1. How is your organisation, you or your sector involved in the current cross-subsidisation model of TSS through the Prescribed List?
To what extent does this model impact your organisation (positively and/or negatively)?

- Professionals in Cardiac Sciences Australia (PiCSA) plays a crucial role as a key stakeholder in the cardiac healthcare sector, **representing the entire cardiac physiology workforce**, which is essential to cardiac procedures, including cardiac implantable electronic device (CIED) support services. This workforce includes professionals working in public, private, and industry settings, with individual cardiac physiologists often transitioning between these environments.
- By advocating for the **workers** rather than the employers or manufacturers, PiCSA serves as a unique and essential voice. It is vital that decisions concerning workforce planning and funding models consider the input and perspective of PiCSA.
- Cardiac physiologists who specialise in CIEDs (CIED physiologists) comprise a relatively **new and developing profession**. In Australia there is currently a limited understanding about who we are and the vital services we provide. The current cross-subsidisation model of technical support services through the Prescribed List has created a paradigm that misunderstands and blurs the lines between the roles of IEAPs vs non-industry CIED physiologists.
- Compared to New Zealand and the UK, Australia lags in workforce development and regulation for the CIED technical support workforce, and the previous funding model and general lack of oversight has **impaired** the progress of the profession:

    - the practice of cross-subsidising the costs of CIED technical support services through the Prostheses List (PL) benefits, which are designed to cover the cost of the devices themselves, is problematic and lacks transparency.
    - It has directly impacted the CIED physiologist workforce, by creating a financial bias that **has disincentivised cardiology centres from employing their own staff**.
    - Lack of employment opportunities outside of industry has diminished the role of the CIED physiologist, especially in the private sector. A workforce model without IEAP workforce substitution would encourage clinics and hospitals to employ their own staff and enjoy full interdisciplinary collaboration without the limitations imposed by the reductive “company rep” scope of practice.
    - Some non-industry CIED physiologists report being overlooked in discussions when an IEAP is present, leading to de-skilling and a decline in the reputation of local staff.
    - Guidelines (from the Heart Rhythm Society HRS, and British Heart Rhythm Society BHRS) describe predominantly CIED physiologist run technical support services, with competent non-industry employed physiologists operating independently for routine tasks, working with multiple brands of devices, under comprehensive clinical guidelines and collaborating as needed. They do not require continual oversight, and shoulder much of the workload burden of patient interaction and clinical decision-making. **Centres that substitute IEAP for independent CIED physiologists do not enjoy equivalent support.**
    - The cross-subsidisation funding model does not align with international guidelines.

        - Lindsay et al. stated in 2008 that it is not appropriate for company representatives to substitute for directly employed cardiac device specialists [Article Link: https://www.hrsonline.org/guidance/clinical-resources/2008-heart-rhythm-society-policy-statement-update-recommendations-role-industry-employed-allied].
        - More recently, a 2023 international position statement states that “although manufacturer representatives can play an important role in training clinic staff, it is

not their role to perform, collect, or triage data on behalf of the clinic staff or be used as a staffing resource in lieu of local qualified personnel." [See sections 11 and 12 of the HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic, Article link: https://www.heartrhythmjournal.com/article/S1547-5271(23)02011-8/fulltext].

  - Industry-employed cardiac physiologists adhere to regulations that limit their independent involvement in direct patient care to prevent conflicts of interest. They are supposed to only support their own brand of device, are not allowed to access patient hospital records, and are restricted from clinical decision making (e.g., they do not provide prescriptive perioperative or periprocedural advice). **Their primary role is to support and educate hospital staff about their products rather than replace the clinical staff.**

- Funding reforms present an opportunity for **unlocking the untapped potential of CIED physiologists** in Australia, redistributing the existing workforce and opening positions for employment, which support the full clinical scope of practice across both private and public settings. Cardiologists and patients would receive more comprehensive support, and IEAP would also be less pressured to provide services that are outside of their appropriate role.
- PiCSA believes that **improving the funding model** and **establishing a strong regulatory structure** are both necessary to align CIED support services with international standards and develop the potential of the cardiac physiology profession.
  - Proper regulation is necessary to ensure competence and accountability, in line with WHO recommendations for allied health professions.
  - We emphasise the risks of proceeding with funding changes without simultaneously supporting an adequate governance structure. Poorly managed funding and workforce planning risks incompetent care by untrained personnel.
    It would also undermine cardiac services by hindering the development of a legitimate CIED physiology workforce as a competent, recognised and regulated allied health profession.
- **CIED service requirements include (but are not limited to):**
  - CIED implantation (basic and complex)
  - Outpatient CIED clinics
  - Outreach CIED clinics
  - Inpatient CIED evaluation and optimisation
  - Weekend and out of hours CIED evaluation and optimisation
  - MRI (Magnetic Resonance Imaging) and radiation device support including risk assessment and customised CIED programming
  - Perioperative support, including giving prescriptive advice to anaesthesiologists and performing customised CIED programming
  - Palliative Care and Voluntary Assisted Dying support including education and CIED programming
  - Remote monitoring and associated tasks (many of which are unfunded and "invisible" to the current discussion, and many of which cannot be performed by IEAPs)
  - Responding to phone enquiries from patients, family members and health professionals, including unscheduled review of remote monitoring data
  - Patient education: including why the CIED was needed and how it works, giving advice about wound management and recovery, driving restrictions, travel, electromagnetic safety, first aid, trauma etc.
  - Therapeutic Goods Australia (TGA) advisory and recall management
  - Supporting the CIED related education needs of other health professionals
  - Complex troubleshooting

- Documentation and reporting of patient interactions
- Data and records management

CIED physiologists work in various sectors including:

- **In public sector**- i.e. employed by public hospitals – these staff are generally trained to follow up and implant all vendors CIEDs including remote monitoring platforms. Cardiac physiologists that work with CIEDs are also trained to perform other cardiac physiology roles, including non-invasive and invasive investigations/procedures to supplement workforce.
- **In private sector-** i.e. employed by private hospitals or Cardiologists/Cardiology groups- these staff perform the same role as in the public sector, being trained to follow up and implant multiple brands of CIEDs including remote monitoring platforms. They may also assist with other non-invasive and invasive cardiac investigations/procedures.
- **Industry-** i.e. employed by CIED vendor and known as Industry Employed Allied Professionals (IEAPs)- these staff although may have had prior training on other vendors CIEDs ***only*** implant and follow up their own vendors devices. They do not assist with non-invasive and invasive investigations/procedures that are not related to CIEDs.

The overall impact of the current cross-subsidisation model of technical support services through the Prescribed List upon the workforce has been negative. It has only benefited the employers (e.g., profit for vendors and cardiac centres who received payments without having to paying for workforce labour). Vendor-reported "patient benefits" attributed to this model would have been more appropriately delivered by non-industry CIED physiologists.

Public sector:

- There is an established highly qualified CIED physiologist workforce that currently exists within various public hospitals. This workforce has niche skills to be able to manage CIEDs across multiple vendors and has an expansive scope of practice, shouldering much of the workload burden of patient interaction and clinical decision-making.
- Lack of recognition of this workforce has led to inadequate succession planning and career pathways for staff working in this field Australia wide.
- Significant reliance on industry support has been created due to this lack of workforce development and IEAP have been used as labour substitution (e.g., providing on-call services or implant support instead of a local public sector CIED physiologist).
- The CIED market is witnessing a high degree of innovation, with companies introducing devices with remote monitoring capabilities to enhance patient care and management. This service needs to be appropriately developed and supported within public hospitals. The scale of predicted growth in demand for device procedural activity must be taken into consideration when considering the future. Once a CIED is implanted it requires lifelong management (unlike most other prostheses).
- Proper support of the public hospital CIED physiologist workforce is required to avoid compromising patient care with the reduction in industry support.
- Across various public health sites without any formal consultation there has already been a significant reduction in technical service provision since 2021. This is despite PL benefit already being paid for devices prior to this date. This work is now being absorbed by CIED physiologists working in public and is not sustainable without adequate staffing levels.

Private sector

- Many private hospitals and Cardiologists/Cardiology groups have used IEAP as a labour substitution instead of employing their own CIED physiologists. Thus, for these private hospitals and Cardiologists/Cardiology groups who have utilised this model there is likely to be significant gap in service provision initially as there has not been adequate succession planning and career pathways for CIED physiologist working in private sector Australia wide.
- For private hospitals and Cardiologists/Cardiology groups who employ their own CIED physiologists there will be very minimal impact. The main immediate risk would be competition for retaining staff given limited number of trained CIED physiologists in private sector currently.
- Innovative technologies such as devices with remote monitoring capabilities to enhance patient care and management will be able to assist in following CIED patients in private sector, however, these technologies still required trained CIED staffing resources. Remote monitoring may increase rather than decrease the overall labour burden.

Industry

- IEAP have been used as labour substitution for independent CIED physiologists in both public and private sectors.
- IEAP with appropriate training and qualifications have provided valuable technical support services Australia wide – both inside and outside of their appropriate scope of practice.
- There will still need to be for IEAPs for programmer maintenance, consignment stock management, product specific education and training, and additionally industry specific technical advice including complex troubleshooting support.
- IEAP have been utilised to support follow up of CIED patients and some cardiologists/cardiology groups have used their services to access Medicare payments.

2. What are the alternative options for funding the reasonable value of TSS?

PiCSA's vision is (1) a competent, safe, and regulated Cardiac Physiology workforce meeting current and future health needs of the Australian community, and (2) ethically appropriate use of government and private healthcare funds.

It is imperative that the Australian CIED funding model is transparent and enables patients to receive an appropriate unbiased international standard of care.

This means:

- Supporting the appropriate roles of industry and non-industry professionals
    - the system should provide financial incentives for cardiac centres to utilise non-industry staff.
- Supporting accreditation and registration of the cardiac physiology profession (e.g., making reimbursement conditional on registration of accreditation as is the case for echocardiography)
- Withholding (or reducing) rebates from services that misuse IEAPs as a staffing resource in lieu of local qualified personnel.
- Ensuring that payments are made only for necessary services, avoiding advance payments for years of services that may not be required.
- It is essential that compensation goes to those who actually perform the work, preventing double payments—first to those who did not provide the service, and then again to another party for the service that was actually delivered.
- Completely uncoupling the prosthesis price from associated labour (including implant labour).
    - Most CIED implants can be supported by local staff without assistance from IEAPs.
    - If IEAPs are present it should be to support local staff rather than to replace them. We want to ensure that public and privately employed non-industry CIED physiologists are not locked out of the implant support role.
    - We suggest a completely different PL price code be utilised when IEAP presence is necessary, rather than adding industry labour to the cost of all implants (whether IEAPs are present or not).
- Gains or savings achieved through procurement activities and reduced prosthesis costs should be redirected towards funding the necessary staffing and services at the State, Hospital, or Department level.

We do not necessarily need to invent a brand-new funding model from scratch. Australia represents < 5% of the international CIED market, and we can look to other countries for existing roles, pricing structure and reimbursement strategies. We can also adapt the existing funding model to better deliver its intended purpose.

With the above vision in mind, here are some further considerations:

Activity Based Funding (ABF):

The Independent Hospital Pricing Authority (IHPA) could establish a fair price to cover CIED follow-up costs for both inpatient and outpatient services. This could be achieved through:

- **Tier 2 Specific Codes:** Implementing codes for CIED follow-up, including remote monitoring, using the National Weighted Activity Unit (NWAU) rather than state-specific units like Queensland Weighted Activity Units (QWAU).
- **ICD-10 Codes:** Utilising specific ICD-10 codes for CIED services to shape Diagnosis-Related Groups (DRGs) and determine reimbursement.
- **New codes** (see below)

Own Source Revenue (OSR)/Medicare item code rebates:

- **Current CIED Medicare item codes:** These MBS item codes require review and clarification to ensure their continued applicability for medical officers working under Granted Private Practice Agreements in public systems.
- **New codes**: Develop new item codes with variable reimbursement rates depending on the labour model. For instance, establish different codes for activities where an IEAP was used instead of a non-industry CIED physiologist. Eligibility for these codes could be defined based on factors such as clinic size, geographic location (e.g., small regional clinic vs. large private hospital), and/or whether the centre is actively trying to establish alternative support. These codes and conditions could be periodically reviewed as the workforce model evolves.

Direct contractual payment agreements between providers and vendors/private companies for CIED services:

With appropriate oversight to ensure (1) restriction to circumstances when a non-industry CIED physiologist is unavailable, (2) the cost structure does not perpetuate an ongoing reliance on industry, and (3) the CIED physiologist is listed on an Australian register of accreditation.

- **Public health care providers:** Can engage to outsource technical support services directly with vendors (IEAP) or 3rd party private companies. Funding would be sourced through ABF and OSR, with payments then made directly to the vendors or 3rd party private companies.
- **Private health care providers**: Can similarly outsource technical support services to vendors (IEAPs) or 3rd party private companies. Funding would come from Medicare item codes and patient payments, with direct payments made to the vendors or companies.

3. Are there specific stakeholders/group(s) that have the responsibility to develop and own an alternative model of care? Who are they and why do you/your group hold this view?

The responsibility for change lies with the stakeholders currently using IEAPs as substitute labour for implants and ongoing CIED follow-up and support, despite their restricted scope of practice as manufacturer representatives. This practice blurs the lines between technical, clinical, and sales roles. PiCSA strongly believes that discussions about "models of care" must address the non-equivalency between an industry-employed and non-industry-employed workforce. This is not just a funding issue—it's about ensuring the workforce can operate with less restrictions and without conflicts of interest, under a proper governance structure.

A non-industry-employed workforce would be better positioned to provide comprehensive patient care. These professionals can manage multiple device brands and follow clinical guidelines independently, without continual oversight. In contrast, IEAPs are limited by regulations that prevent them from fully engaging in patient care, including accessing patient records and clinical decision-making. While they are usually skilled and ethical, their primary role is to support their employer's products rather than replace clinical staff.

PiCSA emphasises that many IEAPs could fill the broader, non-industry role, but they are prevented from doing so due to limited employment opportunities and lower remuneration outside the industry. Healthy competition between industry and non-industry employment is essential to creating a balanced workforce and ensuring better patient care. The salary also needs to be non-inferior to other advanced cardiac physiology modalities of specialisation (see PiCSA's 2024 publication "Australian Guidelines for Entry and Practice in Cardiac Physiology" which can be found at https://picsa.org.au/about/#core-documents).

Private and Public sector providers who rely on IEAP labour substitution:

- Hospitals and cardiology groups that have used IEAPs as a substitute for employing their own CIED physiologists need to reassess their model of care.
- Without proper investment in a non-industry CIED workforce, patient care will suffer as industry support diminishes. There is an opportunity to improve the care model by moving away from IEAP labour substitution and unlocking less restricted roles.
- There is already a highly qualified workforce across public, private, and industry settings. Redistributing this workforce will enable more comprehensive scopes of practice and would facilitate a more ethical use of funding.
- National recognition and support for the CIED workforce, with oversight to reduce pay and governance disparities, is crucial. Current differences between states and territories have hindered training, succession planning and career pathways for staff.
- The CIED market is rapidly evolving, with innovations like remote monitoring enhancing patient care. However, both public and private services must develop and expand their capabilities to meet the growing demand. Unlike most prostheses, CIEDs require lifelong management, meaning the increasing demand for these services must be carefully planned and addressed.
- Investment in certifying and accrediting the entire CIED workforce is essential to sustain and safely deliver future services.

4. What do your organisation, you or your sector see as the likely options for a new model of care? What the key features of these options? Is there a clear preference? Please provide ideas for alternative, evidence-based models of care for all patients with CIEDs (both private and public health systems).

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It is imperative that the Australian CIED funding model is transparent and enables patients to receive an appropriate unbiased international standard of care.

This vision applies to both the public and private sectors.

Guidelines (from the Heart Rhythm Society HRS, and British Heart Rhythm Society BHRS) describe predominantly CIED physiologist run technical support services, with competent non-industry employed physiologists operating independently for routine tasks, working with multiple brands of devices, under comprehensive clinical guidelines and collaborating as needed. They do not require continual oversight, and shoulder much of the workload burden of patient interaction and clinical decision-making. **Centres that substitute IEAP for independent CIED physiologists do not enjoy equivalent support.**

The service provided by IEAPs is subject to role restrictions, and the practice of labour substitution blurs the lines between technical, clinical, and sales roles (and does not align with international guidelines). PiCSA strongly believes that discussions about "models of care" must address the non-equivalency between an industry-employed and non-industry-employed workforce. This is not just a funding issue—it is about ensuring the workforce can operate with less restrictions and without conflicts of interest, under a proper governance structure.

Public CIED Model of Care **(MSAC Model 1)**

- The existing model of care within public systems is fit for purpose, supported by a highly qualified workforce of CIED physiologists capable of managing CIEDs across multiple vendors (unlike vendor-specific IEAPs).
- There is potential to expand this model through innovative technologies, offering both face-to-face and virtual care to cover metropolitan, rural, and remote areas. With the appropriate resources, CIED physiologists could leverage remote monitoring and telehealth services, providing services locally, regionally, and at outreach sites while training and developing the talent pool within the public sector.
- Insourcing would become viable, as assessments would show the competitiveness of this workforce. Additionally, CIED physiologists, trained in CIEDs, can assist with other non-invasive and invasive cardiac procedures, further enhancing the public sector's capabilities.
- This approach would be the clear preference for public systems, as CIED physiologists provide an independent, holistic approach to patient care. Unlike IEAPs or vendor-provided remote monitoring services, CIED physiologists in the public sector do not merely supply a report to a doctor; they review patient history (with access to patient records, which IEAPs cannot), assist in management plans, and provide correspondence to relevant stakeholders to ensure optimal patient outcomes.

Private Model for public health care (Services provided through private cardiologists who employ in-house cardiac technicians or with industry representatives, MSAC Models 2 & 3)

- While this is a common model, it involves fees for services and may not be the most suitable alternative to a public health service. Access to data and patient records in these settings can sometimes be problematic. Some private companies do offer remote monitoring platforms and services; however, these can be expensive to set up and maintain, and their long-term value to the public health system may require further consideration.
- Some public patients choose to have their CIED follow-up performed by private cardiologists, often supported by industry technicians. The relevance to the public sector is that when CIEDs require replacement due to battery depletion, this occurs within the public system. Although the private cardiologist is responsible for patient care, industry technicians have played a crucial role as liaisons, ensuring information flow and follow-through for these patients.

Private Model for private health care sector

Services provided through private hospitals/healthcare funds/cardiologists/cardiology groups who employ in-house CIED physiologists Model 2

- This would be preferred method as staff are independent to industry and these staff are generally trained to follow up and implant all vendors CIEDs including remote monitoring platforms. They may also assist with other non-invasive and invasive cardiac investigations/procedures.

Services provided through private hospitals/healthcare funds/cardiologists/cardiology groups who utilise IEAP.

- This would also be a viable option. The key to this model would be that there are no government payments made directly to industry for any service provided. This should be responsibility of provider and these contracts can be arranged independently of government funding models. It should also be noted that necessary tasks and clinical responsibilities relevant to CIED support but outside of the IEAP scope of practice would need to be assigned to other staff.

Note: *Errors or incorrect programming can result in serious adverse events, including death. A "supervising" cardiologist may be absent or unable to provide competent oversight of CIED programming. For all potential models of care, it is therefore imperative that CIED technical support is provided by individuals who are properly qualified and accredited to practice, with the relevant registry of accreditation being the Australian Council of Clinical Physiologists (ACCP). PiCSA recommends mandatory registration of the workforce.*

5. What is required to transition from the current funding of the reasonable value of TSS through the PL benefits for CIEDs to the proposed alternative model/s of care?

PiCSA's response to this question integrates key points from our 2024 publication "Australian Guidelines for Entry and Practice in Cardiac Physiology" (which can be found at https://picsa.org.au/about/#core-documents) including the need for workforce expansion, structured training, and national governance.

The key requirements are:

- **Increase in the CIED physiologist workforce:** There must be a substantial increase in the CIED physiologist workforce based on professional recommendations, such as the Heart Rhythm Society staffing calculator and workforce minimum number guidelines https://www.heartrhythmjournal.com/article/S1547-5271(23)02011-8/fulltext and https://www.hrsonline.org/guidance/CIED-RemoteMonitoringStaffCalculator However, adjustments need to be made for local services, considering that the American calculator is based on a 40-hour workweek and does not account for the implant role. For example, the Royal Hobart Hospital's staff requirement calculation adjusts to approximately 3.3 FTE per 1,000 patients.
- **National succession planning and workforce development:** Succession planning and a structured workforce development plan for CIED physiologists must be implemented on a national level. This will ensure a sustainable and skilled workforce ready to meet the demands of the public healthcare system.
- **Recognition of CIED physiologists:** There needs to be formal recognition of CIED physiologists through more consistent professional title and award conditions. This includes consistent classification as professional (rather than technical) staff, with appropriate remuneration and CPD support.
- **Governance structure and mandatory registration:** The governance structure for CIED physiologists must be strengthened by transitioning from voluntary self-regulation to mandatory registration under the ACCP or a national body like AHPRA. Accreditation, through appropriate certifications, should also be required to ensure CIED physiologists meet the standards necessary for independent and safe practice. This is crucial for ensuring patient safety, given the significant responsibility CIED physiologists hold in programming and managing devices, where errors could result in serious consequences, including death.
- **Cost-effective solutions:** Employing non-industry CIED physiologists provides a cost-effective solution for delivering these services. CIED physiologists are vendor-neutral, offer holistic continuity of care, and have transferable skills that allow them to support other non-invasive and invasive procedures. This model not only reduces reliance on vendor-specific services but also ensures that follow-up care, such as CIED programming and troubleshooting, remains consistent across all patient care.
- **Technological integration and innovative care:** The alternative model should incorporate innovative technologies to support remote monitoring and telehealth services, allowing for the expansion of care to metropolitan, regional, and rural areas. By resourcing CIED physiologists adequately, these services can be delivered through insourcing within the public sector, expanding access to quality care.

- **Ongoing requirement for follow-up services:** It is important to note that there will always be a need for CIED follow-up services, and the costs associated with these services must be funded appropriately. Ensuring that CIED physiologists are employed to provide these services ensures continuity of care while maintaining patient safety and reducing costs.
- **Vendor Services:** Prosthesis tender agreements and TGA requirements should clearly define the minimum levels of service that vendors are obligated to provide, and specify which services are unnecessary or unwanted (e.g., state IEAP activities are to be aligned with international guidelines).

6. What are the likely timeframes required for your organisation, you or your sector to transition from the current to the proposed model/s of care? A timeline of key events/stages would be beneficial.

PiCSA's vision is (1) a competent, safe, and regulated Cardiac Physiology workforce meeting current and future health needs of the Australian community, and (2) ethically appropriate use of government and private healthcare funds.

We support the proposed transition to a model of self-sufficiency to manage CIEDs without reliance on inappropriate IEAP labour substitution: The proposed changes prioritise long term patient welfare and uphold internationally accepted industry and non-industry workforce roles. It is essential that the Australian CIED funding model is transparent and ensures patients receive appropriate, unbiased, international-standard care.

We believe that transitioning to a guidelines-based care model is unlikely without changes to the funding model. However, there is a moderate/high risk to patient safety if industry support is removed immediately. Temporary measures during the transition must be carefully managed to ensure funding transparency and avoid perpetuating the misuse of industry supports.

While some timeline aspects are beyond PiCSA's control, our organisation's activities—past, present, and future—align with our vision. We will continue to actively support, represent, and guide the workforce.

The government must lead the review of service-oriented architecture (SOA), tender agreements, and TGA requirements nationwide. These revisions should include terms for industry-delivered technical support and education, such as supporting product-specific training, troubleshooting, and patient assistance, especially during the transition and for the long term. The governance structure proposed by PiCSA and the ACCP must be upheld to prevent vendors assuming a regulatory role over non-industry CIED physiologist training. Additionally, steps should be taken ASAP to ensure appropriate pricing by 3rd party providers.

There are existing tender agreements and roles (e.g., public sector in Tasmania) that already align with international guidelines for IEAP labour. Additionally, some private centres employ their own CIED physiologists or use non-industry 3rd party providers. These examples could be leveraged to assist with the transition.

We note that there is already a labour shortage in CIED physiology, even without the transition process. **The training process, assuming a strong foundation in cardiac physiology, typically requires 18 - 24 months** and may take longer depending on the type and location of the CIED service.

The removal of non-guideline-based industry support must be paired with the creation of paid positions to allow workforce redistribution and the training of additional staff. One of the specific intentions of PiCSA's "Entry and Pathway" guideline document (see below) is assist employers through this process. Additional initiatives are noted below.

Chronology of Key Milestones and Ongoing Initiatives in PiCSA's Development of the Cardiac Physiology Profession

- **2015** – *National Census of Cardiac Science Professionals*: Conducted to gather workforce and employer views on professional identity, education, and training pathways, across all 5 modalities of practice.
- **2016** – *Unified Identity Established*: The title "Cardiac Physiologist" was adopted as the nationally recommended professional title, aligning with New Zealand and UK counterparts.
- **2020** – *Voluntary Registry of Accreditation Established*: PiCSA combined with neurology, respiratory, and sleep associations to form the Australian Council of Clinical Physiologists (ACCP), allowing cardiac physiologists in ECG, Cath Lab, Cardiac Devices, and Electrophysiology to become registered health professionals. The ACCP registry started with a grandparenting period.
    - Note: Echocardiography registration remains with the Australian Sonographer Accreditation Registry (ASAR), which began as a voluntary registry.
- **2022** – *ACCP Grandparenting Period Ends*
- **2024** – *PiCSA Guidelines Updated*: The "Australian Guidelines for Entry and Practice in Cardiac Physiology" revised. This resource supports policy makers, employers, students, and cardiac physiologists and provides practical guidance on education, remuneration, and regulation. (the document can be found at https://picsa.org.au/about/#core-documents).
- **In Progress** – *Recognition of CIED Physiologist Governance and Career Pathways*: PiCSA's 2024 guidelines become recognised and supported (from graduate through to post graduate levels) by universities, state and federal governments and employers.
- **Ongoing** – *Education:* PiCSA continues to provide and support non-industry-led education through monthly meetings, newsletters, and CIED masterclasses.
- **Ongoing** – *Advocacy:* PiCSA and members remain engaged in developing guidelines and position statements, and engaging with government and other stakeholder organisations.
- **2024** – *Working Group on CIED Scope of Practice*: A PiCSA working group is drafting formal "Scope of Practice" and "Competency Standards" for CIED physiologists, expected to be completed before 2025.
- **Nov 2024 (TBC)** – *CIED Self-Education Pathway*: An article in the PiCSA newsletter will outline a pathway for isolated physiologists who cannot access a formal training course or local mentor to help them prepare for the IBHRE Cardiac Device Specialist examination.
- **Nov 2024 (TBC)** – *Reciprocal Membership*: The PiCSA constitution will be revised to enable reciprocal (non-voting) membership with New Zealand's professional association, the Society of Cardiopulmonary Technology (SCT), which has already updated their constitution.
- **2025 (TBC)** – *CIED Course Delivered in Australia*: PiCSA, in collaboration with New Zealand's Society of Cardiopulmonary Technology (SCT), plans to deliver their CIED training course in Australia. This course is currently under review by NZQA for formal recognition as equivalent to a Master's degree.
- **2025 (TBC)** – *ACCP Updates*: ACCP registry updates to include practice modalities and accreditation status for each (including student categories).

- **TBC** – *Professional Indemnity*: Professional indemnity insurance will be made available to PiCSA "professional" members, conditional on ACCP and/or ASAR registration.
- **TBC** – *Mandatory Accreditation for Reimbursement*: Cardiac physiologist registration (e.g., ACCP) may become mandatory for reimbursement, with support from employers and the workforce across all modalities. Timeline TBC by the Australian Government.
- **TBC** – *Transition to AHPRA Registration*: ACCP and ASAR may be replaced by AHPRA registration or an equivalent governance structure, pending Australian Government decisions.
- **TBC** – *Provider Numbers for Cardiac Physiologists*: The profession may evolve to receive provider numbers, akin to other allied health professions (e.g., optometry or audiology), if deemed appropriate.

7. What are the consequences for your organisation, you, or your sector of moving away from the current cross-subsidisation of CIED TSS through the Prescribed List benefits for CIEDs?

Moving away from the current cross-subsidisation model of CIED technical support services through the Prescribed List benefits would have significant consequences for PiCSA, the CIED physiologist workforce, and the broader cardiac healthcare sector, promoting transparency, workforce development, and patient-centred care. However, careful planning is essential to manage short-term disruptions and ensure a smooth transition.

1. *Improved Workforce Development:* Transitioning away from the cross-subsidisation model could encourage cardiology centres and hospitals to employ their own CIED physiologists. This would provide opportunities for workforce growth, improve career pathways, and reduce reliance on industry-employed allied professionals (IEAPs) for labour substitution. It would also support full interdisciplinary collaboration without the limitations imposed by the IEAP model.

2. *Enhanced Patient Care:* Removing cross-subsidisation would align Australia more closely with international standards, where non-industry CIED physiologists operate with greater independence and provide more comprehensive patient support. This would lead to improved patient outcomes, as local CIED physiologists would have a broader scope of practice and greater clinical independence.

3. *Financial Transparency:* Moving away from the current model would address the lack of transparency associated with using PL benefits to fund services rather than devices. This would create a clearer, more equitable financial model where healthcare funding is directed appropriately to support clinical care and workforce needs.

4. *Reduced Industry Dependence*: The shift would reduce the sector's dependence on industry support for CIED services, thereby decreasing potential conflicts of interest and ensuring that CIED physiologists provide unbiased, patient-centred care. This change would also enhance the reputation and role of non-industry CIED physiologists.

5. *Temporary Service Gaps:* In the short term, there may be challenges in transitioning, particularly for private centres and hospitals that have relied heavily on IEAP substitution. These facilities may face initial service gaps or need to implement succession planning to employ and train their own CIED physiologists.

6. *Long-Term Sustainability*: Moving away from cross-subsidisation would support a more sustainable model for the CIED workforce, as employing in-house physiologists across both public and private sectors would ensure more consistent and competent care, especially in areas like remote monitoring and complex device management.

Below are the key short- and long-term impacts expected across various healthcare settings, highlighting the potential benefits and challenges, with a focus on workforce development and improved patient care.

Public sector

- The withdrawal of Prescribed List (PL) benefits has already led, and will continue to lead, to companies discontinuing services, with non-industry CIED personnel taking on those responsibilities.
- At current CIED physiologist staffing levels, this will create an inability to perform essential tasks such as follow-up and troubleshooting of CIEDs over their lifetime, which could negatively impact patient health outcomes.
- Tasks commonly assisted by industry include attending MRI procedures, providing on-call services, staffing clinics, and assisting with CIED implantation (including ordering, storage, and replacement of specific supporting items). Ideally, these responsibilities would be transferred to local CIED physiologists.
- Absorbing work previously handled by IEAPs will increase staff workloads, leading to higher levels of fatigue and burnout, which could affect broader cardiology and hospital services.
- In centres that rely on industry support for after-hours care, delays are common due to the limited availability of industry staff, who may be covering large regions. Without dedicated after-hours services, bed occupancy and waiting times are expected to increase, necessitating the allocation of funding for in-house recall services.
- Rural and remote patients will be disproportionately affected, as many present to smaller centres with no CIED capabilities and rely on industry response. Expanded travel or remote communication services will be necessary to support these centres and provide guidance from tertiary locations.
- The loss of PL benefits will likely lead to higher prosthesis prices in the public system, adding strain to departmental and HHS budgets in the coming years. However, discontinuing labour substitution by IEAPs should eliminate the justification for increased prosthesis pricing in the public sector.
- High-level technical support, product-specific training, programmer resources and remote monitoring infrastructure from vendors will still be necessary.

Private sector (short term)

- As with the public sector, the withdrawal of benefits will lead to companies discontinuing services previously offered during implants and in CIED clinics..
- This creates a significant risk of labour substitution by non-trained, non-certified, and non-accredited personnel, which could lead to adverse patient outcomes. CIED management requires significant training, as errors can be life-threatening.
- Rural and remote patients will experience these disadvantages more acutely, as many rely on industry responses in smaller centres. Increased travel or remote communication services will be required.

Private sector (long term)

- Long-term consequences can be mitigated if the recommended measures are adopted.
- High-level technical support, product-specific training, programmer resources and remote monitoring infrastructure from vendors will still be necessary.

8. What additional information is important for the consideration of the development of implementation options for implementation of the MSAC advice?

Role, Remuneration and Career Progression:

At present, the specific functions and responsibilities of Cardiac Physiologists in Australia are not universally consistent. Variations exist based on the health industry sector, clinical service capability framework, and specific modality of practice. Professional role classifications, regulatory requirements, and remuneration frameworks additionally exhibit diversity. This has created inequity within the profession in some jurisdictions.

- There is often a lack of recognition or incentives for the existing CIED physiologist workforce, specifically for those with certification and accreditation in CIEDs.
- Retention and remuneration for CIED physiologists in some jurisdictions are significantly lower compared to other allied health professionals (e.g., CIED physiologists in QLD health have no financial incentive to attain or maintain certification, and some are leaving due to disparity in award classification between the cardiac physiology modalities of practice).

Registration of all Cardiac Physiologists:

- **PiCSA's Position on Registration**: PiCSA firmly believes that all Australian Cardiac Physiologists should be registered health professionals for safety and quality assurance. Many patients and medical colleagues already assume that the profession is fully regulated.

- **AHPRA Registration**: Serious consideration should be given to registering cardiac physiologists under AHPRA. In the interim, the following governance applies:

    - ECG, Cath Lab, Cardiac Devices, and Electrophysiology registration is voluntarily available through the ACCP (www.theaccp.org.au).
    - Echo registration remains with the ASAR, which also began as a voluntary registry (www.asar.com.au). Some cardiac physiologists work in multiple modalities and are encouraged to join both registries.

- **Funding and Regulation**: The transition in funding and labour presents an opportunity to reinforce regulation. Funding models for CIED services should only support providers whose qualifications are recognised by PiCSA and who are registered with an appropriate body (e.g., ACCP).

- **Lessons from New Zealand and the NHS**: CIED physiologists in New Zealand and the NHS are better regulated and recognised. Australia can advance the profession by following a similar approach.

- **Support from CSANZ and the Australian Government**: This ongoing discussion is an opportunity for CSANZ and the Australian government to support the regulation of the cardiac physiology workforce.

- **CSANZ Position on Registration**: The 2023 CSANZ Position Statement on Atrial Fibrillation Ablation recommends that CIED physiologists in New Zealand must register with the CPRB. In Australia, while registration is voluntary, it is strongly recommended via ACCP. **A similar statement should be included in all CIED-related position statements.**

- **Advanced Sub-Specialist Training**: The 2023 CSANZ AF statement also recommends advanced training in Cardiac Electrophysiology, such as the Grad Dip EP (CEPIA) and IBHRE. A similar recommendation should be included in CIED related documents, referencing the qualifications listed in PiCSA's 2024 publication "Australian Guidelines for Entry and Practice in Cardiac Physiology" which can be found at https://picsa.org.au/about/#core-documents).

MRI Services:

The provision and funding of services for CIED patients undergoing MRI scans remains a challenging issue. Substantial resources are required for preparing, monitoring, and reprogramming devices to minimise patient risk before, during, and after MRI scans. In private MRI settings, patients are already incurring significant out-of-pocket costs, while radiographers and CIED physiologists (with or without input from physicians) spend considerable time ensuring risks are assessed and managed appropriately. With the withdrawal of industry support, there is a risk that patients will be denied timely local imaging or that the workload will shift disproportionately to large public hospitals. Additionally, there is concern about unscrupulous fees and service delivery by unregulated 3rd party providers operating with unknown competency and inadequate indemnity insurance.

Remote Monitoring: More Than It Seems:

- **Inconsistent Use of "RM" in Australia**: The term "RM" is used inconsistently in Australia. Does it refer to the communication appliance, the alert, or the many follow-up tasks? Many current discussions risk misunderstanding due to these differing interpretations.
- **International Insights**: The 2023 HRS/EHRA/APHRS/LAHRS consensus statement highlights the complexity of remote monitoring (RM). A 2021 study found each RM transmission required at least 15 tasks (review, diagnosis, patient communication, clinical action, charting) and 17 additional tasks (triage, scheduling, troubleshooting, etc.). Without proper infrastructure and dedicated staff, RM's benefits for patient care and clinic efficiency cannot be realised, leading to burnout and staff turnover.
- **Non-Industry CIED Physiologists' Role**: In public hospitals, non-industry CIED physiologists review RM transmissions and perform most of the associated tasks. Their involvement reduces the workload for cardiologists and ensures better patient care. Time estimates provided by vendors and 3rd party RM providers reflect a different paradigm.
- **Clinic Limitations Without CIED Physiologists**: Clinics without dedicated CIED physiologists cannot rely on 3rd party or industry teams to completely manage RM and its associated tasks.
- **Care Model Planning**: Thoughtful care model planning is essential, particularly in defining team roles and staffing needs. Reducing reliance on industry requires discussion on task allocation and overall staffing.
- **Allocating RM Responsibilities**: CIED service providers must assign RM tasks to properly qualified and registered team members.
- **Concerns with Unqualified Personnel**: Some centres use unqualified personnel, such as receptionists or nurses without CIED qualifications, to triage RM tasks. This practice is unsafe. More information on qualifications is available in the PiCSA Guidelines Updated: The 2024 "Australian Guidelines for Entry and Practice in Cardiac Physiology (Adult and Paediatric)".

Understanding the overall CIED care model, including big differences between Remote and In-Person follow-up:

The attached table has been designed to help clarify differences between the various types of follow-up that are used for cardiac device patients in Australia.

Includes the figures re mean time required, and the emphasis on bidirectional communication.

Why this table is important: It demonstrates that the different forms of follow-up are NOT equivalent. Each has advantages and limitations, and that they can (and should) be used to complement each other. It also discredits false claims about how long follow-up activities actually take when a comprehensive service is provided by non-industry CIED physiologists.

What Medicare doesn't provide: There is currently no reimbursement code for phone calls or telehealth discussions made by Cardiac Physiologists to complement **remote transmissions** and **remote monitoring** (scheduled and unscheduled), despite their very significant clinical value.

It is often *essential* to speak with the patient in order to correctly interpret their device data and provide appropriate advice and follow-up care. A centre that allocates resources to phone calls gets the same rebate as a centre that does not. We hope that this omission can be flagged and rectified with a future Medicare rebate code.

Making the most of all the options: Different centres have different resources at different times, but it would be ideal to aim for capability in all 4 types of follow-ups, for optimal flexibility and access to the specific advantages of each.

For example, in an ideal world:

- the local hospital has **ED transmitters** for rapid data retrieval and off-site data analysis,
- the patient will have a **bedside transmitter** capable of both automatic **scheduled** and **unscheduled** "**alert"** transmissions,
- there will be access to **in-person CIED follow-up** via an **on-call** physiologist (after hours) and an **on-site** physiologist (during work hours), and
- there will also be a suitably experienced **cardiologist** available for in-person clinical review, oversight of data/programming and telephone advice as required.

Table references:

Leitch J, Asakai H, Dawson L, Medi C, Norman M, Stevenson I, Toal E, Turnbull S, Young G. Cardiac Society of Australia and New Zealand (CSANZ) Position Statement on the Follow-Up of Cardiovascular Implantable Electronic Devices 2022. Heart Lung Circ. 2022 Aug;31(8):1054-1063.

Seiler A, Biundo E, Di Bacco M, Rosemas S, Nicolle E, Lanctin D, Hennion J, de Melis M, Van Heel L. Clinic Time Required for Remote and In-Person Management of Patients With Cardiac Devices: Time and Motion Workflow Evaluation. JMIR Cardio. 2021 Oct 15;5(2):e27720.

Cronin, E. M. (2012). Remote monitoring of cardiovascular devices: a time and activity analysis. Heart Rhythm, 9(12), 1947 - 1951

Differences between Remote and In-Person follow-up of CIEDs

Action	**Remote Transmissions** (manually generated, e.g., via a shared communicator)	**Remote Monitoring** (automatically generated **scheduled** and **unscheduled** "**alert**" transmissions)	**In-Person CIED Follow-up** with Cardiac Device Physiologist	**Clinician review** May be combined with in-person CIED follow-up
Perform programming changes	N	N (PPM & ICD) Varies* (ILR)	Y	N
Complete view of all device and patient diagnostics	Varies	Varies	Y	N
Full list of device settings	Y	Y	Y	N
Accurate lead measurements	Varies (required measurements may be absent or inaccurate)	Varies (required measurements may be absent or inaccurate)	Y	N
Wound evaluation	N***	N***	Y	Y
Record both presenting and underlying rhythm for all patients	N	N (underlying rhythm not recorded in all patients)	Y	N
Early identification of device integrity or rhythm event alerts	N	Y	N	N
Patient inconvenience (travel, parking, physical exertion, and potential exposure to infection)	N	N	Y	Y
Mean time required (mins) including all necessary clinical and administrative tasks**	9.4 - 13.5	9.4 - 13.5	37.8 - 51.0	15.0
Identify and resolve patient concerns	N***	N***	Y	Y
Provide routine patient education	N***	N***	Y	Y
Identify and initiate management of clinical concerns such as heart failure	N***	N***	Y (e.g., via referral for clinician review)	Y
Obtain detailed verbal history (e.g. to evaluate clinical significance of device diagnostics, rhythm events, chronotropic performance, heart failure symptoms, reported changes since previous review)	N***	N***	Y (may be augmented by device data)	Y
Perform provocative manoeuvres (e.g. to test lead integrity or chronotropic competence)	N	N	Y	Limited
Physically observe patient mobility and breathlessness	N	N	Y	Y
Identify relevant physical symptoms – e.g., cannon waves, peripheral oedema, mobility, and respiratory effort	N***	N***	Y	Y
Perform additional required tests (e.g. 12 lead ECG, Holter, BP and O2 saturation measurement)	N	N	Y	Y
Address psycho-social issues	N***	N***	Y	Y
Improve patient confidence in their device (best achieved with a hybrid care model)	Varies	Y	Y	Partial

*Some newer generation ILRs can be programmed remotely

** Australian/New Zealand data is lacking. These figures are from Seiler A, Biundo E, Di Bacco M, Rosemas S, Nicolle E, Lanctin D, Hennion J, de Melis M, Van Heel L. Clinic Time Required for Remote and In-Person Management of Patients With Cardiac Devices: Time and Motion Workflow Evaluation. JMIR Cardio. 2021 Oct 15;5(2):e27720. doi: 10.2196/27720. PMID: 34156344; PMCID: PMC8556635.. See also Cronin, E. M. (2012). Remote monitoring of cardiovascular devices: a time and activity analysis. *Heart Rhythm, 9*(12), 1947 - 1951.

***The addition of bidirectional patient communication (e.g., phone call/telehealth appointment) adds significant clinical value to both scheduled and unscheduled transmissions and is especially important if substituting Remote for In-Person follow-up.