2020

Part One: Increase dependants age from 24 to 31 years

Suggest this is again the PHI knee jerk reaction to dropping enrolments in the younger cohorts and assumes they are more price sensitive than the rest of the consumer population. As graph two indicates the rate of

participation drop off is similar in the 25-29 and 30-34 cohorts where the LHC incentive should be acting. Based on graph one, from LHC inception the impact on membership appears minimal. Hence, as an instrument, it is a stick which is discriminatory based on ability to engage based on financial means which has ongoing penalties. Hence by moving cohorts closer to the trigger point will have minimal impact on arresting the decline. Whether increasing the MLC will make it a bigger stick and therefore more effective is unlikely as people will seek to establish a minimum position to cover off their tax liability rather than cover their real health risk.
A subjective assessment of potential underlying reasons for drop off is that 25-34 perceive no difference from a private vs public health service, which makes efforts by the PHA to drive to the same price points and product offer, only accelerating members to this decision point.
By extending family inclusion to 31 will it improve retention or just delay the decision to leave. It assumes at 31 those that dropped out will have a renewed value of the product. Maybe, if circumstances change but unlikely. In any event where is the evidence? Importantly does this mean an increase in policy premiums overall to account for the maintenance of risk without a matched policy increase to cover the risk? Or will it just be families that will pay through out of pocket increases?

Recommendation – DoH undertake or commission a transparent market analysis before making the proposed changes to the Age categories. Especially understanding the embedded effect of the product simplification approach to policy offers across the age segments, has it change the perceived value needle?

Alternative Approaches
Pragmatically, why restrict PHI to product segment the risk by clinical coverage, age and socialising patterns. Assuming segmenting by clinical need, gold/silver/bronze has not significantly changed purchasing patterns (since completed April 2020 is too early to positively confirm impact) is further segmentation by age likely to arrest the current trend.
Similarly, Biotronik would recommend consideration to segment by **Health Technology** access, as this will inform and highlight differences. Also engage the consumer more in the healthcare story and in its private benefits –
Some suggested segmentation for Cardiac Technologies is demonstrated below:
Full cardiac coverage – CRM, TAVI, CVI-DES/BMS/DCB, Ablation;
Part cardiac coverage – CRM minus service, TAVI – only one device type, DES – not available but DCB as substitute, Ablation – only SVT not AF etc….
No Cardiac coverage –

Note: The drop off in the 0-4 age group, which is outside scope, which is in all likelihood driven by dropping population growth should be a consideration of PHI business strategic in the medium term.

Part Two: Remove age dependant age limits for disabled
Age based coverage of disabilities is the tip of a larger iceberg. PHI's philosophy of engaging with patients earlier in their journey to manage the risk and health options is driving the Home care and Hospital Admissions restrictions and as such should they not take the holistic view with disabilities and its alignment with publicly funded NDIS. There is overlap with **Health Technology** in this space and as such coverage provided by either two risk policies need to be clear to industry and consumers to encourage investment in this space.

Recommendation – Agree with the removal of age limits for disabled but request an industry wide investigation of the interface between traditional health/medical provisions and the wider environment being facilitated by the NDIS. Alignment of **Health technology** resources in delivering improved Disability Life Years to those disabled or inflicted with chronic disease has opportunities not yet fully explored. Capabilities around robotics, remote monitoring and AI are a few industry segments which offer opportunities.

RESPONSE TO QUESTIONS FOR ALL STAKEHOLDERS: DEPENDENTS

1. Should the maximum age for child dependents be 31 or when LHC typically applies (i.e. 1 July following an individual's 31st birthday)?

Suggest the criteria be a measure around financial dependence as even with intent to cover, if income limits capabilities to afford cover then extension should be given to stay in the protects of a family or legally recognised socialising unit. Hence qualification as a dependent, like the 30% rebate it should be income means tested. What is a qualifying income should be investigated based on the trend in drop out rates on membership datasets?

2. Should eligibility of a dependent continue to be limited to people without a partner?

No- refer above

3. Should the age ranges of different categories of child dependents be standardised for all private health insurers?

Yes- child dependent should be redundant – see Q1.

4. Should the conditions of dependence for the different categories of child dependents be standardised for all private health insurers?

Yes – refer above

5. Should the definition of 'dependent child' be simplified?

Removed and based on income

6. What purpose does the distinction between non student and student dependents serve and should this be retained?

Removed and based on income

7**. Should the current 10 insured groups be rationalised by removing groups not being used by insurers?**

Remove

8. What is the preferred criteria and mechanism for determining eligibility of people with a disability?

Align with the NDIS definition.

9. Should there be standardised arrangements for determining eligibility of people with a disability, or is it preferable to allow each insurer to determine its eligibility criteria?

Standard arrangement as recognised by NDIS

10. Should eligibility of a dependent with a disability be limited to people without a partner?

No

11. What are appropriate metrics for measuring the impact of this proposal?
Aim is improved sustainability of PHI through perceived and delivered value driving membership retention on the demand side plus a shift in the price through improved efficiencies. At a macro level it is membership retention and premium changes.

12. What is the regulatory burden associated with this proposal?
If dependent definition simplified based on income, then regulation around age can be stripped back.

Consultation Two- Expand Home and Community Based Rehabilitation

Problem Definition
Process for identifying the most appropriate rehabilitation arrangements.
If the PHMAC indicated regulation as not being a barrier it is perplexing why this is identified as a significant barrier for review. It could be considered as a potential conflict of interest for the PHI as it pushes into the provider space unless regulatory barriers are established around market structures.
Development of a rehabilitation plan
Consider that no MBS changes are identified to accompany the need for rehabilitation plans plus clinical guidelines are not yet developed would suggest that there is not full clinical alignment around the proposed planning step. Under normal circumstances, any change or review of MBS items would be subject to a peer review at least and a full MSAC submission at best. We would recommend such a route before any changes be implemented. The process adopted in developing the case plans in place under the current MBS structures should be adopted for consistency, even where resourcing may be primarily allied services based.
It is recommended evidence development around Home and Community Based Rehabilitation needs to be undertaken or reviewed at least across the core conditions requiring rehabilitation prior to adoption and a value based approached to regulation be considered. A key issue is the attempt to glue the various inputs of care into an integrated model of care where all players are incentivised in achieving a patient centred quality of life outcome that, if quantifiable, is a driver of consumer engagement.

Health technology has a great deal to offer in developing these integrated care pathways, providing diagnostics, therapeutic and information integrating networks that can bring diverse clinical resources and care locations together on the one page/or patient in a quality and cost-effective manner.
Piece meal regulation around parts of the care pathway, while supportive, does not present a strategic approach to private health delivery across the full patient care pathway. Cost is driving engagement with alternative care environments other than acute/hospital care in attempt to mitigate the affordability of the existing PHI offer.

Recommendation- A whole of industry review seeking key stakeholder engagement to map a market that engages all the resources of private care in managing a consumer's whole of life needs incorporating flexible and selectable care pathways. A key component is the sources of value and methods of reward to encourage ongoing investment, growth and innovation in developing private market infrastructure.
Health technology offers opportunities in linking care pathways – procedural – after care – rehabilitation-ongoing chronic disease management and provide productivity efficiency solutions. As an example

Biotronik offers a technology platform which links patients with implant devices to an integrated care team via mobile networks which is independent of care environments.

"The payment of PHI benefits would be dependent upon an appropriate plan"- once valued and clinically acceptable guidelines which detail the planning are developed, we again run into potential conflict over PHI assessment of the plan as appropriate. If the rules are not clear and clinical discretion incorporated based on patient needs, then there is no 'one plan fits all 'approach around alternate site care adoption, hence the check and balance needs to be elsewhere other than the insurer.

QUESTIONS FOR ALL STAKEHOLDERS: REHABILITATION SERVICES

1. Which procedures and/or MBS item numbers should have a rehabilitation plan?

Rehabilitation requirements should be determined by the presenting patient needs. Age and psychosocial circumstances are also significant contributors. To the extent that MBS or ARDRG would be secondary indicators of need. Hence the flow diagram identifying firstly the need for rehabilitation and secondary the optimum location for that rehabilitation should be first steps in any planning process.

We note that Cardiac Rehabilitation and Cardiac Heart Failures programs have been clearly shown to deliver real patient benefits and cost saving through reduced 30day readmissions, yet the adoption rate are low in both a public and private settings. These programs are offered both within and outside hospital settings and it is unclear whether clear access to funding is a driver around utilisation in private markets.

2. How prescriptive should the plan be, regarding the type of care services to be included? What exemptions if any should be available? In moving away from a Fee-For-Service environment that is prescriptive based it is recommended that plans work towards quantifiable outcome measures rather than prescriptive steps.

3. What mechanisms should be in place to ensure compliance with developing and reviewing a rehabilitation plan?

Rehabilitation is covered by existing rules in the private hospital delivery environment, hence any mechanism developed need to smoothly interface with all potential care environments. Partly or wholly digital solutions should be a consideration and engagement with **Health Technology** companies in supporting those needs means they should be a key stakeholder as the DoH develop the framework for these mechanisms.

Where rehabilitation goals or outcome is a return to a physical and mental status which supports the return to independence or dependence living at home or elsewhere but the disease is chronic in nature requiring on going engagement and management by the key specialist – Cardiac, Respiratory or Nephrology etc then the specialist should be the clinical lead in co-ordinating the car team from rehabilitation through to Chronic Disease Management. Again, **health technology** companies supporting ongoing therapies, monitoring or diagnosis at inflection points should be included as a consulting member of the care team

4. It is expected that the plan would be developed in consultation with the patient and potential rehabilitation providers. Which parties should the rehabilitation plan be made available to once created?

Like NDIS disability plans, the rehabilitation plan should be owned by the patient and the clinical care team depending on the pathway developed and other resource stakeholders. PHI, **Health technology**, allied health providers should be engaged and have visibility to the rehabilitation goals and their role and outcome metrics deliverable in the plan.

5. What arrangements, if any, should be in place to assist medical practitioners identify appropriate home or community-based rehabilitation services and oblige insurers to fund these services?
A registry of accredited resource suppliers managed through the DoH would assist the growth of the market and allow for a strong referrer network to evolve. Further the evidential basis of rehabilitation plans should have a costed program where it is clear of each payer's liability in delivering the plan.
Understanding the need for sustainability in the PHI product offer, then the funds potential liability should potentially be framed around the expected savings in other areas of liability of the PHI offer e.g. Acute Re-admission.

6. What transition arrangements and timeframe would be appropriate to implement this reform?
Three years after a comprehensive review to align all planning processes in the patient journey . Consider the need for agile engagement of resources as the industry innovates and develops through the expanded funding capabilities.

7. What are appropriate metrics for measuring the impact of this proposal?
Similar to CDMP reporting requirements of PHI , Rehab Plans should be a reporting requirement indicating policy uptake, members covered, resources engaged and evolving effectiveness- readmission rates, morbidity and mortality measures vs benchmark. Current reporting on CDMP is uninformative, indicating most PHI members has coverage and the utilisation data being aggregated by age brackets with medical costs identified.
Health technology platforms should be required to report via establish patient registry structures e.g. proposed Cardiac Patient Registry

8. What is the regulatory burden associated with this proposal?
In current form significant as minimum standard around key components would need to be established. Each Rehabilitation plan would require multi-stakeholder input to develop and resource of PHI stakeholders in accessing the appropriateness of each plan.

9. Service providers: what services would you deliver under this proposal?
Cardiac technical services, cardiac digital platforms.

Consultation Three- Out of Hospital Mental Health

Problem Definition
The evidence around preventative mental health interventions effectiveness in order to prevent hospitalisation should be presented to a peer review committee before the expectation of PHI coverage. If equity of access is an issue and such services are provided via a public funding model, then that evidence should be presented as a benchmark in performance. The net value of improved access through funding in reducing the overall long-term cost and quality of life of mental health pathways.
We not however the Productivity Commission guidance to develop a sustainable national digital platform to facilitate the assessment and referral process to ensure access to mental health care matched to an

individual's level of need should be a first step. Hence investment in triaging resources may deliver greater healthcare efficacy across both public and private engagement solutions.
Rules around access should be incorporated into the PHI product simplification matrix in understanding and linking pathways and service access for disease states. This will inform the market and allow some investment around structures to establish.
Concern is that preventative health programs have returns across the full breadth of presenting clinical conditions and could it be considered a cost for the PHI to absorb in lowering the risk profile of potentially presenting populations. Hence decisions to fund should be driven by expected returns to the PHI's and that they do not form part of the risk equalisation arrangements. The benefits of prevention should rest with the individual insurers who make the investment.

Part One- Preventative mental health
Strong clinical evidence should inform investment in preventative health programs. The opportunity to engage traditional health resources in going up the care pathway is important. **Health technologies** are actively moving in this space with wearable technologies, AI engines (particularly around voice recognition for mental health assessment) and a range of App based solutions. Some formal clinical and scientific drive to investment around these technologies would benefit the whole industry.

Part Two- CDMPs wider range
Before widening the remit of CDMP it would be informative as to the value generation of current programs. 8,063 programs with an expenditure of $9.4 mill or approx. $1000 per program. Are the current rules restrictive around allied health professional engagement or alternative low-cost interventions? Over 80% of CDMP are classified Risk factor management or Other so the scope is not access able through public datasets. The historic datasets for CDMP shows over 68,000 programs in 2018 but a value of around $200 per program, hence considerable activity. If the case it needs to be addressed across the whole of CDMP regulation.

Part Three- CDMP include service delivery of low-cost interventions
Agreed although incentivising PHI engagement should be through risk mitigation, creating member stickiness, rather than through risk equalisation. Engagement with digital tools provide by **health technology** would be the single biggest opportunity in this space followed by AI engines which could develop of the back of this engagement.

QUESTIONS FOR ALL STAKEHOLDERS: MENTAL HEALTH SERVICES

1. **What additional mental health services funded by insurers under this proposal would be of value to consumers?**
   Health technologies such as behaviour-based apps designed around gamification of behaviour modifiers plus other agile developments around **health technology** wearables and home monitoring platform and tools.

2. Should an expanded list of allied health services available for direct PHI benefits as part of a CDMP be limited to only mental health conditions?
No, however in ensuring a co-ordinated approach the allied services should have clinical evidence in support and be peer reviewed as a suitable service for funding as a minimum.

3. To be eligible for direct CDMP related funding from insurers, should professions have additional requirements, such as accreditation standards, professional memberships or educational levels?
Yes, Refer above

4. How should the definition of coordination and planning be expanded to best support the funding of out of hospital, non-MBS related mental health services?
N/A

5. Are there any mental health services insurers should not be permitted to fund?
N/A

6. How should the relevant patient cohort be identified as eligible for services?
N/A

7. Who should identify relevant patient cohorts and should insurers set criteria for which members would be eligible?
Consumer engagement should an open market where visibility of services and solutions should be promoted by all peer reviewed or accredited stakeholders. Multiple touch points would be required to get appropriate engagement. Filtering the inappropriate consumers would require investment from PHI as the key beneficiary.

8. What are appropriate metrics for measuring the impact of this proposal?

9. What is the regulatory burden associated with this proposal?

10. Service providers: what services would you deliver under this proposal?
Patients with comorbid cardiac condition – home monitoring of cardiac condition as an indicator of changing physiological lead indicators.

Consultation Four- Admissions Certification Rigour

Problem Definition
Appropriate Length of Stay (LOS) for private hospital procedures should be based on clinical need as accessed by the treating doctor. But as all these proposed reforms are linked so is this reform. Firstly, categorising at the point of Admissions by Type and MBS item when the response to treatment or therapy is yet to be determined seems counter intuitive. Especially where you are seeking to add value to the perceived PHI product offer. The intent may be Type C -same day but there needs to be flexibility should a patient respond outside normal boundaries. Hence classification at discharge would be more appropriate and incentivising and gaming around this process would be reduced but not removed. Gaming to support capacity capabilities needs to be regulated outside an admission grouping scheme and efficiency incentivises engaged around optimising LOS. Informed financial consent around type of admission is an issue but there appears to be no PHI product delimitation along LOS criteria.
Rather than increasing the Rigour of the process, implying unregulated activity is creating inefficiencies, a consideration at a redesign or removal of regulation to incentivise all stakeholders in achieving best outcomes would be a preferred approach. Length of stay is reasonably well captured and managed with

Type A and B procedures across a rough DRG range and there are processes and opportunities in managing this patient cohort. Under a public system there are sticks and carrots driving Activity Based Funding approaches of which we are yet to see efficacy gains at DRG level around LOS. Even still can there be regulation within the private market which drives efficacy while protecting QALY outcomes. If the regulation around admission codes was removed and funds/hospitals required to incorporate procedure mixes into the HPPA's would the market, then self-regulate and develop solutions that delivered efficiencies for all stakeholders?
Health technologies can also work towards efficiency gains around LOS with certain digital solutions allowing early discharge where the risk is mitigated through remote/home monitoring solutions. Where such efficiencies are evident then incentives should be available to engage health technologists to this end.

Part One- Industry Panel
Self-regulation is always a preferred approach where potential conflicts occur. Transparency may also prevent the need for regulation as visibly may deter aberrant behaviours.

Part Two- Type C Procedure Clinical Guidelines
Concern that clinical guidelines may cement LOS outcomes per procedure code and reduce the systems flexibility in seeking efficiency gains. Hence based on historic evidence accumulated by PHI there is an opportunity to set industry wide performance standards which should benchmark negotiations for HPPA's in setting cost structures and incentives around LOS.

Part Three- Utilise PSR for Breaches & Disputes
Consider beyond scope of the PSR. Resources best deployed in gaining efficiencies in the MBS and PBS public funded markets.

QUESTIONS FOR ALL STAKEHOLDERS: CERTIFICATION FOR HOSPITAL ADMISSION

1. Should an industry mediation panel be established to resolve hospital certification disputes?
No, benchmarked LOS performance should be published through DoH in incentivising and negotiating current HPPA contracts.

2. If an industry mediation panel is established, what process should be undertaken to establish it, including determining membership?
N/A

3. What parties should be involved in the development of advice on the appropriate criteria for certification?
Benchmarking LOS's by AR-DRG plus outlier reports.

4. Should PSR, or another regulatory body, provide a regulated and enforceable process for reviewing Type C certification?
No

5. Should there be a specified list of 'special circumstances' allowable for Type C certificates?

No. LOS always at clinical discretion based on patient needs

6. Should hospitals be potentially liable for Type C certificate statements, and if so, in what circumstances?
No

7. What is the likely impact upon premiums of this proposal?
N/A – Analysis should have been presented within the consultation.

8. What is the likely impact on the number of people and/or policies covered of this proposal?
N/A

9. What are appropriate metrics for measuring the impact of this proposal?
LOS by procedure against industry benchmark performance

10. What is the regulatory burden associated with this proposal?
High if all components as proposed adopted. More regulation, not less.

11. Are there any other reform options that should be considered?
Refer previous Problem Definition input. Suggested to regulate around LOS in achieving visible efficiency gains.

Michael Reynolds
Director Healthcare Economics & Advocacy

BIOTRONIK Australia Pty. Ltd.
Level 4 Building 2
20 Bridge St., Pymble
Sydney NSW 2073 Australia
M: +61 (428) 763 288
P: +61 (2) 9497 3713
E michael.reynolds@biotronik.com