Creating a more dynamic and resilient economy inquiry

Questionnaire response 78

Name: Medical Software Industry Association

Submission date: 8/06/2025

1. Support business investment through corporate tax reform

1. What features of the Australian business environment have encouraged or restrained investment over the past 10 years?

The participant did not respond to this question.

2. What elements of the corporate tax system encourage and/or discourage investment and risk-taking?

The participant did not respond to this question.

3. Which parts of the corporate tax system do you find the hardest, or most time or cost-intensive to comply with? How could the compliance burden of the business/company tax system be reduced?

The participant did not respond to this question.

2. Reduce the impact of regulation on business dynamism

1. What areas of regulation do you see as enhancing business dynamism and resilience? What are the reasons for your answer?

1. Tiered accreditation models that calibrate the risk- to benefit.
a. The work by the Department of health, Ageing and disabilities provides the possibility of fit for purpose regulation. It is being developed with input from industry and end users in a genuine co-design. The net effect will be reduced procurement red tape and cost to government and industry. It will also increase certainty and confidence for users of health systems.
b. The current Software as a Medical Device (SaMD)regulatory scheme by the Therapeutic Goods Administration (TGA) provides a harmonized framework which assists in the reduction of red tape by industry exporting overseas because of the TGA involvement with the International Medical Device Reform Forum (IMDRF). It also maps to the 11 proposed mandatory Guardrails proposed by the Department of Industry Science and Resources. Risk- based regulation which is supplemented by Essential principles is an excellent example regulation providing the safety and security without stifling business sustainability and innovation.

2. How has your regulatory burden changed over time?

The MSIA is currently finalising a member survey which demonstrates that the requirement s on industry have grown from approximately 20% of resources being allocated to government compliance to 80%. The survey will be available following release of the PC interim report.

3. What regulations do you find time-consuming, overly complex or otherwise constraining business dynamism and resilience? What are the reasons for your answer?

There are three good examples.
1. Privacy and Security Regulation - Currently multiple and various security and privacy regulations from Commonwealth and Jurisdictions mean that companies are compelled to conform to varying standards which could be harmonised for a better result for industry, health care providers and consumers. Procurement would be improved and KPMG modelling for the Australian Digital Health Agency (2023) found that every month shaved from procurement lead-time in clinical software equates to AU$50 million in earlier benefits. A risk-tiered accreditation process alone is expected to remove four to six months from 70 % of first-time deployments, implying a net present value of AU$1.2 billion over ten years.

2. Schedule 8 Medications - Similarly each Jurisdiction has its own Schedule 8 drug list which means companies have to code for safety in several different ways which is illogical, inconsistent and inefficient.

3. Online Prescription Authorities - Finally, the regulation of Online Prescription Authorities which account for over $5B of PBS medications per annum have been found to be poorly executed by the ANAO which found Services Australia delivery only “partly effective”.
. Key facts & findings from the 2025 ANAO Report on the Delivery of the PBS
1.As at 30 June 2023, there were 928 medicines (across 5,261 brands) listed on the Schedule of Pharmaceutical Benefits.
2. Budgeted expenditure for the PBS for 2024–25 was $19.5 billion (excluding recovery revenue).
3.In 2022–23, there were 223.1 million over co-payment PBS prescriptions (67.9 per cent) and 105.6 million under co-payment PBS prescriptions (32.1 per cent) dispensed in Australia.
The ANAO found arrangements to manage the delivery of PBS services and payments are partly effective. Deficiencies related to ensuring legislative requirements for certifying claims are met and performance reporting.
There were seven recommendations to improve the administration of the PBS — three to Health, two to Services Australia and two to both entities. Services Australia did not agree to one recommendation. [This was the one on OPA- which the MSIA has recommended a solution for years ago].
29.4%of PBS medicines require prescribers to gain authority approval from Services Australia prior to prescribing. These are the OPA which account for $5.733B.
The Australian National Audit Office (ANAO) report on the administration of the Pharmaceutical Benefits Scheme (PBS) scrutinized the processes surrounding online prescription authorities, focusing on the efficiency and effectiveness of authority approvals. The report identified significant concerns regarding the timeliness of these approvals, which are essential for patient access to certain medications.
Key Findings:
• Timeliness of Authority Approvals: The ANAO observed that the existing performance measures for authority approvals were not aligned with the agreed targets. Specifically, the report highlighted that Services Australia's performance metrics did not reflect the goal of issuing authority approvals within 30 seconds, as stipulated in bilateral

agreements.
• Surge in Online Authority Requests: There has been a notable increase in the use of the Online PBS Authorities system, accessed via Health Professionals Online Services (HPOS). This shift indicates a preference among healthcare providers for digital channels over traditional phone-based methods, likely due to efficiency and convenience.
Recommendations:
To address these issues, the ANAO made specific recommendations:
1. Performance Reporting Alignment: Services Australia should align its reporting on the timeliness of issuing authority approvals with the agreed performance measures and targets. This alignment would ensure transparency and accountability in meeting established service standards.
2. Inclusion in Annual Performance Statements: The timeliness of authority approvals should be included in Services Australia's annual performance statements. This inclusion would provide stakeholders with a clear understanding of the agency's efficiency in processing these approvals.

Implications:
The misalignment between performance targets and reporting can lead to inefficiencies in processing authority approvals, potentially delaying patient access to necessary medications. The increasing reliance on online systems underscores the need for robust digital infrastructure and responsive service delivery to meet healthcare providers' expectations.
Addressing these recommendations is crucial for enhancing the efficiency of the PBS and ensuring timely access to medications for patients.
The MSIA submission to the Services Australia and Department of Health suggest a fully integrated OPA. Just as online PBS was not fully embraced in 2006-2007 until it was fully integrated, so too should the OPA be integrated with each provider system using internationally adopted standards like SMART on FHIR.
Adopting this recommendation would enable Services Australia to achieve the timeline and reporting targets recommended by the ANAO, improve productivity of the health sector, and most importantly, improve the timeliness of medication to Australians.

4. Can you share any specific examples of where you think a regulator has done a good or bad job of understanding and reducing regulatory burden on businesses and why?

See above The Department of Health , Ageing and Disabilities including the TGA

Cover sheet: Supporting document #1

MSIA
MEDICAL SOFTWARE
INDUSTRY ASSOCIATION

Online Prescription Authorities

By MSIA
Proposal for OPA Connect model and
business case for funding interoperability
and integration with
Clinical Information Software Systems

Date: 14 April 2025

Contact: Emma Hossack | ceo@msia.com.au | 0413 483 096
BA (Hons), LLB, LLM

Over 90% of Clinical Information Software (CIS) and health administration tools in use in Australia are MSIA members. This provides a reliable channel of communication for assistance and sharing of information with and between industry.

Date	Version	Comments
1 Dec 2022	0.1	Initial version created by MSIA
16 Mar 2023	0.2	Updates following industry discussions for submission to IDMO
23 Mar 2023	0.3.2	Reviewed by MSIA following feedback from RACGP
29 Mar 2023	0.4.1	Clarify that this program relates solely to Online PBS Authorities as against Online Prescription Authorities
05 Apr 2023	0.4.2	General revisions following restricted industry briefings prior to release.
11 Apr 2023	1.0	Initial release version
12 Apr 2023	1.1	Include PBS Online authority statistics
13 Apr 2023	1.2	Pre-Release draft for SA discussions
1 Sep 2023	1.3	Ministerial submission
1 April 2025	1.4	Revised Submission for Services Australia, RACGP and DHAC

CONTENTS

Acknowledgements

Special thanks to the RACGP digital health committee, Industry and Services Australia (SA), for their input and assistance during the numerous discussions leading to the development of this document.

Executive Overview

This document describes the current process for Online PBS Prescription authority (OPA) applications which the users describe as time inefficient and complex.

Following extensive consideration and MSIA input from 2016, this document proposes an interface to the existing SA PBS authorities web portal thereby providing CIS developers with a simplified development path to provide their clients with full OPA integration.

Many OPA requests emanate from the aged care sector, particularly Residential Aged Care Facilities. The proposed change to the way these requests are currently processed via the eNRMC program and will ensure that many of the delays and obstacles faced by this vulnerable sector of the community, will either cease or be significantly reduced. The positive ripple effect of benefits achieved by the proposed OPA Connect architecture will be experienced in other verticals in medication prescriptions, but the workforce shortages in aged care mean any efficiencies are valuable.

The proposal requires no additional SA development prior to its implementation, thereby reducing the time for broad potential take-up by developers and prescribers and saving costs. Support to industry to implement the proposed interface to assist prescribers would be minor compared to the ongoing savings to government.

The improvements proposed would result in uplift for consumer and provider experience with major cost savings to the Government. If accepted and implemented, the work proposed would be a good news story for productivity, innovation, co-design and deliver significant savings to the health budget.

1. Scope of Authority Applications - PBS and Jurisdictions

Additional reporting requirements and authorities to prescribe medicines may apply under the drug Schedules regulated by Australian state and territories.

These jurisdictional requirements are independent of the regulations applicable for a drug to be eligible for a PBS supply under the Commonwealth schedule.

The authority applications discussed in this document are limited to the prescribing events associated with PBS prescriptions.

1.1 Channels Available for Obtaining Authorities

There are four channels available to a prescriber when a non-streamlined (non-SAC) authority to prescribe is required for the particular drug.

1. Manual

- Telephone (manual)
- Written (manual)

2. Online PBS Authorities System (OPA)

- HPOS Online Authorities
- Web services Online interface integrating directly with the CIS

Despite the introduction of the online interface since 2016, adoption remains low. Nearly a decade after its launch, only one ophthalmology system has integrated OPA through the web services online interface, with an average of 560 applications per month in 2023-24, accounting for less than 0.1% of PBS authority applications[1].

While HPOS applications have increased from 22% in Q1 2022-23 to 40.5% in Q4 2023-24, telephone-based applications still constitute 54.5% of all requests[1]. A September 2024 RACGP poll[2] of 1,183 prescribers found that 48% spent 3-5 minutes on the phone for approvals, while 27% waited 6-10 minutes, and 4% waited over 10 minutes.

[1] Auditor-General Report No.19 2024–25 Performance Audit - Administration of the Pharmaceutical Benefits Scheme - Department of Health and Aged Care, Services Australia.
[2] https://www1.racgp.org.au/newsgp/poll

1.2 Why has the health software industry take-up been minimal?

The web services have a complex software interface requiring significant development and as numerous other government policies have required software changes without financial support there has been no business case for change.

Authorities regulations require that specific reasons for prescribing the medicine be consistent with the patient's medical condition to be eligible for PBS supply.

In replicating the process which the telephone staff implement, the OPA web services software is required to present the relevant questions to the prescriber associated with that authority. This in turn requires the prescriber's appropriate answer(s) to support that request.

Many of these have multiple acceptable answers required to be returned by the prescriber. Multiplying this complex software development effort by the substantial number of individual CIS systems identifies a major issue relating the lack of current integrated take-up accounting for the almost negligible (0.3%) usage of this channel for authorities requests.

With less than 3% of CIS systems integrations incorporating the 7-year-old process, it is time to consider a workable alternative solution consistent with the legislative requirements.

1.3 Scope of "Authority Required" PBS Items

The PBS includes approximately 10,000 drug listings covering over 900 different medicines in 5,200 brands[3]. Nearly 30% of these require prior approval from Services Australia (Table 1), translating to over 7 million authority requests in 2023-24.

In addition to these numbers, any of the 10,000 listings where the prescriber requires increased quantities and repeats also require contact to Services Australia for an authority.

[3] Australian Institute of Health and Welfare - Pharmaceutical Benefits Scheme Prescriptions: Monthly Data.

Table 1: Percentage of PBS schedule items requiring authority approvals in FY 2023-24 (Adapted from Table 4.5 Restriction level for PBS medicines, Auditor-General Report[4])

Table 4.5: Restriction levels for PBS medicines

PBS restriction level	Description	Percentage of PBS Schedule as at June 2024[a] (%)
Unrestricted	Can be prescribed for any purpose without prior approval and be eligible for PBS subsidies.	18.8
Restricted	Can be prescribed only for specific purposes to be eligible for PBS subsidies, though no check or control is applied at the time of prescription or dispensing.	19.9
Authority-required (streamlined)	Can be prescribed only for specific reasons defined in the Schedule. An authority code recorded against the item in the Schedule must be included on the prescription for checking at the time of dispensing.	31.9
Authority-required	Can be prescribed only with an approval from Services Australia. Applications for approval can be made by phone, in writing, or online.	29.4

Note a: Calculated by ANAO using Services Australia data.

Source: ANAO analysis of Department of Health and Aged Care publications and Services Australia PBS processing data.

1.4 HPOS Online Issues raised by prescribers.

The existing HPOS option as an alternative to prescriber telephoning has had limited prescriber take-up because it is complex and requires major duplication of input. Prescriber feedback to MSIA has advised that it can typically take 7 minutes all-up to transact, usually while the patient waits.

For several years prescribers and their peak body representatives including the AMA and RACGP have been advocating for the seamless integration of the current Services Australia's online facilities with their normal prescribing CIS workflow.

This would avoid the manual duplication of the data required for OPA.

To assist in the understanding of the issues raised by prescribers, a "PBS Online Authorities user journey" presentation by RACGP was kindly provided by the RACGP and shared for release[5]. A copy of this paper is being provided with this proposal.

[4] Auditor-General Report No.19 2024–25 Performance Audit - Administration of the Pharmaceutical Benefits Scheme - Department of Health and Aged Care, Services Australia.

[5] A copy of the workflow is provided with this paper. Cognisant some changes to workflow has been implemented by Service Australia to reduce data entry, however the process remains complex.

In spite of the introduction of the HPOS/OPA solution, the vast number of prescribers prefer to use the traditional manual contacts because:

- The interface is onerous.
- The Online PBS Authorities ("OPA") system requires the prescriber to login with the now accepted two tier authentications of password and SMS to obtain access to the service for each OPA request.
- It requires transcription of the drug, Medicare and numerous other duplications.
- The accuracy of transcription is impacted and results in a high error rate and frustration to prescribers, pharmacies and consumers;
- Prescribers have no appetite for re-entering the data which they have just entered during their prescribing process and take-up will be limited until a fully integrated process is available.
- It is simpler for the doctor to call the authorities line which most do.

Data confirms these challenges (Table 2). The rejection rates for HPOS applications are twice as high as those processed via the telephone helpline.

Table 2: Comparison of rejection rates (Adapted from Table 4.8 Restriction level for PBS medicines, Auditor-General Report[6])

Table 4.8: Rejection rate of authority applications by phone and HPOS, 2019–20 to 2023–24

Application channel	Applications — total	Applications — rejected	Rejection rate (%)
Phone	12,118,255	278,844	2.30
HPOS	4,807,859	269,223	5.60

Source: ANAO analysis of Services Australia data.

[6] Auditor-General Report No.19 2024–25 Performance Audit - Administration of the Pharmaceutical Benefits Scheme - Department of Health and Aged Care, Services Australia

As a corollary, the manual channel and prescriber time is also a significant cost impost to Services Australia which runs the authorities help desk.

In 2023-24, this equates to nearly 4.3 million interactions[6], so there is the opportunity for major savings for SA, but also the productivity and satisfaction impact across prescribers Australia wide would be considerable.

Recent HPOS Enhancements

In June 2024, Services Australia announced several enhancements to the OPA system[7], including:

- The ability to upload supporting documentation
- Improvements to the authority prescription number function
- Dynamic questions and answers
- A delayed assessment function

While these changes are beneficial, they do not address the fundamental complexity of OPA, which still requires significant manual data entry.

While the enhancements to HPOS in June 2024 may have contributed to increased adoption, it is likely that some of the shift from the telephone Helpdesk to HPOS is also influenced by the lengthy wait times prescribers experience when seeking approval via phone.

A March 2025 RACGP poll[8] of 1,828 prescribers found that 94% believe further changes are needed to streamline the PBS authority approval process.

[7] Service Australia - PBS Authorities for Software Developers Presentation 13 March 2025.
[8] https://www1.racgp.org.au/newsgp/poll

1.5 Web Service Implementation Challenges

Web services have a complex software interface which requires significant development. Many other government policies have required software changes without financial support to industry, including eprescribing PBS Data distribution model, and aged care. Consequently, there has been no business case for change.

To integrate with OPA, software developers need to engage with four separate Service Australia teams (Table 3).

Table 3: Service Australia Technical Team Contact for OPA integration (Adapted from Service Australia Presentation[9]).

Services Australia Team	Role Description	Contact
Developer Liaison	Online Technical Support team responsible for software developer liaison and onboarding software developers to use the Developer Portal.	developerliaison@servicesaustralia.gov.au
ITEST	Online Technical Support team responsible for managing software developers engaged in Notice Of Integration testing for PBS integration (Authorities and Claims)	PBSOL.ITEST@servicesaustralia.gov.au
Online Technical Support	Online Technical Support team responsible for software developer support during development and in production.	pbsonline@servicesaustralia.gov.au
PBS Authorities section	Business team in Pharmaceutical Benefits Branch responsible for managing policy and supporting software development with PBS Authorities.	PBS.Authorities.Developer@servicesaustralia.gov.au

Authorities regulations require that specific reasons for prescribing the medicine be consistent with the patient's medical condition to be eligible for PBS supply.

In replicating the process which the telephone staff implement, the OPA web services software is required to present the relevant questions to the prescriber associated with that authority. This in turn requires the prescriber's appropriate answer(s) to support that request.

Many of these have multiple acceptable answers required to be returned by the prescriber.

A recent review of the PBS restrictions rules in order to facilitate OPA automation revealed extensive ongoing editorial efforts (Refer to the Table in section 9.3 below).

1.6 Lack of Future-Proofing for FHIR

Services Australia has indicated that FHIR (Fast Healthcare Interoperability Resources) is not being considered for OPA, as the system is viewed as a payment platform rather than a clinical service. However, FHIR is specifically designed to accommodate both administrative and clinical

[9] Service Australia - PBS Authorities for Software Developers Presentation 13 March 2025.

workflows[10]. Its Financial Module supports claims processing, coverage verification, and payment reconciliation, making it a suitable framework for OPA. FHIR is supported and its development is partly funded by the Department of Health and Aged Care.

A SMART on FHIR APP would be ideally suited. It would be consistent with the healthcare modernisation adopted by the Department of Health and Aged Care as a part of sharing by default.

1.7 Future Mandatory OPA Integration

OPA integration is being considered as a mandatory requirement in future electronic prescribing conformance frameworks. If mandated, the MSIA proposal provides a practical and efficient pathway for seamless CIS integration, benefiting both prescribers and the healthcare industry as a whole.

2. MSIA Member Consultation

The overwhelming pressure to implement this system motivated MSIA to explore online alternatives to telephone and written authority requests with the membership.

MSIA canvassed members via several teleconferences to explore interest in a proposal to automate this dialogue using a common interface provided by a simplified data exchange between OPA Web Services and the CIS software.

The outcome from this consultation was a proposal for the “OPA Connect” solution from a member company with over 60 years of experience in medication management integrated with over 100 CIS.

A limited tender is proposed to ensure compliance with Commonwealth Procurement Rules, and an assurance of value for money. The MSIA is agnostic in respect of which entity does the work provided they offer the best possible existing integration to avoid the need for each member company to re-develop interfaces which would be unproductive and unnecessary.

2.1 The OPA Connect Proposal

Under the Proposed Architecture the software companies would pass the applicable data elements required to the OPA Connect API which would process the request via the existing Web Services,

[10] HL7 FHIR Release 5 - 13.0 Financial Module - https://hl7.org/fhir/financial-module.html

thereby eliminating the necessity for the prescriber to re-enter the data and would subsequently return the Authority Approval Number to the CIS (Refer to 9.2).

Such an interface to the OPA Connect API would be significantly simpler to implement for those CIS companies not wishing to individually develop the total OPA solution as specified on the of Services Australia Developer Portal.

MSIA could support the development of the OPA Connect interface and subsequently assist in the change management of its members as it has done successfully in other programs including Safe Script in Victoria.

Based upon our discussions with prescriber peak bodies, we are confident that prescribers and consumers would embrace the proposal. This is because it would cut red tape and enable greater time for providers and patients to discuss their healthcare issues.

Should the MSIA proposal be accepted and implemented, the 26 steps described in the "RACGP user journey" would be reduced to the 4. This is because most of the current HPOS data entry has already been captured in the CIS. The examples illustrated in steps 23 to 26 associated with the checks for patient eligibility against the PBS item restrictions captured via OPA Connect demonstrate the improvement.

Please refer to 9.1 for a summary of the duplicated prescriber input required for the use of PRODA/HPOS and OPA.

2.2 The Productivity Commissioner

The Productivity Commissioner[11] commented in a speech to the Consumer Health Forum in 2019 that the health system is highly labour intensive and real cost reductions are hard to achieve.

Where technology and innovation have been evident, in the past these have focussed on improving quality rather than cost. The MSIA proposes a solution that will reduce costs to the Government and improve the quality of the consultation for consumers and providers.

> It is time to "re-imagine the business model and re-shape it around the consumer." [12]

[11] https://www.pc.gov.au/media-speeches/speeches/healthcare-wide-view/healthcare-wide-view.pdf
[12] Supra page 5

PBAC provides guidelines for auditing. These could be incorporated and updated creating greater transparency and cost saving.

The recent PC Report, "Leveraging Digital Technology in Healthcare" [13] reinforces the value of adopting processes which improve the provider and consumer experience and stimulate productivity and innovation. This submission reflects these values.

2.3 The Potential

A streamlined integrated process could dramatically reduce cost and time and improve patient experience.

PBAC provides guidelines for auditing. These could be incorporated and updated creating greater transparency and cost saving.

The January 2025 ANAO Performance Audit of the PBS[14] found the administration of the PBS is "partly effective." Seven recommendations were made and the only one which PBS did not agree to was revision of the OPA. 29.4% of PBS medicines require an OPA, that is medications worth $5.73B. And the administration is "partly effective".

The MSIA has offered a more streamlined approach for almost a decade. Savings would be immediate, and provider and consumer outcomes would be significantly improved.

3. The MSIA Industry Support Proposal

MSIA proposes that it work with key software providers, Services Australia, peak bodies and other relevant stakeholders to streamline the process to ensure appropriate and effective conformance. Previous successful examples of funded MSIA involvement in other programs include:

1. PBS Online for pharmacies
2. Closing the gap indigenous co-payment reduction
3. E-Prescribing
4. RTPM Safe-Script in the DHHS Victoria
5. COVID-19 conformance including AIR, Booking Services and updates.

[13] https://www.pc.gov.au/research/completed/digital-healthcare
[14] Auditor-General Report No.19 2024–25 Performance Audit - Administration of the Pharmaceutical Benefits Scheme - Department of Health and Aged Care, Services Australia

In order to achieve widespread integrated online PBS prescription authorities into clinical systems, the task must be co-designed with the systems which comprise the Australian health software industry.

MSIA has an established relationship with its member companies that represent over 98% of the prescribing systems to achieve this outcome.

4. Suggested Timelines and key decision points

- The Department and Services Australia to consider the proposed MSIA concept for integration of the Web services OPA Connect.
- If accepted, continue the co-design in consultation between Services Australia, the software industry and stakeholders.
- MSIA / Services Australia agreement for project support and management
- Develop an agreed OPA Connect interface with and prescribing software noting that the full requirements are as specified in the SA Authorities Service SV Specification.
- Agree on a timeline for the OPA Connect availability.
- If the concept is rejected, then terminate the discussion and continue with the status quo of minimal timely uptake of OPA and the cost and professional concern around the wasteful four million plus telephone requests by highly specialised health professionals who are a very valuable and expensive asset.

5. OPA Connect Priorities and Scoping.

The PBS proposal applies to the scenarios and staging listed below.

5.1 Initial Stage 1 Implementation

1. Authority Required Items including those CAR and S100 HSD's flagged by SA for immediate assessment. (Excludes ARLS, delayed assessment CAR and HSD's requiring written postal or form upload and eCMC).
2. Restricted Items with increased Quantity or Repeats.
3. Unrestricted Items with increased Quantity or Repeats.

5.2 Future Staged consideration

4. Extemporaneously Prepared Items
5. ARLS, Complex Authority Required (CAR) Items and other delayed assessment S100 programs requiring written postal or form upload and the Growth Hormones (GH) program.
6. Streamlining the PBS approval of electronic prescribed chemotherapy medicines when the eCMC program is implemented.

5.3 Stage 1 Scope and Usage Statistics for YE 30 June 2022

Usage statistics for the items proposed for Stage 1 – refer to categories listed in 5.1	Authority Reason Code	# authorities
Authority only drug	1	2,467,447
Increased quantity	2	3,258,231
Increased repeats	3	173,115
Increased quantity and repeats	4	460,464
Authority only with increased quantity	5	318,037
Authority only with increased repeats	6	100,564
Authority only with increased quantity and repeats	7	56,946
Authority not required (streamlined and not assessed by SA)	8	48,417
Indicative totals across this phase represents greater than 98% of all authorities		**6,883,221**

These statistics demonstrate that these new authority applications plus the functionality to view/update/delete previous approvals account for all but a small percentage of all authority requests.

Our discussions with peak bodies concluded that there would be no issue in maintaining the existing manual application procedure for items not included in Stage 1 as these represent a small percentage of authorities, typically restricted to specialist prescribers.

5.4 Out of scope for Stage 1

- Extemporaneous (compounded) preparations.
- Written Authorities and S100 programs requiring delayed assessment written postal or form upload.
- Applications for complex authority items, Hepatitis C, eCMC and Alzheimers items.
- Growth Hormone authority applications.
- Repatriation Pharmaceutical Benefits Scheme (RPBS) Authority approvals to continue to be sought in writing or phone application from the Department of Veterans' Affairs.
- Discussions with Services Australia and peak bodies have raised no issue with these out-of-scope items, particularly relating to the immediate benefits resulting from the timely implementation of Stage 1.

6. Summary of OPA Connect Benefits

Benefits through the implementation of this facility implemented OPA Connect.

To Services Australia

- Reduction of telephone call wait times and interactions.
- Provides an accountable and auditable transaction.
- The system automatically includes the system checks for patient eligibility against PBS item restrictions via the incorporated Q & A functionality.
- Improved data richness (collection and quality).
- Flexible Questions and Answers system.
- Reduction in red tape.

- Major financial savings.
- Implementation of this proposal would go a significant way to remediation of the administration issues of OPA which are signaled in the ANAO 2025 Report.

To Prescribers

- Seamless integration into prescribing routine.
- No longer required to telephone SA.
- Self-service channels provide 24/7 access.
- No duplication of data entry – Refer to 9.1
- Functionality to view/update/delete previous approvals.
- A major resource to complement the ongoing prescriber RACF medication review requirements of the developing eNRMC Aged Care systems under current implementation.
- Streamlining the electronic prescribing of chemotherapy medicines when the eCMC chemotherapy program is implemented.
- Improved patient satisfaction.

To Patients

- Consultations are not interrupted by telephone calls to SA.
- Increased quality time spent with health professionals.

To Prescribing Software Developers

- Increased interoperability.
- Improved user satisfaction.
- Straight forward implementation.
- With the exception of the OPA Connect API application, there will be no requirement for a new Notice of Integration required with SA.

7. Support considerations for Industry Developers

Options include the following, or a combination of all three:

1. Funding on an initial successful timely implementation of electronic authority requests available to prescribers.

2. As Services Australia has foreshadowed the likelihood of extensions to the program, funding must be considered for the costs associated with updating, maintaining and supporting the platform as these extensions are introduced.

3. Funding on the number of OPA authorities approved over a sunset period.

8. Next Steps

The MSIA proposal would achieve the outcome required by the legislation and desired productivity and innovation signals from Government.

It would involve minimal risk or cost to the Commonwealth.

Although the current manual authority service request channels would continue to be a requirement for non-computer-generated prescriptions, the predicted increase in online requests beyond the existing adoption would deliver millions of dollars in savings annually[15].

The MSIA would welcome the opportunity to meet with decision makers in Government and Services Australia to discuss the viability, opportunity and next steps for this proposal.

[15] Represents the cost of call centres requested by Services Australia for seven million communications in addition to longer doctor patient consultations while red tape was processed.

9. Appendix

9.1 Data Integration

The data elements no longer require duplication when the prescriber uses OPA Connect as an alternative to the current HPOS system are detailed below.

The RACGP User Journey identifies the duplication which will no longer be required limiting the data entry to the Q & A and patient diagnosis requirements, examples which are shown in Steps 21 to 24.

9.1.1. Fully Integrated data elements workflow

The following data elements will be auto populated via the data exchanged between the Clinical Information Software (CIS) and OPA Connect.

- Authority Prescription Number
- Prescriber Id
- Recording of patient consent for the external disclosure of personal information
- Patient Details includingMedicare Number, First Name, Surname, DOB, Gender and biological sex.
- Drug details to be prescribed.
- PBS Item Code, Brand, Quantity, Repeat, Dosage
- Codes identifying Restriction and Treatment Details, to be considered.
- Hospital Details if applicable

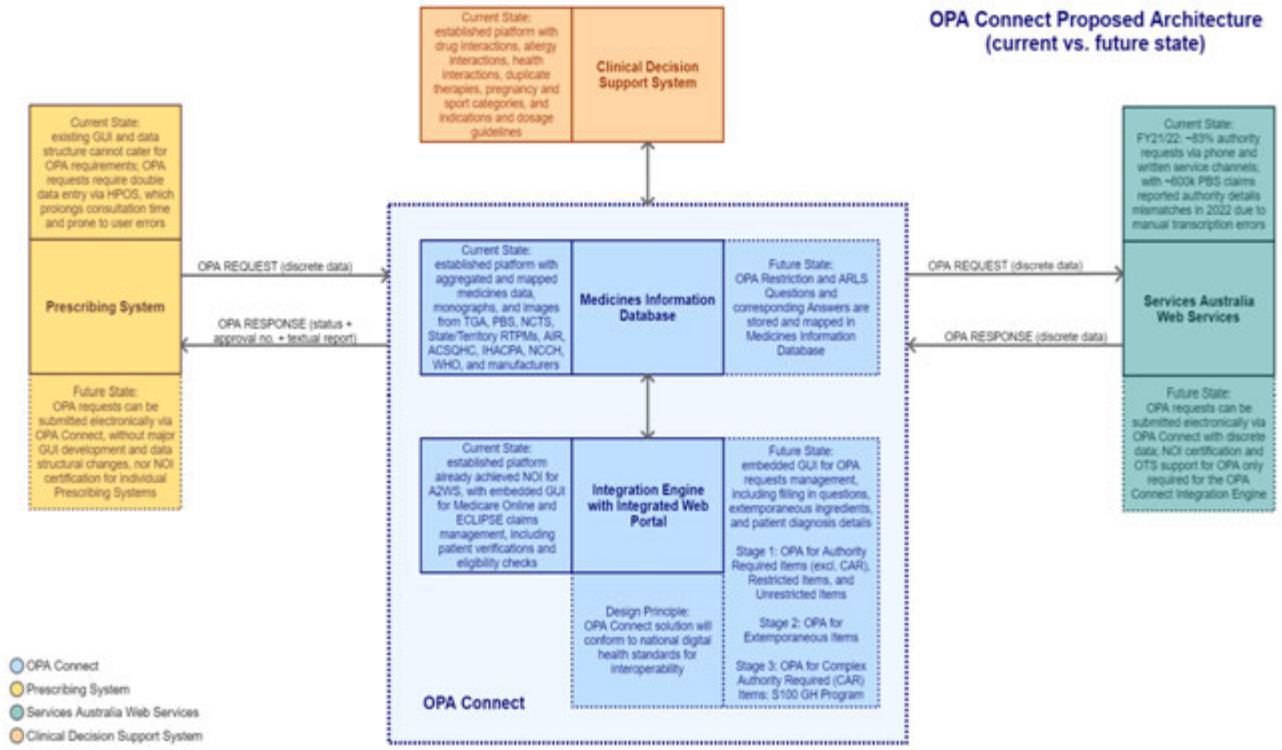
9.1.2 The prescriber Q & A requirement to remain.

The continuation of this Q&A is critical in demonstrating the prescriber's consideration of the due care to the clinical use of these drugs.
This duty of care has been acknowledged by the peak prescriber groups.

9.1.3 The Authority Approval Number returned to the CIS.

The value of the returned Authority Approval Number and status will be available to the CIS thereby negating the need for manual entry by the prescriber for subsequent storage and recording on the PBS prescription.

9.2 OPA Connect Proposed Architecture



9.3 PBS restrictions editorial

Extensive ongoing editorial effort is required to derive authority rules from PBS restriction text in order facilitate OPA automation /validation to guide the prescribers with the authority request process.

Example: PBS item = 2798G:

restriction	treatment phase	restriction texts related to authority rules
restriction #1: myelodysplastic syndrome	initial treatment	The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and (b) details (date, unique identifying number/code or provider number) of the full blood examination report; and (c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and (d) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application. All the reports must be documented in the patient's medical records.
		If the application is submitted through HPOS upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
restriction #2: myelodysplastic syndrome	continuing treatment	The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone. The following evidence of response must be provided at each application: (i) a haemoglobin level taken within the last 4 weeks; and (ii) the date of the last transfusion; and (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; All reports must be documented in the patient's medical records.
		For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

REFERENCE: see Appendix 9.4 for authority application form 'PB012-2207 Lenalidomide - Myelodysplastic Syndrome - Initial & First Continuing.pdf'

If we try to summarise the textual rules in the above prescribing texts to facilitate OPA automation/validation, it may look like this:

sequence	treatment phase	occurrence	online	phone	writing
1	initial	n/a	Y	N	Y
2	continuing	1st	Y	N	Y
3	continuing	2nd and onwards	Y	Y	N

NOTE: PB012-2207 form clearly specifies which authority method is NOT supported in EACH phase, but the same level of clarity is NOT included in the above prescribing texts.

And the linkage to the required evidence for each treatment phase to construct OPA questionnaire and facilitate auto data population from existing clinical records may look like this:

A	Evidence	Data Type	Occurrence	Valid Period
initial	bone marrow biopsy finding = myelodysplastic syndrome	date, IDs, report		
	full blood examination result	date, IDs, report		
	cytogenetics finding = low risk or intermediate-1 (IPSS or FISH)	date, IDs, report		
	transfusion record	date, no. of RBC units	most recent	
	transfusion record	no. of RBC units	total in period	last 4 months
	transfusion record	no. of RBC units	total in period	last 6 months

continuing	haemoglobin result	Hb level	any	last 4 weeks
	transfusion record	date	most recent	
	transfusion record	no. of RBC units	total in period	last 4 months

NOTE: The textual rules in the above prescribing texts do NOT contain adequate details to construct the same questionnaire as PB012-2207 form – although further details on the evidence criteria are scattered in the remaining restriction texts, some information are only included in EITHER the restriction texts OR PB012-2207 form (but NOT both) and thus the combined information from BOTH sources may be necessary to fill in the questionnaire.

9.4 PBS Authority Application Form

Australian Government
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PBS

Myelodysplastic syndrome – lenalidomide initial or first continuining authority application

Online services

Requesting PBS Authorities online provides an immediate assessment in real time.

For more information and how to access the **Online PBS Authorities** system, go to **servicesaustralia.gov.au/hppbsauthorities**

When to use this form

Use this form to apply for **initial** or **first continuing** Pharmaceutical Benefits Scheme (PBS) subsidised lenalidomide for patients with myelodysplastic syndrome.

Important information

Initial or **first continuing** applications to start PBS-subsidised treatment can be made in real time using the **Online PBS Authorities** system or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for myelodysplastic syndrome **initial** or **first continuing** authority applications.

The information in this form is correct at the time of publishing and may be subject to change.

Continuing treatment

This form is ONLY for **initial** or **first continuing** treatment.

For continuing PBS-subsidised treatment, the patient must qualify under the **first continuing** treatment criteria.

After a written authority application for the **first continuing** treatment has been approved, applications for **subsequent continuing** treatment can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Call charges may apply.

Section 100 arrangements for lenalidomide

This item is available to a patient who is attending:

- an approved private hospital
- a public participating hospital, **or**
- a public hospital

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

This item is not available as a PBS benefit for in-patients of a hospital.

The hospital name and provider number must be included in this authority form.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

PB012.2207

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Australian Government
Services Australia

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PBS

Myelodysplastic syndrome – lenalidomide initial or first continuing authority application

Online services

You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to **servicesaustralia.gov.au/hppbsauthorities**

Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

6 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

7 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

8 Hospital provider number

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

9 This application is for:

initial treatment ☐ ***Go to 10***

first continuing treatment ☐ ***Go to 16***

10 Has the patient been diagnosed with myelodysplastic syndrome confirmed by a bone marrow biopsy report from an Approved Pathology Authority?

No ☐

Yes ☐ Date of the report (DD MM YYYY)

Unique identifying number/code or provider number

11 Is the condition classified by the International Prognostic Scoring System (IPSS) as low risk or Intermediate-1?

No ☐

Yes ☐ IPSS score

12 The patient has a deletion 5q cytogenetic abnormality:

☐ with no other abnormalities

or

☐ with 2 or more other abnormalities

or

☐ with chromosome 7 abnormalities.

MCA0PB012 2207

13 Provide details of the cytogenetic report

Date of report (DD MM YYYY)

Unique identifying number/code or provider number

14 The patient:

☐ is red blood cell transfusion dependent and has been transfused within the last 8 weeks

and

☐ has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

15 Provide:

a) date of the full blood examination report (DD MM YYYY)

b) unique identifying number/code or provider number

c) date of most recent transfusion (DD MM YYYY)

d) total number of red blood cell units transfused at most recent transfusion

e) total number of red blood cell units transfused within the last 4 months

f) total number of red blood cell units transfused within the last 6 months.

▶ *Go to 18*

16 The patient:

☐ has received initial PBS-subsidised treatment with lenalidomide for myelodysplastic syndrome

and

☐ has achieved and maintained transfusion independence

or

☐ has achieved at least a 50% reduction in red blood cell unit transfusion requirements compared with the 4 month period prior to commencing PBS-subsidised therapy with lenalidomide

and

☐ does not have progressive disease

and

☐ the condition has not progressed to acute myeloid leukaemia.

17 Provide:

a) date of last transfusion (DD MM YYYY)

b) haemoglobin level within the last 4 weeks

c) total number of red blood cell units transfused in the 4 months immediately preceding this application.

Checklist

18 The relevant attachments need to be provided with this form.

☐ The completed authority prescription form(s).

Privacy notice

19 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at **servicesaustralia.gov.au/privacy**

Prescriber's declaration

20 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine.
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application.
- I have provided the completed authority prescription form(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction.
- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

Prescriber's signature

On completion, print and sign by hand.

Date (DD MM YYYY)

Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

  or

- by post, send this form, the authority prescription form(s) and any relevant attachments to:

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

Reset form Print form

PB012.2207

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10. Abbreviations, Definitions and Terms

Term	Definition
AAN	Authority approval number – the number provided to the prescriber by the Department and subsequently notated on the prescription when an application to prescribe is requested for authority required PBS prescriptions.
AMA	Australian Medical Association
APN	Authority prescription number – the number pre-printed on the top RHS of paper authority PBS prescription form.
Approved Medical Practitioner Approved Prescriber	A medical practitioner approved under section 92 of the *National Health Act 1953* to supply pharmaceutical benefits.
ARLS	Authority Required Logic System (ARLS)
CIS	Clinical Information Software
DoHA	Australian Government Department of Health and Aged Care
DVA	Department of Veterans' Affairs
eCMC	A project to support electronic prescribing of chemotherapy medicines in hospitals and other defined care settings
eNRMC	Electronic National Residential Medication Chart medication
Eligible Approved Supplier	An Approved Pharmacist or Approved Medical Practitioner approved under the *National Health Act 1953* to supply pharmaceutical benefits.
MSIA	Medical Software Industry Association
HPOS	Health Professional Online Services - https://www.humanservices.gov.au/health-professionals/services/medicare/hpos
NHA	*National Health Act 1953*
NOI	Notice of Integration by the Department for PBS Online is issued following the approval of vendor software as the outcome of successful integration testing between the vendor and the OTS Liaison section of Services Australia. Production transmissions to PBS Online may only take place following the issue of a NOI.
Non-SAC	Non Streamlined Authority Code
NRMC	National Residential Medication Chart
PBS	Pharmaceutical Benefits Scheme.

OPA	Online PBS Authorities System
PBS Schedule	Schedule of Pharmaceutical Benefits – means the pharmaceutical benefits declared under section 85 of the *National Health Act 1953.*
PRODA	Provider Digital Access. The PRODA system allows providers to create a centralised account and link to this account with a variety of Relying Parties, including Medicare.
PWS	Prescription Writing Software – usually part of CIS
RACGP	Royal Australian College of General Practitioners
RPBS	Repatriation Pharmaceutical Benefits Scheme
SAC	Streamlined Authority Code. The Pharmaceutical Benefits Schedule (the Schedule) identifies certain items as 'authority required (streamlined)'. PBS Prescriptions for listed quantities or repeats for these items do not require telephone approval to obtain an authority approval number. Prescribers obtain the streamlined authority code in the Schedule next to the text that describes the indications for which the item may be prescribed.
SA	Services Australia
SVIK	Software Vendor Information Kit

Cover sheet: Supporting document #2

PBS Authorities System - GP user journey

March 2023

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What we will be doing today

- ✓ Introduction and overview
- ✓ Process overview
- ✓ Key process steps
- ✓ Summary of pain points and potential solutions
- ✓ Questions

Purpose of the user journey

- Demonstrate current state and process for GPs when requesting PBS Authorities
- Illustrate the current pain points
- Suggest potential solutions that work seamlessly with GP clinical workflow
- Noting with respect to the systems currently used for prescribing medicines and other systems being used by GPs there are still requirements to meet existing legislative requirements
- This presentation uses Best Practice for demonstration purposes only
- SafeScript Victoria is included as an example of how integration can work

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Potential solutions

- While simple solutions are suggested within this presentation, the RACGP supports work on future improvements to ensure the PBS Authorities system:
  - ✓ is efficient and easy to use
  - ✓ works seamlessly in the background
  - ✓ integrates fully with systems used by GPs
  - ✓ does not impact on GP workflow.

- GPs must be consulted during development to ensure future solutions are practical, beneficial and sustainable

- The RACGP is well placed to provide advice and guidance on the development of new technology that is utilised within general practice.

About the RACGP

The RACGP is the voice of GPs throughout Australia. For more than 60 years, we have supported the backbone of Australia's health system by setting the standards for education and practice and advocating for better health and wellbeing for all Australians.

As a national peak body representing over 46,000 members working in or towards a career in general practice, our core commitment is to support GPs to address the primary healthcare needs of the Australian population.

We cultivate a stronger profession by helping the GPs of today and tomorrow continue their professional development throughout their careers, from medical students and GPs in training to experienced GPs.

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About the RACGP

We develop resources and guidelines to support GPs in providing their patients with world-class healthcare and help with the unique issues affecting their practices. We are a point of connection for GPs serving communities in every corner of the country.

Australia's GPs see more than two million patients each week and support Australians through every stage of life. The scope of general practice is unmatched among medical professionals.

Patient-centred care is at the heart of every Australian general practice, and at the heart of everything we do.

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Potential solutions to improve the PBS Authorities Systems process 🎯

Why are we doing this?

To reduce the time and complexity of the current PBS Authorities system process to support general practice and for patients.

How do we measure success?

Long term:

- Fully Interoperable technology in general practice is regarded as business as usual
- The PBS Authorities system is fully integrated with GP Clinical Information Systems (CIS), there is no extra log in requirement and patient and drug details are entered only once within the CIS.

Short term:

- The ability to copy and paste information from the CIS to PRODA/HPOS is enabled.

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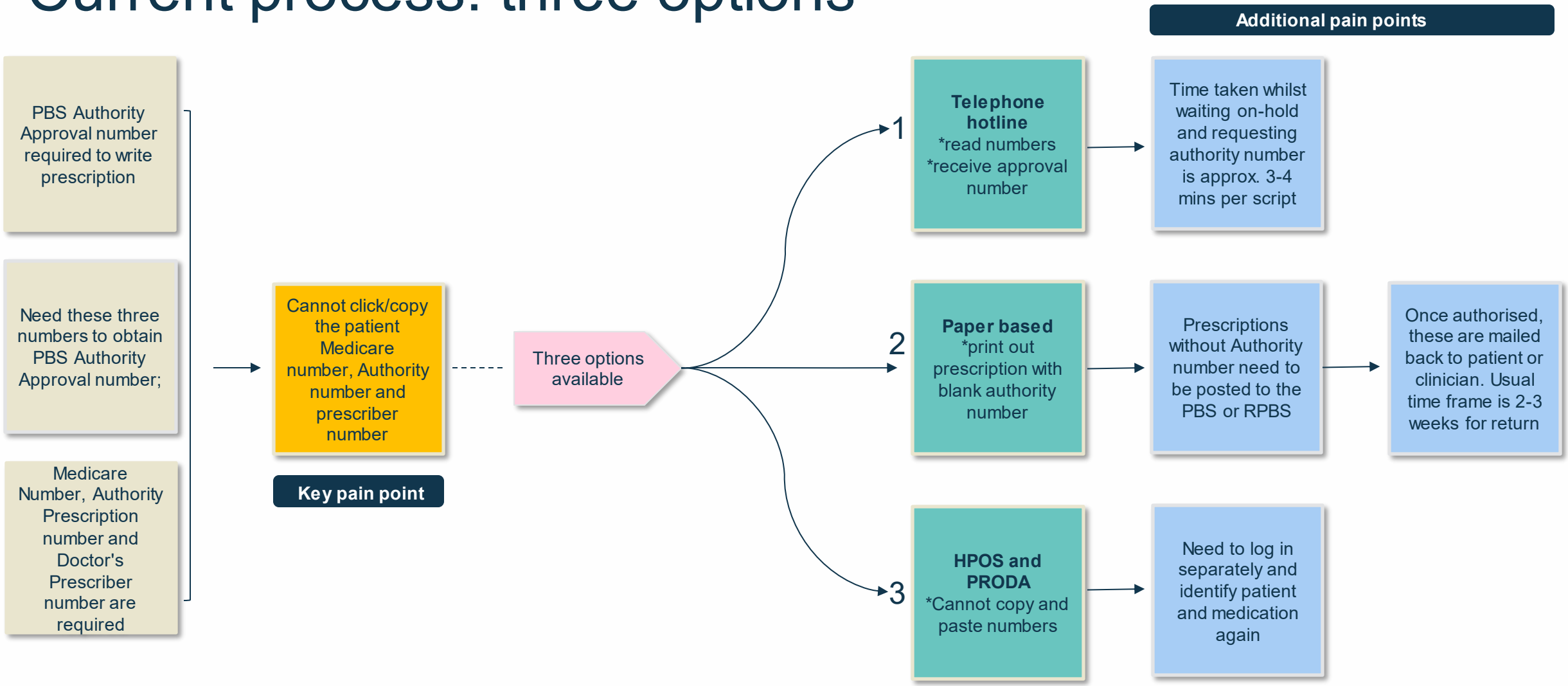
Potential solutions to improve the PBS Authorities Systems process 🎯

Key drivers of success

- Simple, succinct, accessible, streamlined and easy to implement improvements
- Technology that is interoperable with general practice CIS
- Robust communications strategy and education component to educate GPs on updates.

Current process: three options



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Review of pain points and potential solutions

Process: Generating Authorities approval number and transcribing information

Pain points	Potential solution

• HPOS and PRODA
  ▪ cannot copy and paste key information
  ▪ cannot click/copy patient Medicare number, authority number or prescriber number
• Duplication to access the same information in a different system which allows click/copy
• Can transcribe Medicare number, however this is high risk and time consuming.
	✓ Allow click/copy function of Medicare and Authority number as a minimum improvement.

Comments

- Transcription via paper is not congruent with the potential opportunity offered from current technology.

Review of pain points and potential solutions

Process: Exiting CIS and opening new browser	
Pain points	Potential solutions
• Need to exit CIS to generate Authorities Approval number • Need to open a new browser ie. Multiple screens.	✓ Access PRODA/HPOS-from within CIS ✓ Embed PRODA/HPOS access within CIS as authentication has already been proved.

Comments

- Using multiple systems and screens is complex. Most GPs currently use the traditional telephone method.

Review of pain points and potential solutions

Process: User authentication	
Pain points	Potential solution
• Need to use mobile phone to get verification number as part of the two-factor authentication requirement during consultation with patient • Not all GPs have their mobile phones with them when consulting.	Authentication from within CIS (this is acceptable for My Health Record and various implementations of Safe Script-real time prescription monitoring)
Comments • Complex process taking time away from GPs delivering high quality care to patients.	

Review of pain points and potential risks

Process: Medicare number vs IHI number	
Pain points	Additional risk
• Cannot use IHI to confirm identity of patient • Can only use Medicare number • Copy function in CIS allows copy of patient Medicare number (provided not commenced an authority prescription form) • You must separately note a patients line number as well as their Medicare number.	! Medicare numbers leaked in Optus breach ! IHI numbers are a more universal and secure number to use.

Potential solutions and comments continued next slide

Review of potential solutions

Process: Medicare number vs IHI number

Potential solutions

- ✓ Allow IHI's to be used in patient search
- ✓ Allow Medicare line number and Medicare number to be copied across together (after commenced an authority prescription form).

Comments

- IHI's are already required for use in most new systems, including My Health Record
- IHI's are available for people who are not eligible for Medicare and are a universal identifier for all healthcare consumers (noting in SA, PBS Authorities are no available to people without Medicare Numbers)
- IHI's as provide greater certainty that the right information is attributed to the right individual compared to Medicare numbers.

Review of pain points and potential solutions

Process: Key dose and medication information entry is duplicated	
Pain points	Potential solutions
• The CIS and PBS Authorities System do not communicate medication information • Need to re-enter medication and select correct dosage and detail again	✓ Make the CIS and PRODA/HPOS/PBS Authorities system interoperable ✓ Automatically transcribe medicine information and dose from CIS to HPOS ✓ Automatically populate reason for prescription from CIS into HPOS

Comments

- This level of interoperability is already actioned in the use of Safe Script and Cancer screening systems,
- Eliminates the need to enter duplicate medicine information, apart from "reason for prescription"
- Reduced administration time to focus on delivering high quality care in consultation.

Accessing PBS Authorities Prescription number online

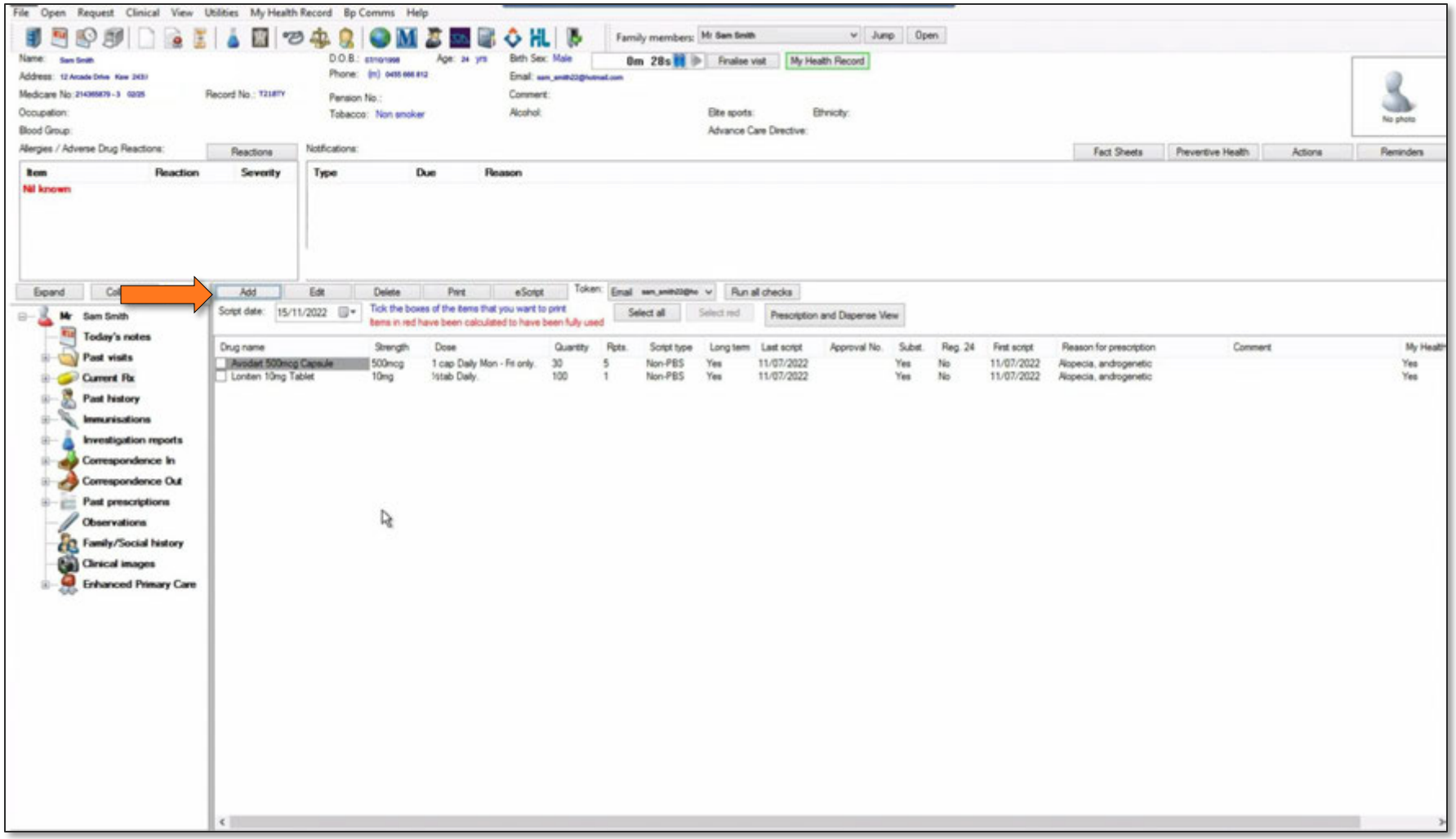
Key steps taken by GPs

Step 1: Load CIS and find patient

Overview

- Open and login to CIS
- Type name of patient.

Step 2: Load patient landing page to add new medication



Overview

- Open page of correct patient
- Click 'Add' to begin prescription for new medication.

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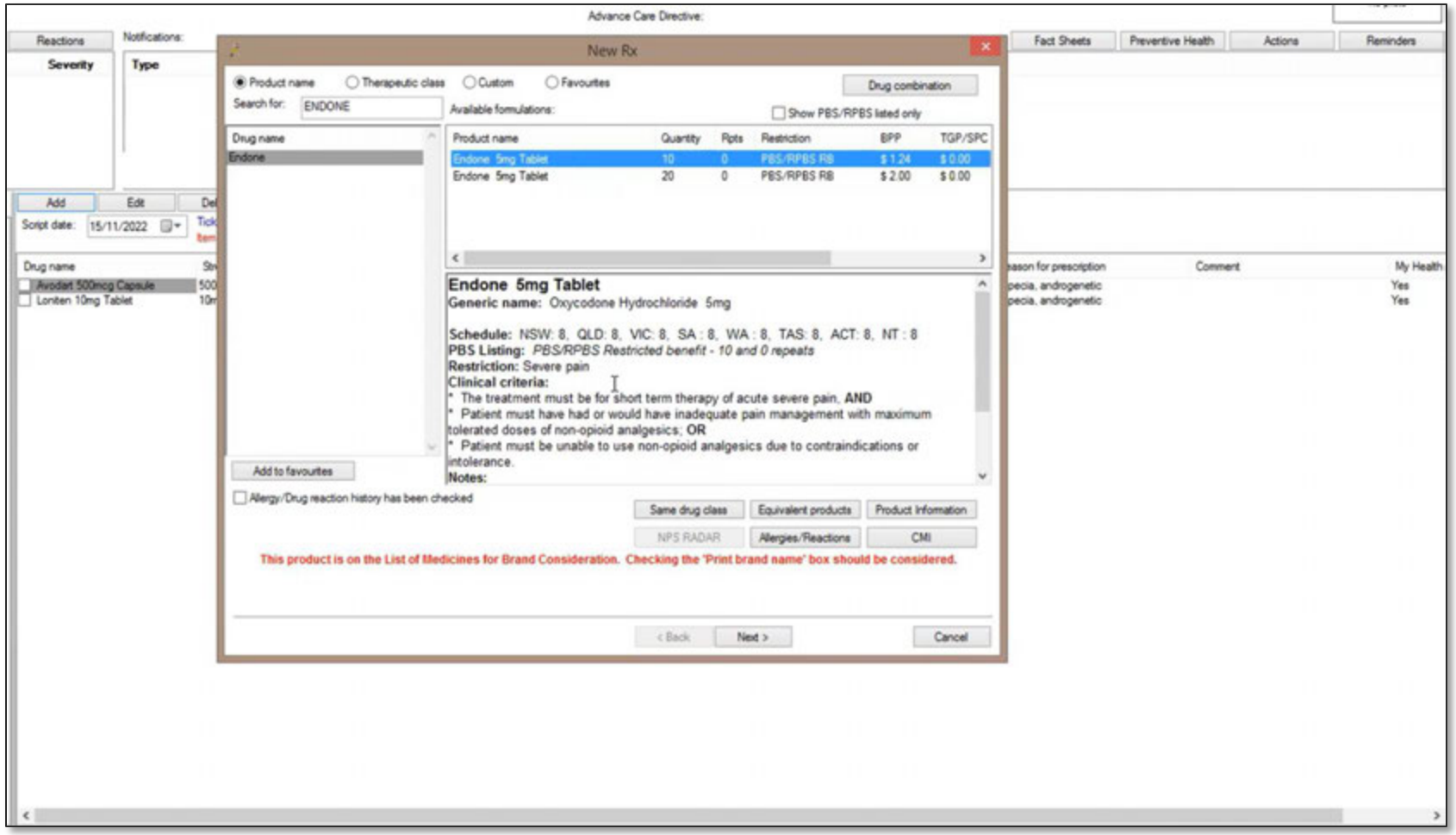
Step 3: Search for new medicine and select correct type



Overview

- Type new medication into search bar (Endone)
- Read clinical criteria (requires extensive scrolling and checking)
- Choose which type (2 options –pack of 10 or 20)
- Check clinical criteria
- Click ‘Next’.

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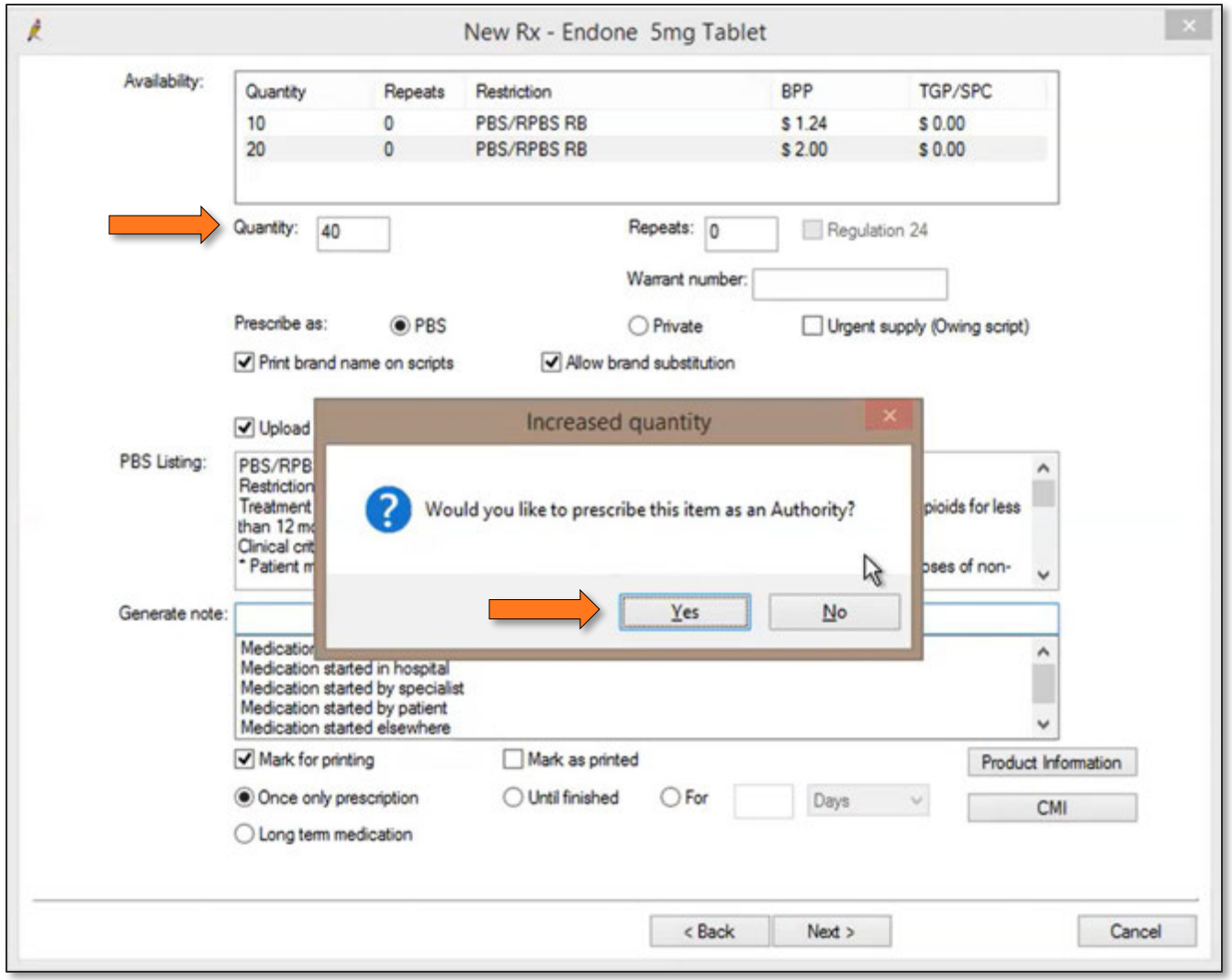
Step 4: Choosing non-standard order for an Authority medicine



Overview

- Note: regular Quantity differs from what is being requested (and increased quantity of 40 in this case)
- Anything more than standard will require PBS Authority for approval of the prescription.

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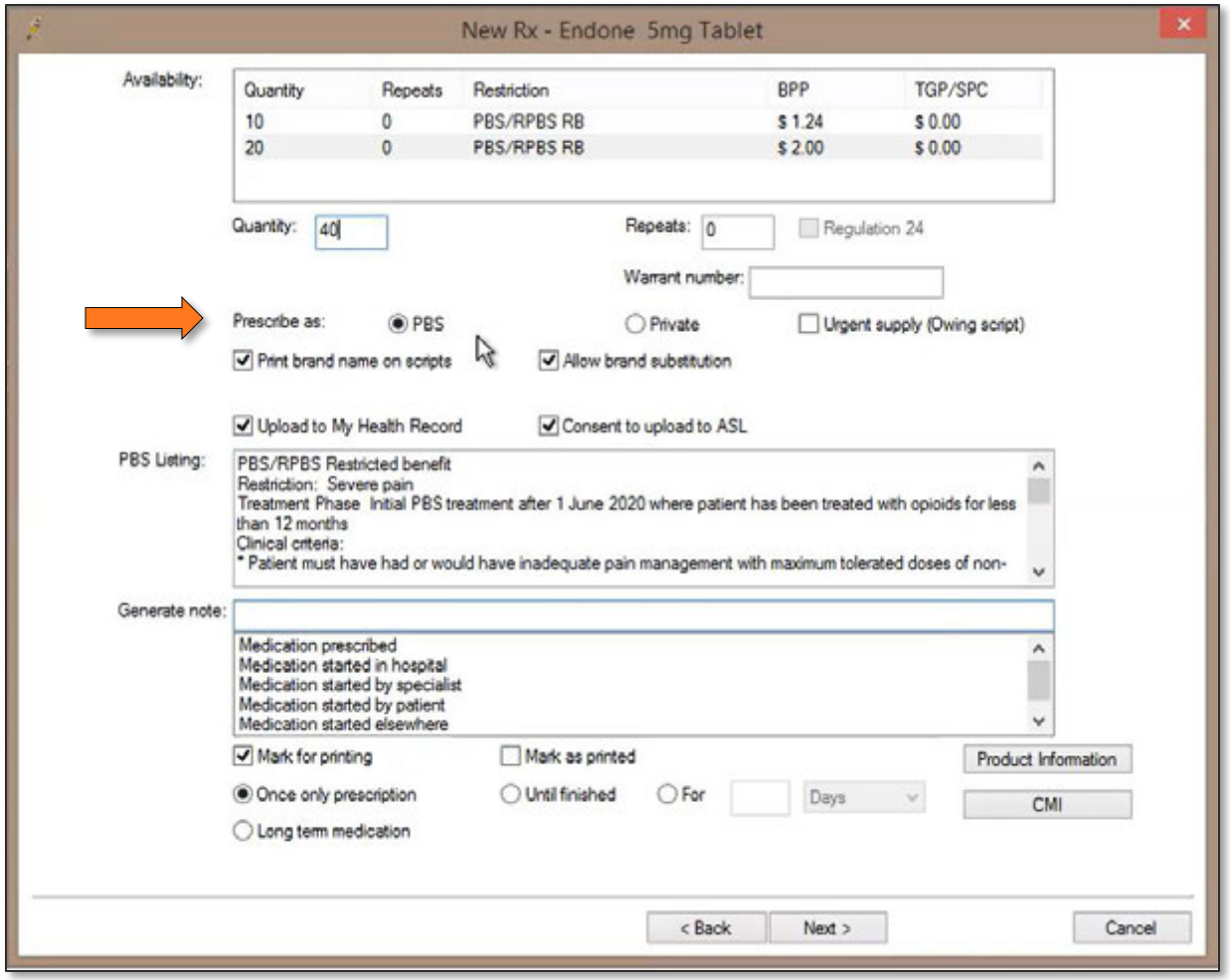
Step 5: Choose to prescribe as PBS or Private



Overview

- Choose and check: PBS or private and medication order
- Click ‘Next’.

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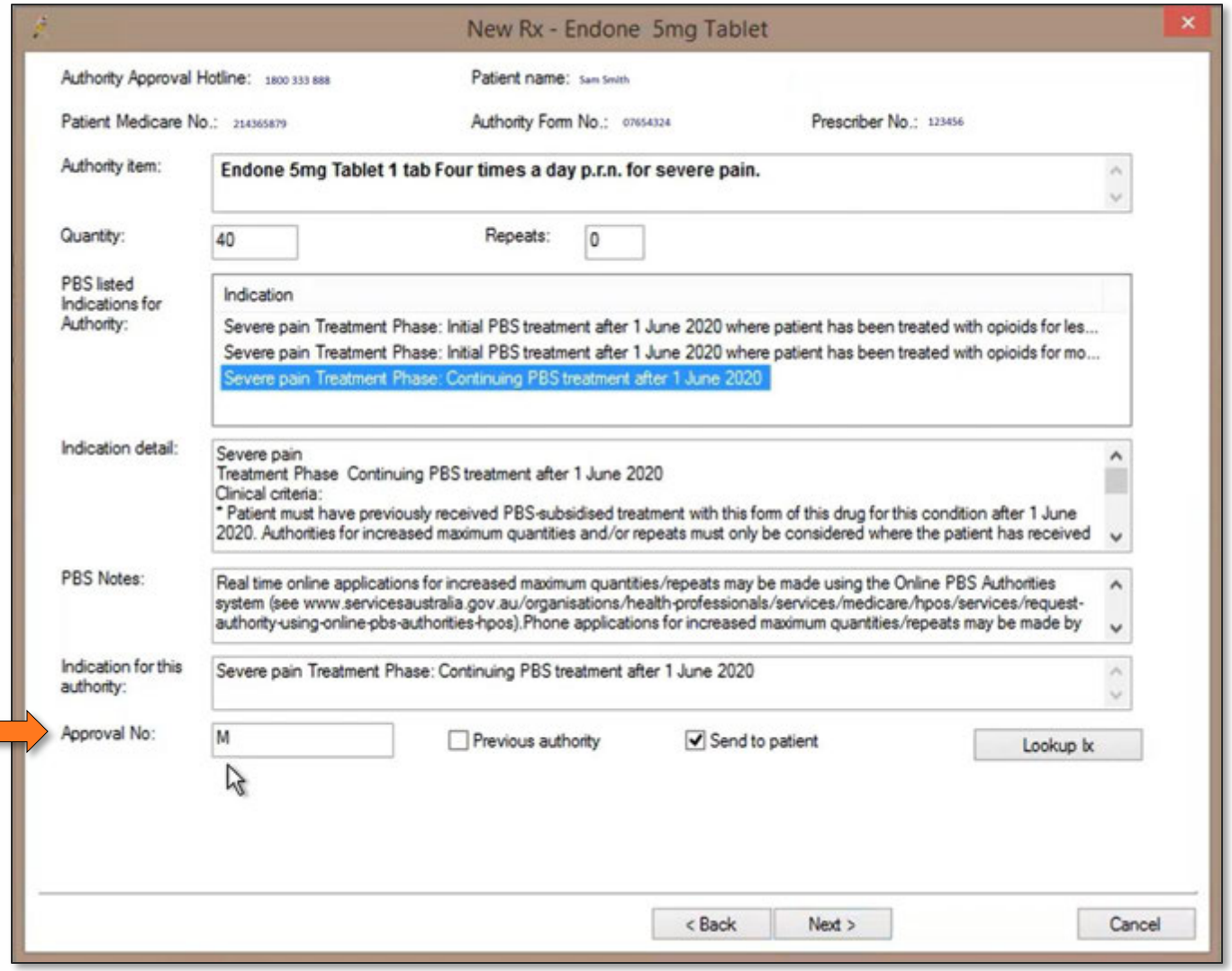
Step 6: Approval number (currently blank)



Overview

- Authority form number is displayed
- Check dosage and select indication
- Approval number is not displayed
- Press ‘Enter’, medication (Endone) is displayed on chart with no approval number yet
- Need the following to access approval number:
  - ❑ Patient Medicare number
  - ❑ Authority form number
  - ❑ Prescriber number.

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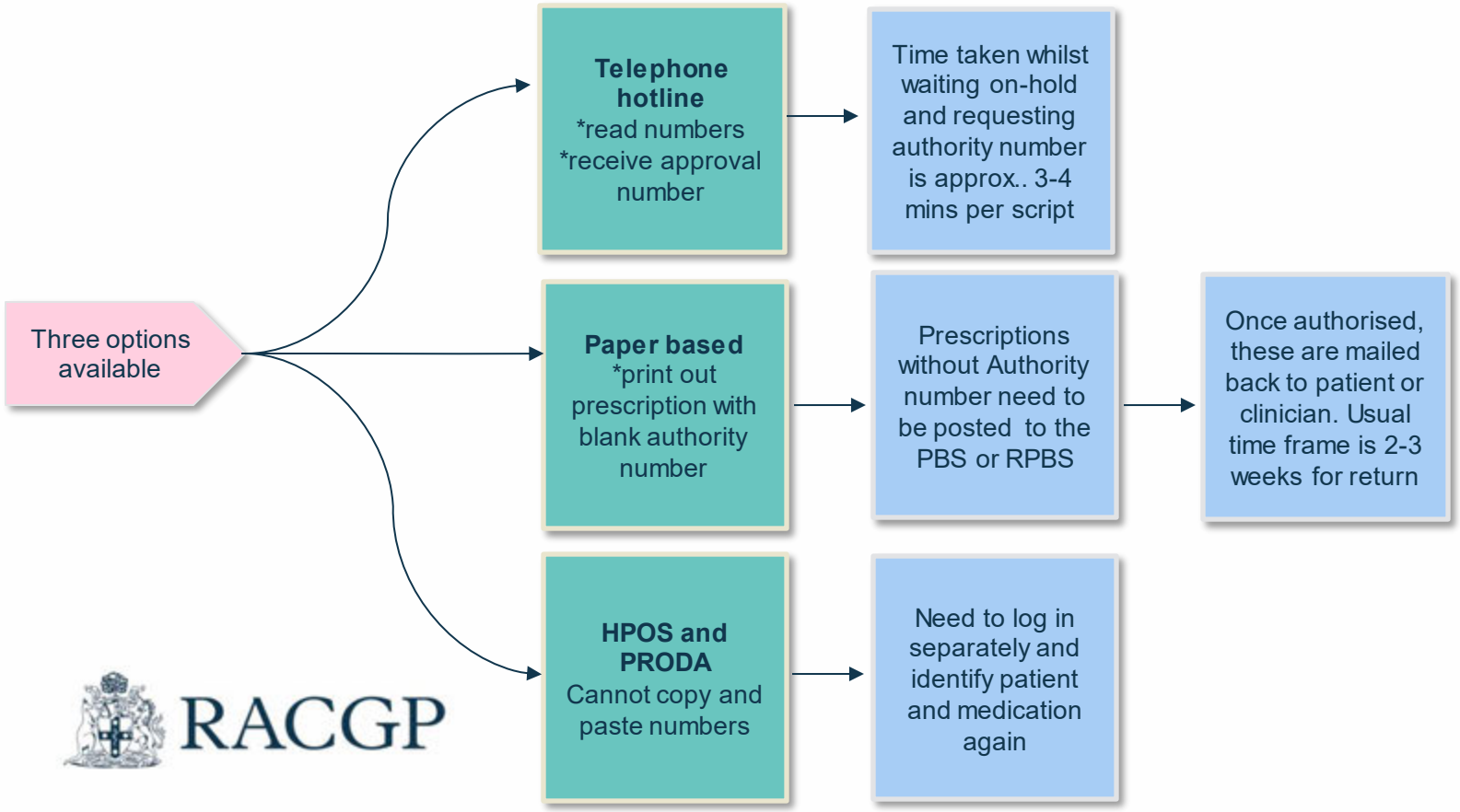
Pain points

- Approval number is not displayed
- Cannot click/copy patient Medicare, prescriber or Authority numbers
- Need all three of the above numbers to create Approval number.



Potential solution

✓ Allow click and copy function of Medicare and authority number as a minimum improvement.

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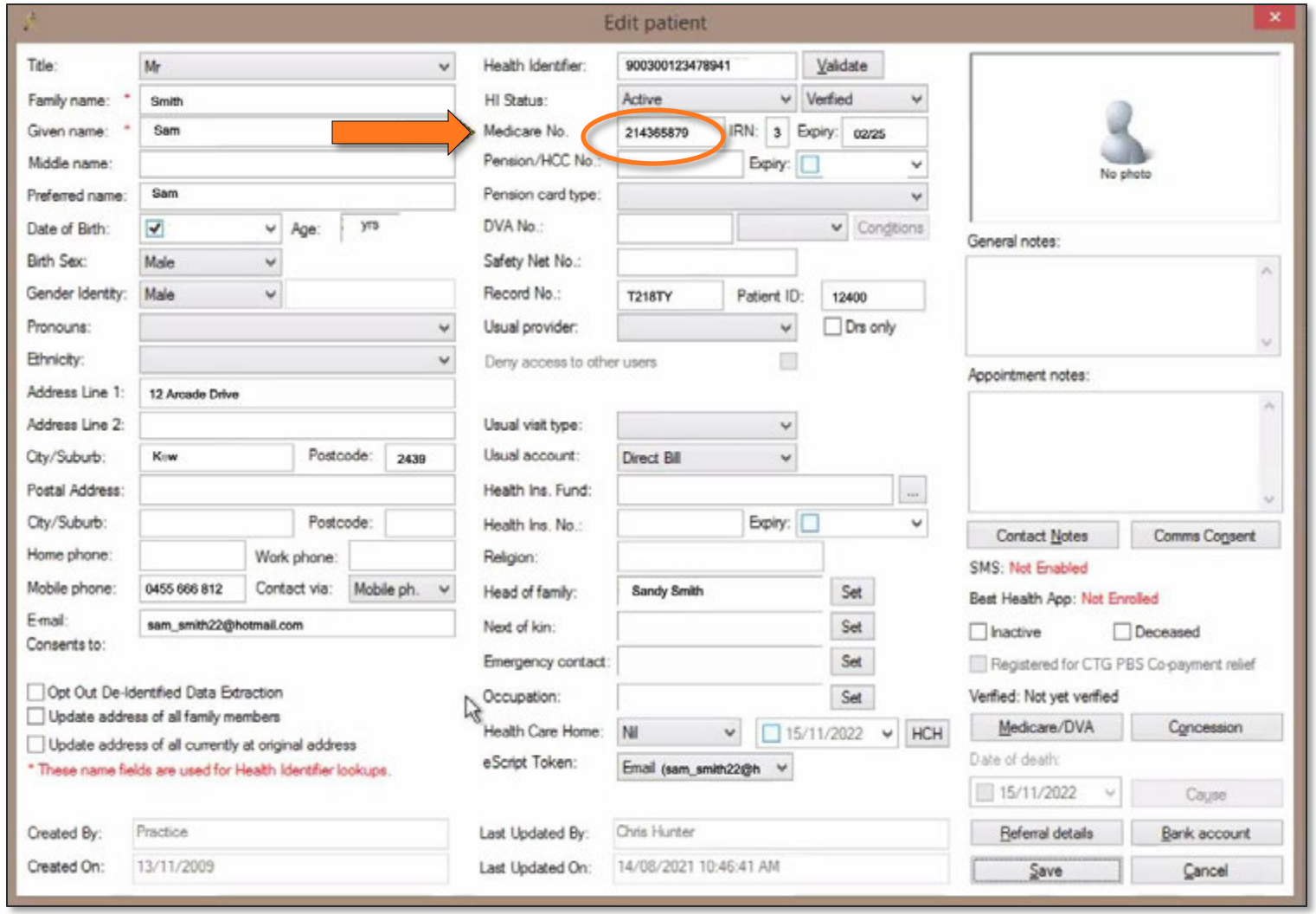
Step 7: Prepare for HPOS and PRODA process to get approval number



Overview

- Copy patient Medicare number from a different ‘Patient demographic’ section of the CIS
- Anticipate that patient Medicare number will be required
- Go to ‘Patient demographic’
- Can copy Medicare number here before going into PRODA.

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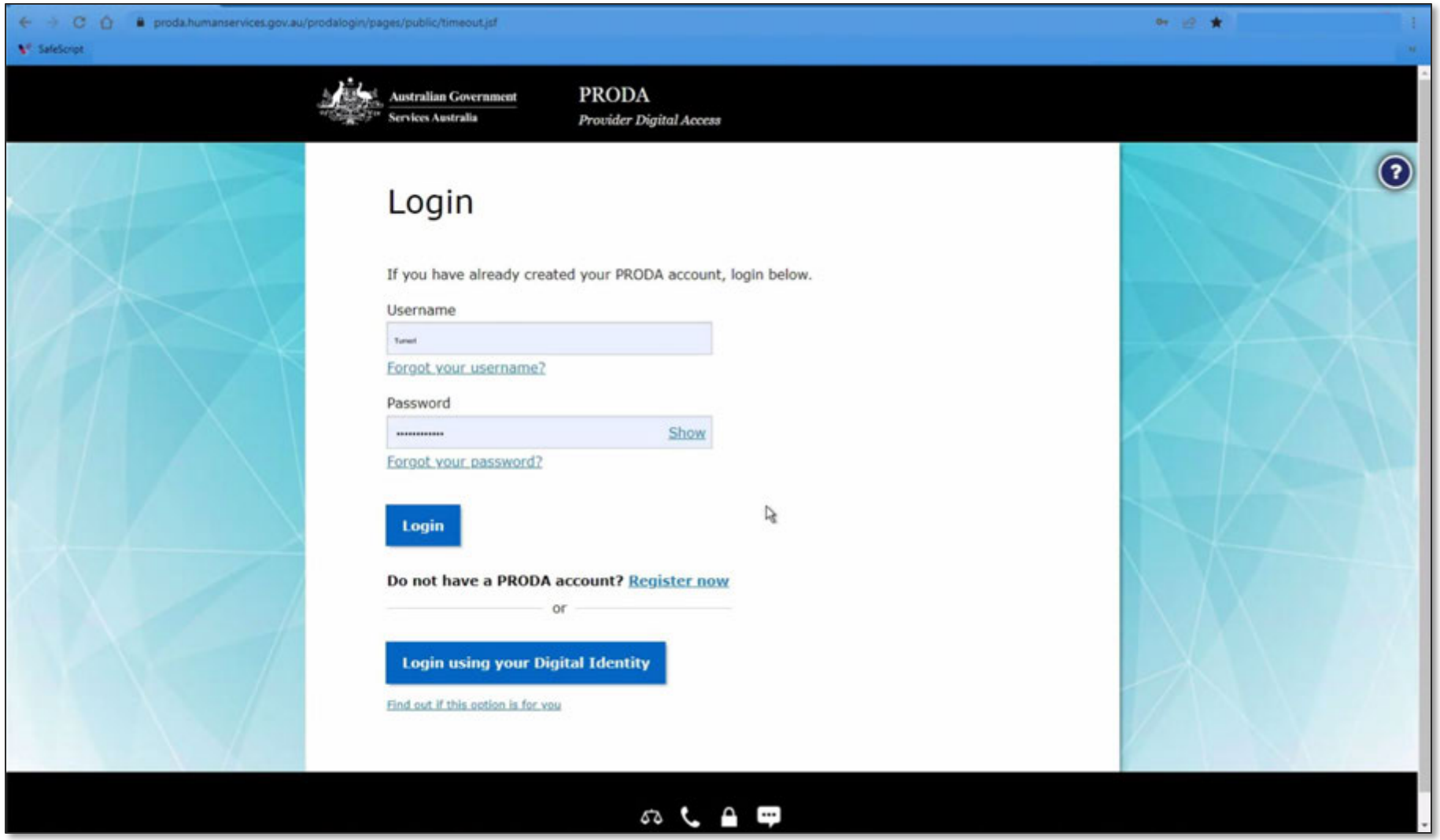
Pain points

- Can transcribe Medicare number although this option is high risk and time consuming
- Duplicating to access the same information but in a different screen that allows click and copy
- Need to close prescription process / page in order to gain access to patient demographic or;
- Copy Medicare number before starting to write script in anticipation
- Overall, this is not a natural workflow & requires pre-thinking.

Potential solutions

- ✓ Re-design process for ease and flow
- ✓ Previous solutions apply.

Step 8: Open new browser / Login page for PRODA



Overview

- Open new browser
- Login to PRODA.

Pain point

- Need to minimise window of CIS and open a new browser.

Potential solution

✓ Embed PRODA/HPOS access within CIS as authentication has already been proved.

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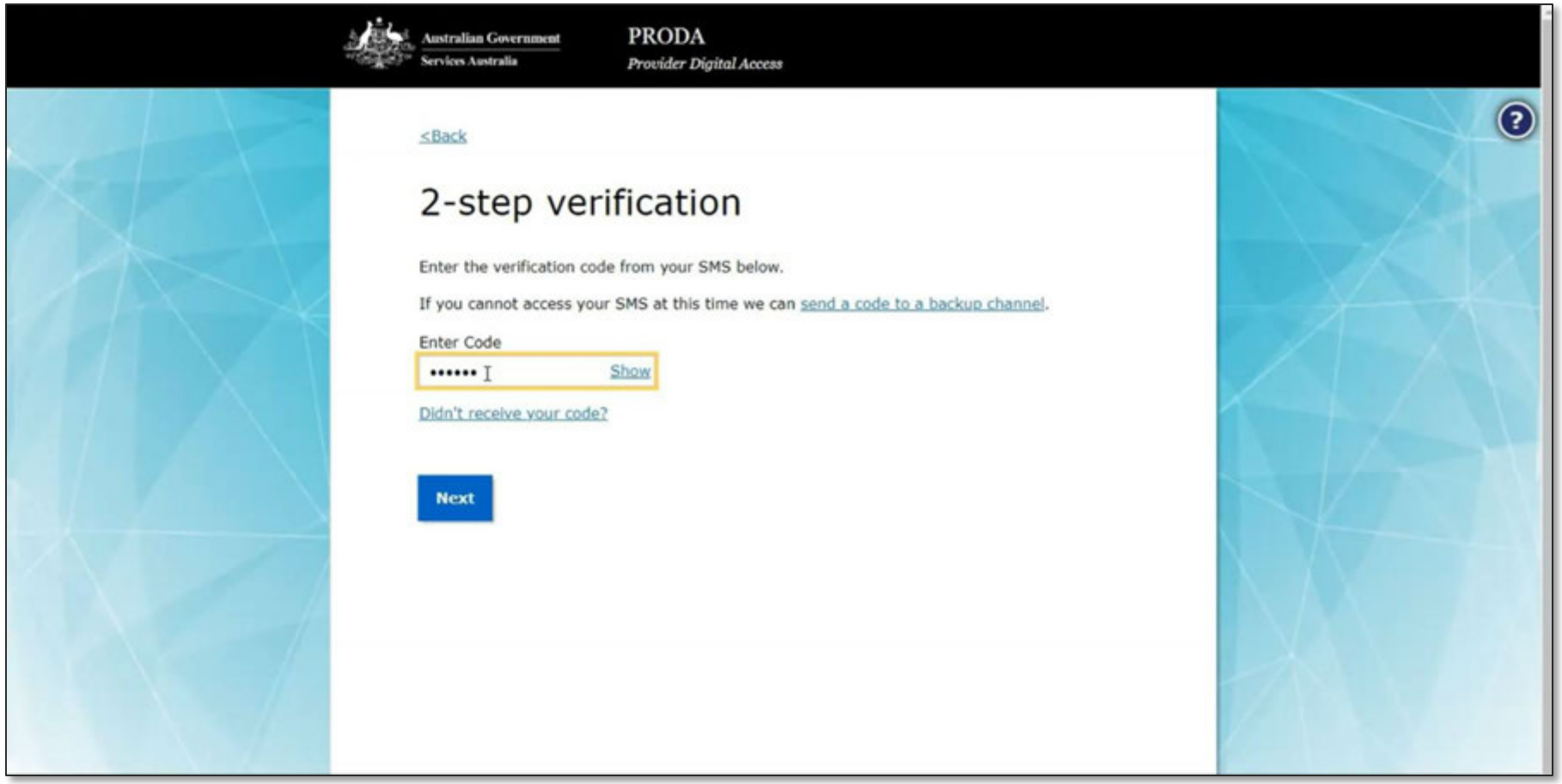
Step 8.2: 2-step verification



Overview

- Request code
- Take out phone and wait for code via SMS
- There is an added wait time for the code.
- Enter verification code
- Click 'Next'.

Pain point

- Need to take out phone to get verification number.

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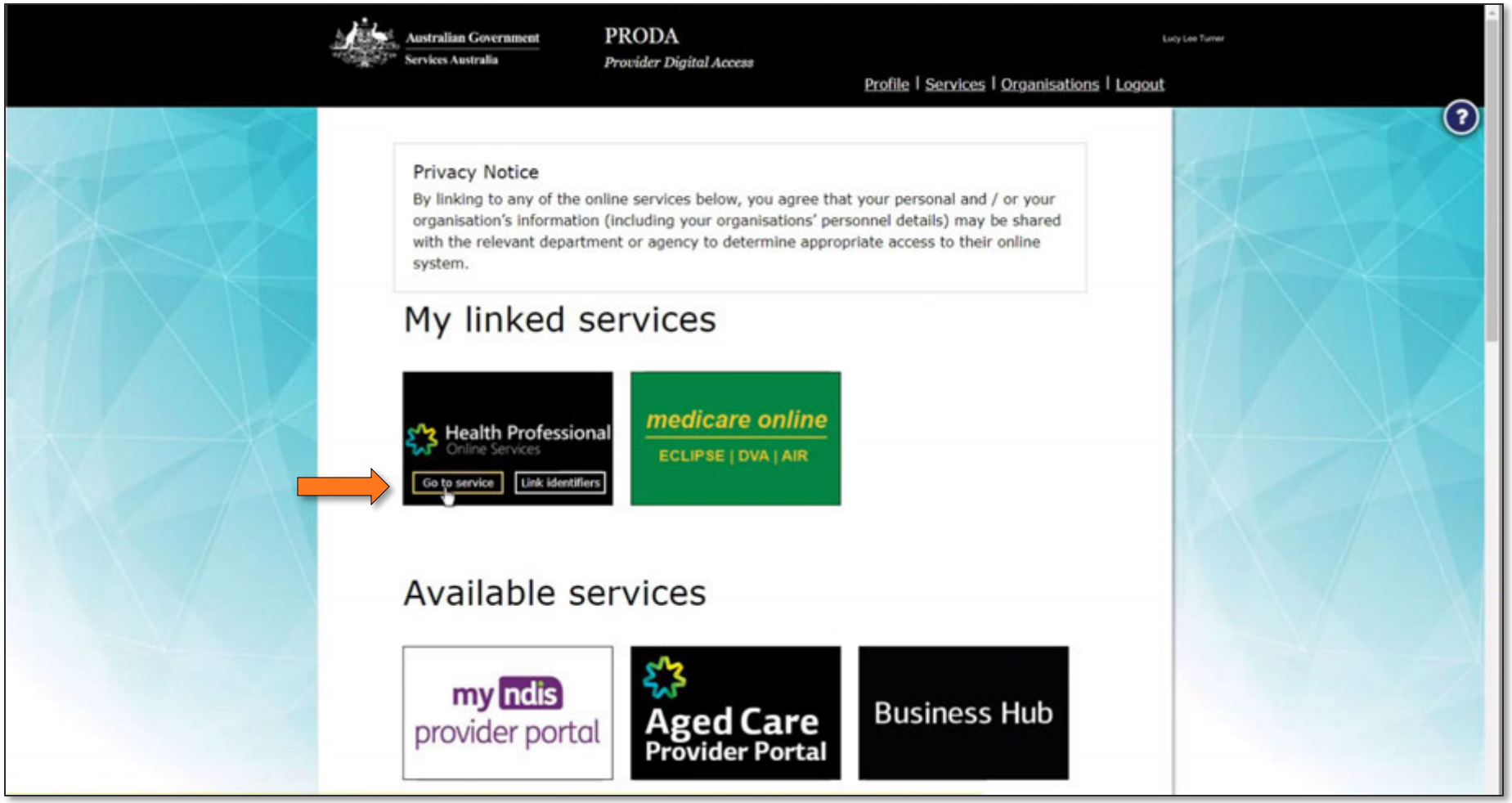
Step 9: From PRODA to HPOS



Overview

- Click 'Go to service'
- Noting some GPs will have another screen after this if they are a practice owner. Withing this additional screen you have to select if you are wanting to enter as an individual or a business entity.

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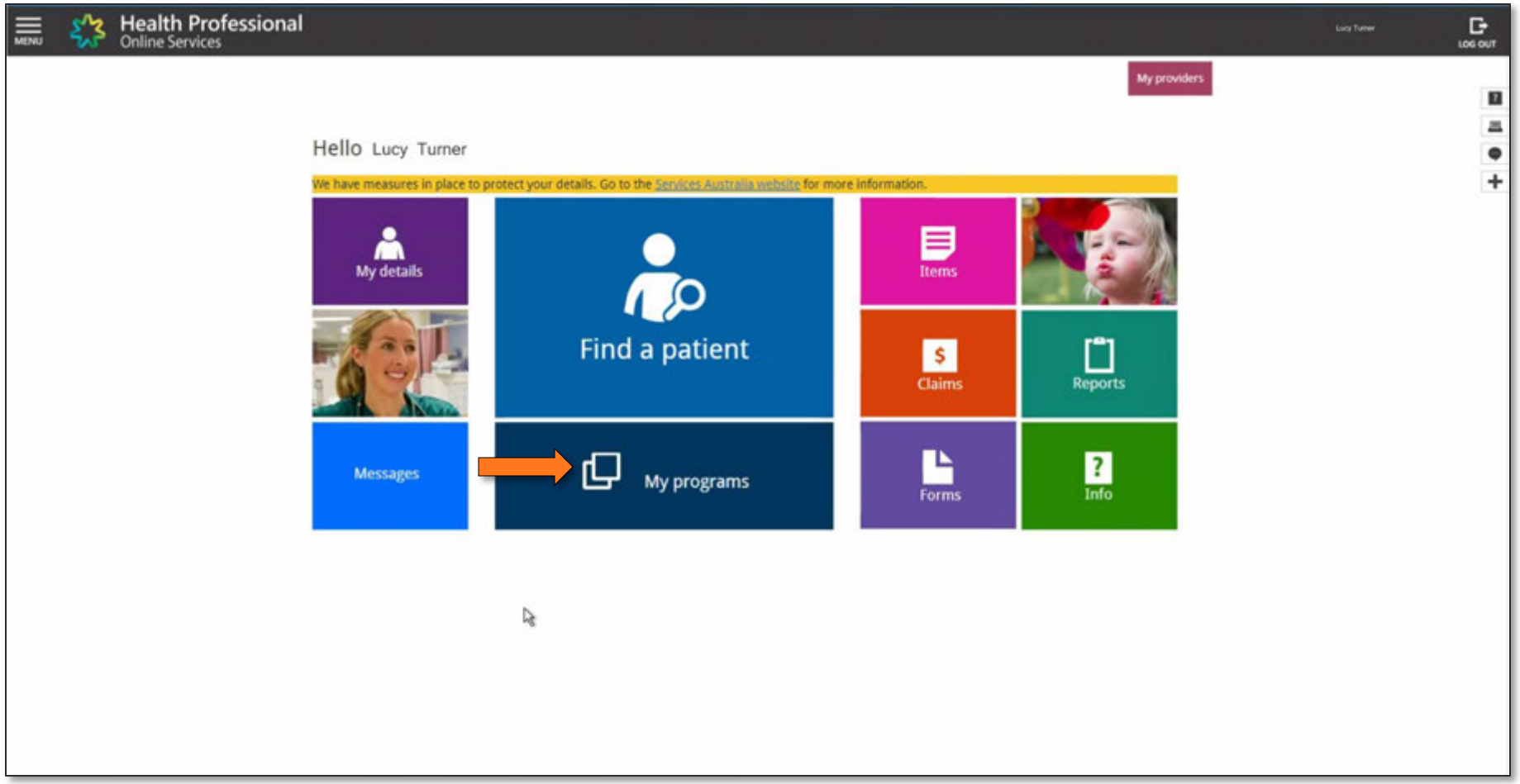
Step 10: Enter 'My programs'



Overview

- Click on 'My programs'.

Pain point

- It is not possible to return to previous screen once you have entered HPOS.

Potential solution

✓ Allow function to return to previous screen after entering HPOS.

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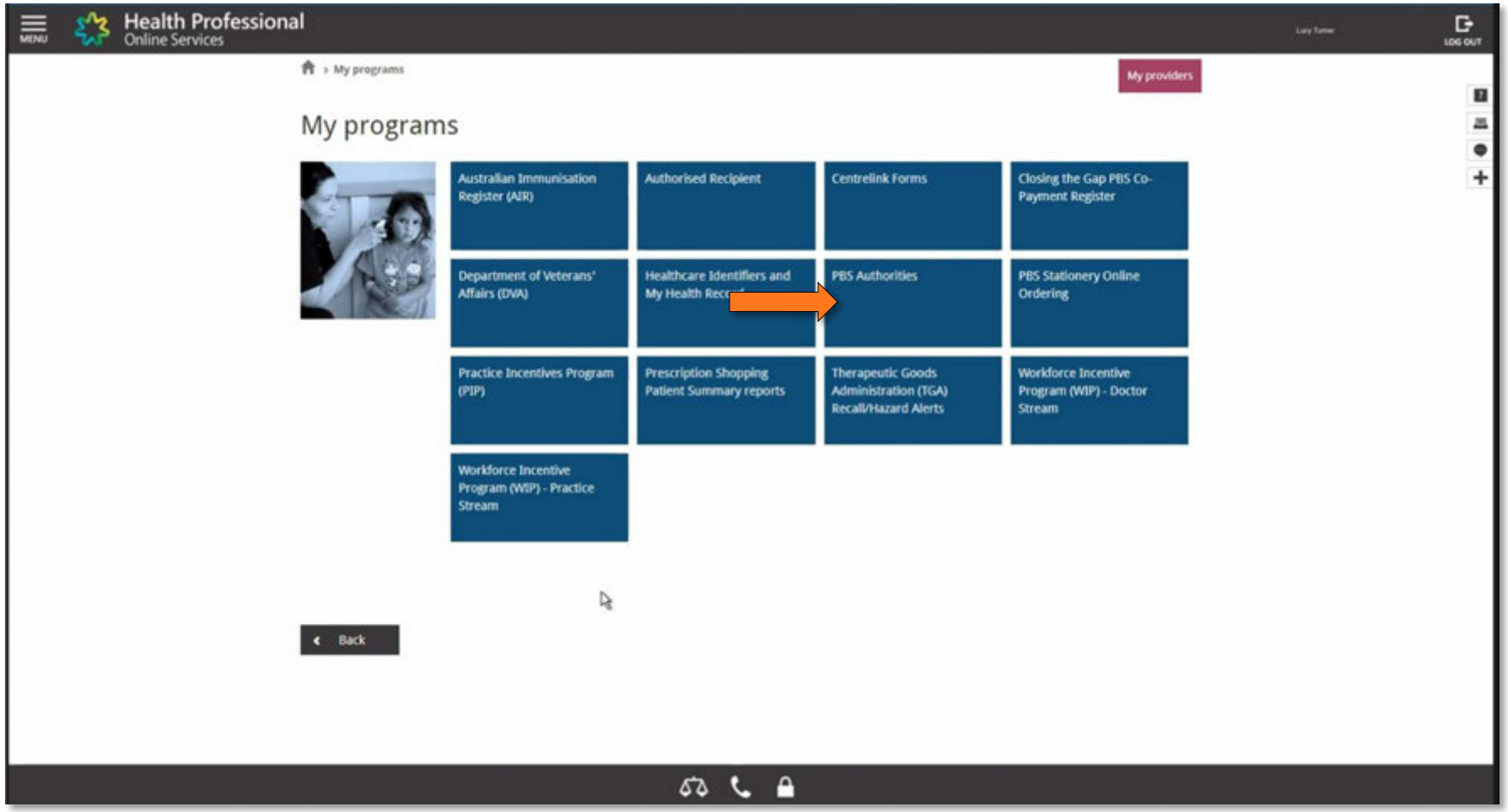
Step 11: Enter PBS Authorities



Overview

- Click on 'PBS Authorities'.

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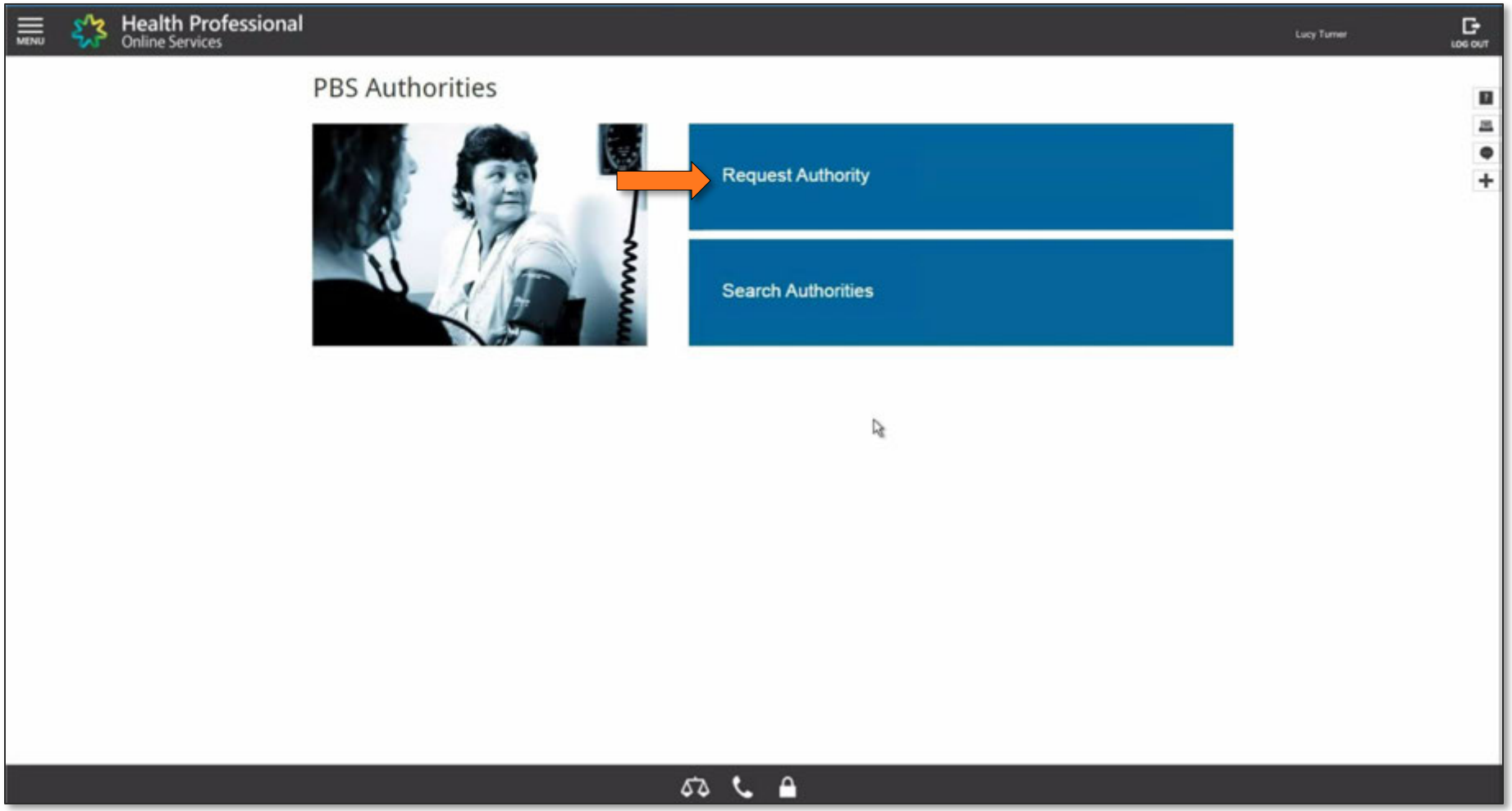
Step 12: Request Authority



Overview

- Click 'Request Authority'.

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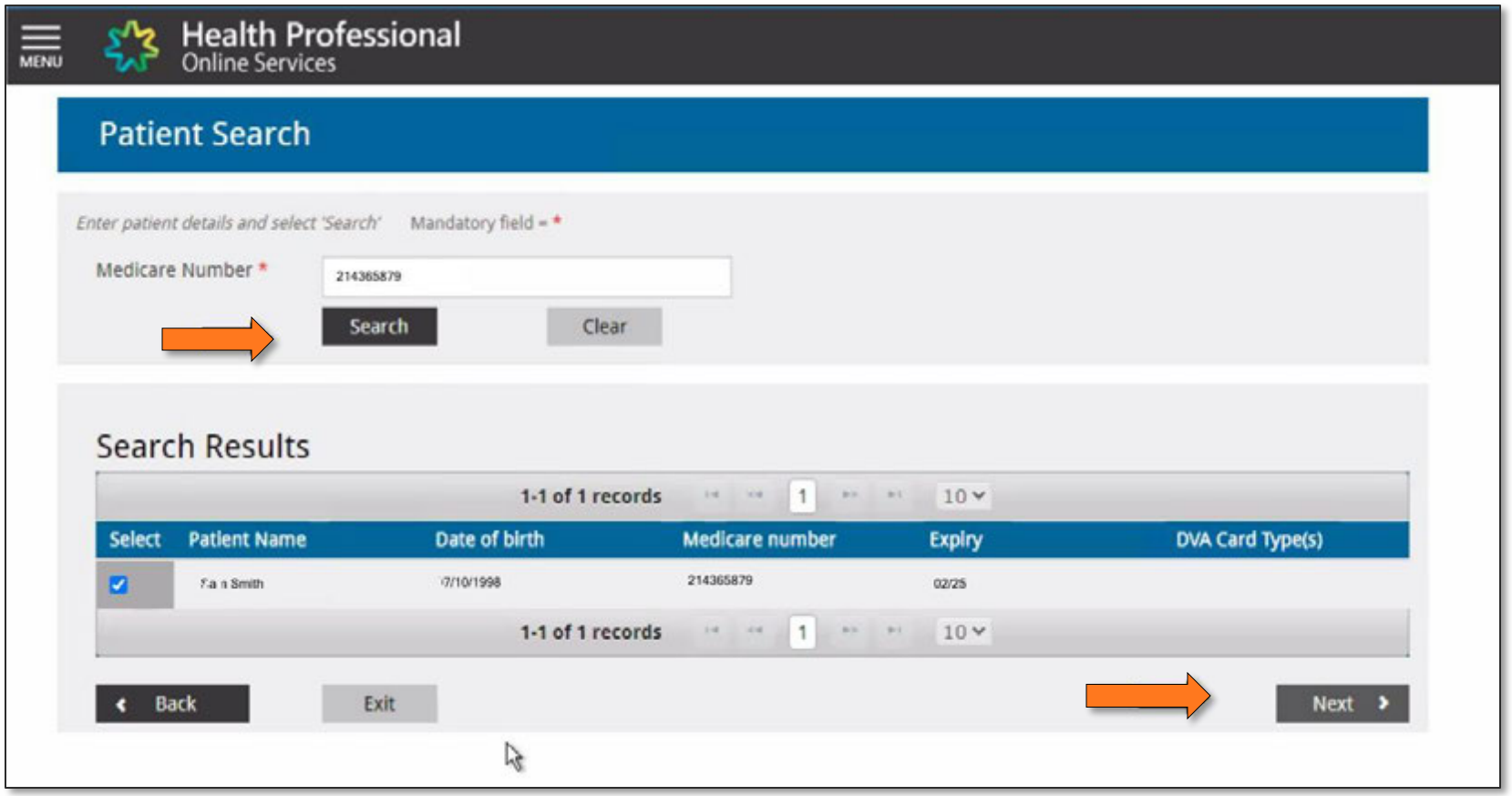
Step 13: Patient search using Medicare number



Overview

- Enter / paste patient Medicare number
- You need to know what number patient is one the Medicare card
- Click 'Search'
- Find patient in Search Results
- Select patient
- Click 'Next'.

Pain points and potential solutions continued next slide

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Pain points

- Can only use Medicare number
- Cannot use IHI to confirm identity of patient
- Copy function does not pick up line number of patient for Medicare number
- You must separately note a patient's line number as well as their Medicare number.

Potential solutions

- ✓ Allow IHI's to be used in patient search
  - IHI's are a more universal and secure number to use
  - Medicare numbers were leaked in Optus breach
- ✓ Allow line number of patient to be easy to copy across, with the Medicare number.

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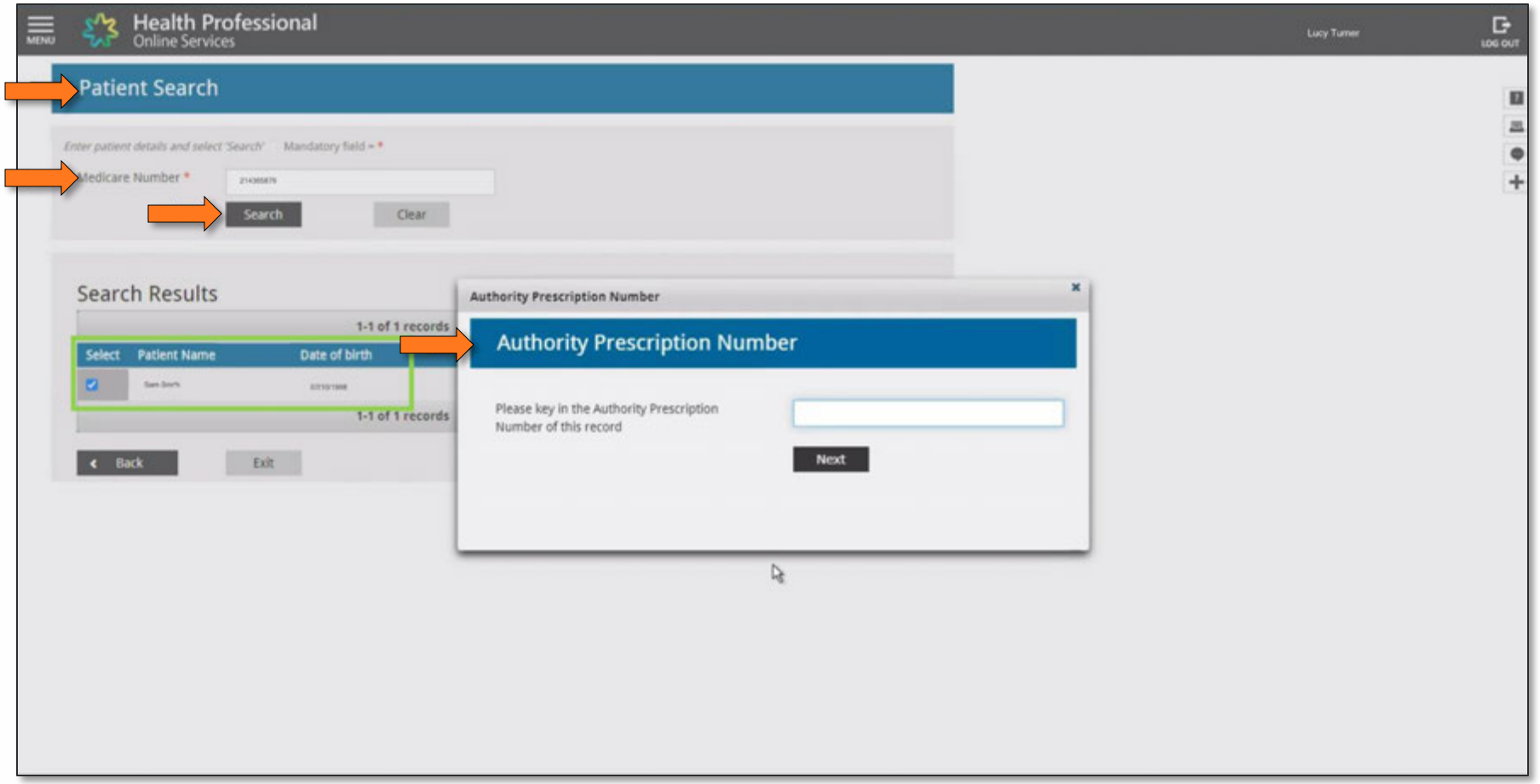
Step 14: Enter patient details, prompt for Authority Prescription Number



Overview

- Use the Medicare number (including line number) to identify the patient
- Need to enter Authority Form number (roadblock).

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Pain points

- Need to go back to CIS to obtain the Authority Form Number.

Potential solutions

- ✓ Have this process accessible directly from CIS
- ✓ Avoids duplication of data entry
- ✓ Minimises risk of error.

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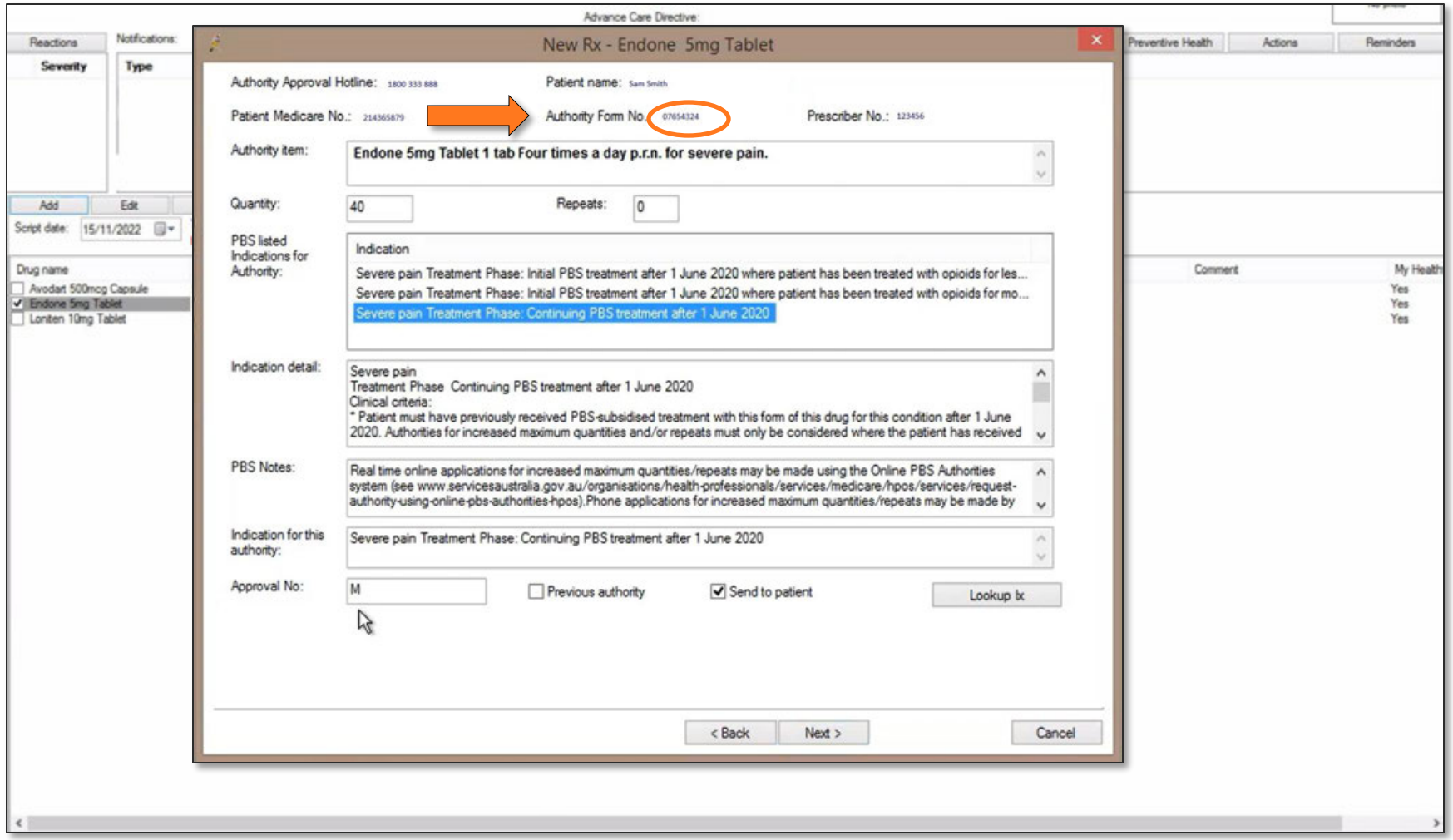
Step 15: Go back into CIS to get Authority Form No.



Overview

- Select and click on medicine being ordered
- Write down/remember Authority Form Number from CIS.

Pain points and potential solutions continued next slide

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Pain points

- Cannot copy Authority Form number from CIS
- Need to copy onto paper. This work-around is not technologically advanced.
    - Should not be a need to write anything down on paper.

Potential solutions

- ✓ Allow copy function of Authority Form number from CIS
    - Eliminates the need to write codes on paper.

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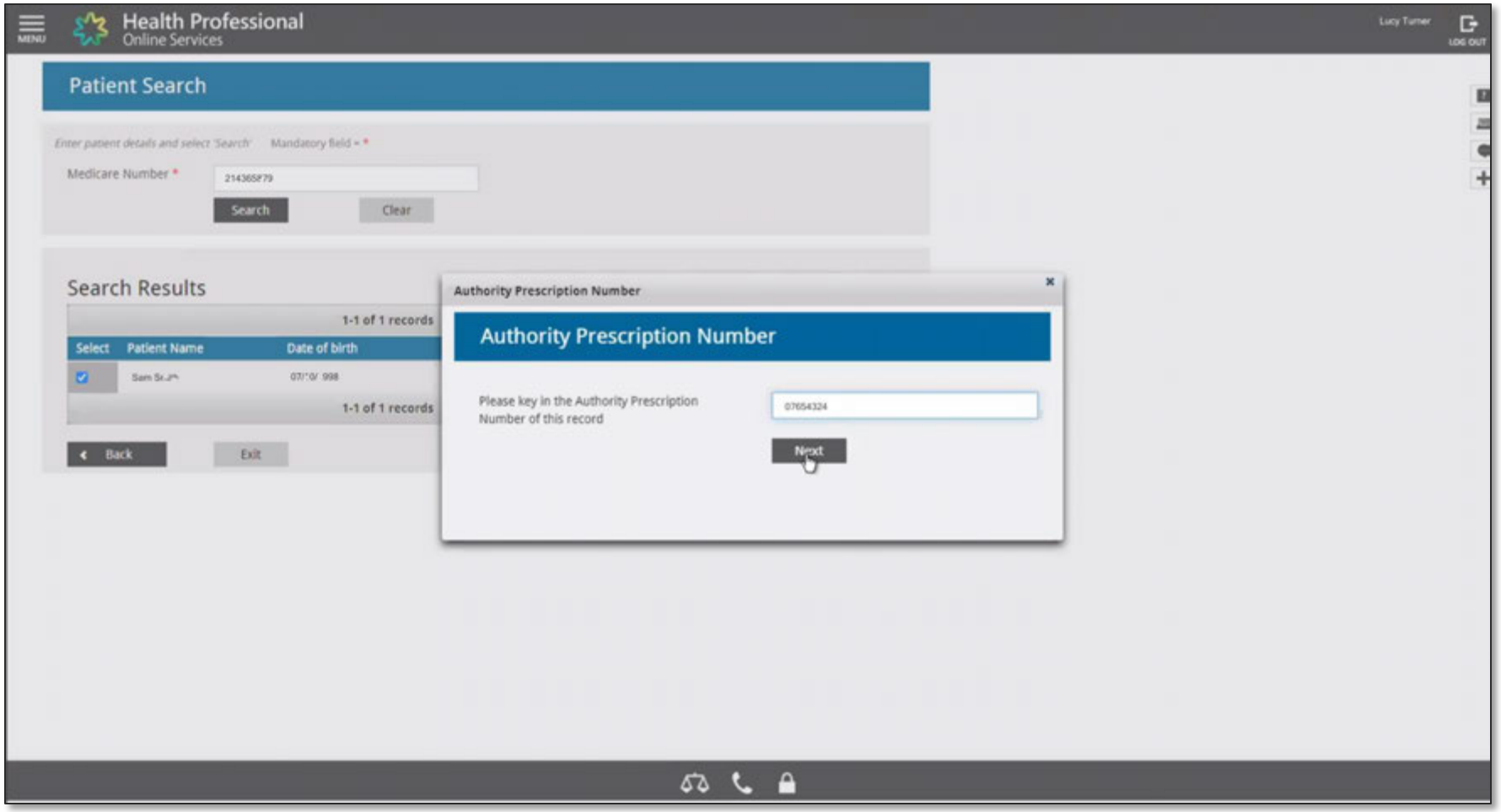
Step 16: Enter Authority Prescription number



Overview

The Prescription number is generated by the CIS, however this cannot be copied (needs to be remembered or written down)

- Enter Authority Prescription Number
- Click 'Next'.

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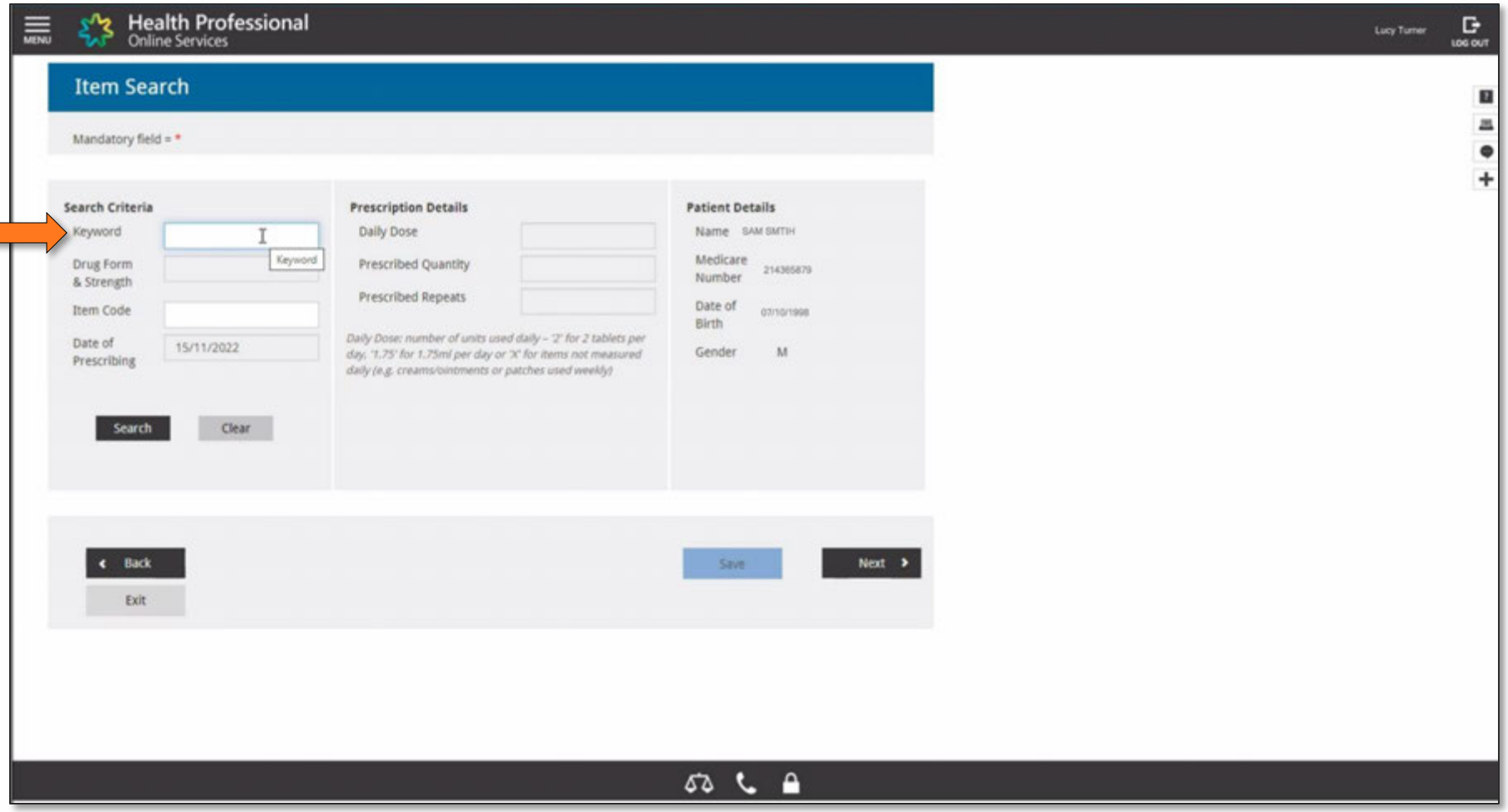
Step 17: Search for desired medicine



Overview

- Search for medicine <u>again</u>.

Pain points and potential solutions continued next slide

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Pain points

- Need to re-enter medicine and select correct dosage again
- The CIS and PBS Authorities system do not communicate.

Potential solutions

✓ Make the CIS and PBS Authorities system interoperable

- Eliminates the need to enter duplicate information of medicine
- Reduced administration time to focus on delivering high quality care in consultation.

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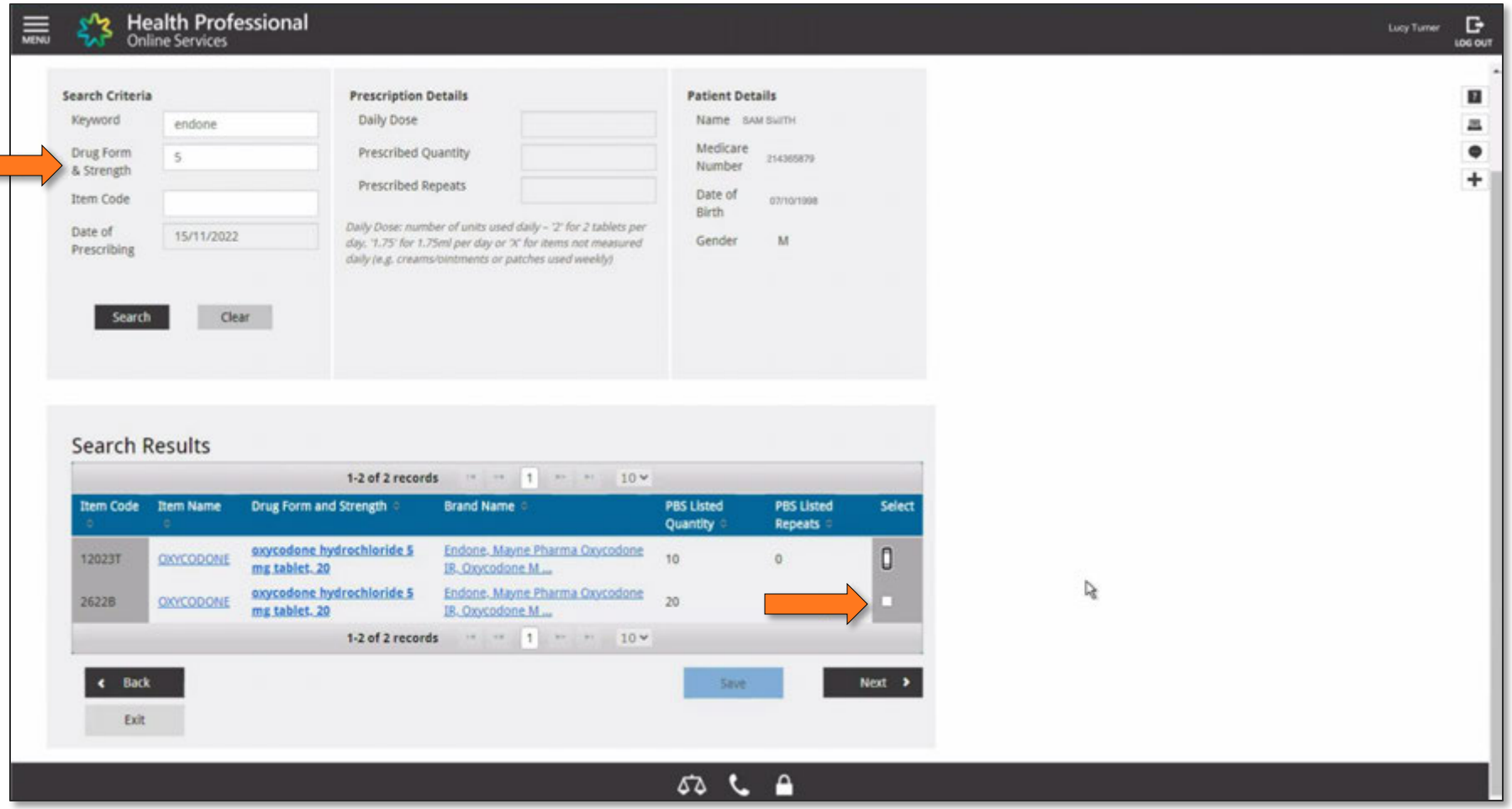
Step 18: Searching for desired medication (again) in HPOS



Overview

- Enter medication form and strength
- Click 'Search'
  - Provides options below to choose from
  - Same choices as previously selected.

Pain point

- Entering duplicate data from CIS
- Using a different medicine search tool.

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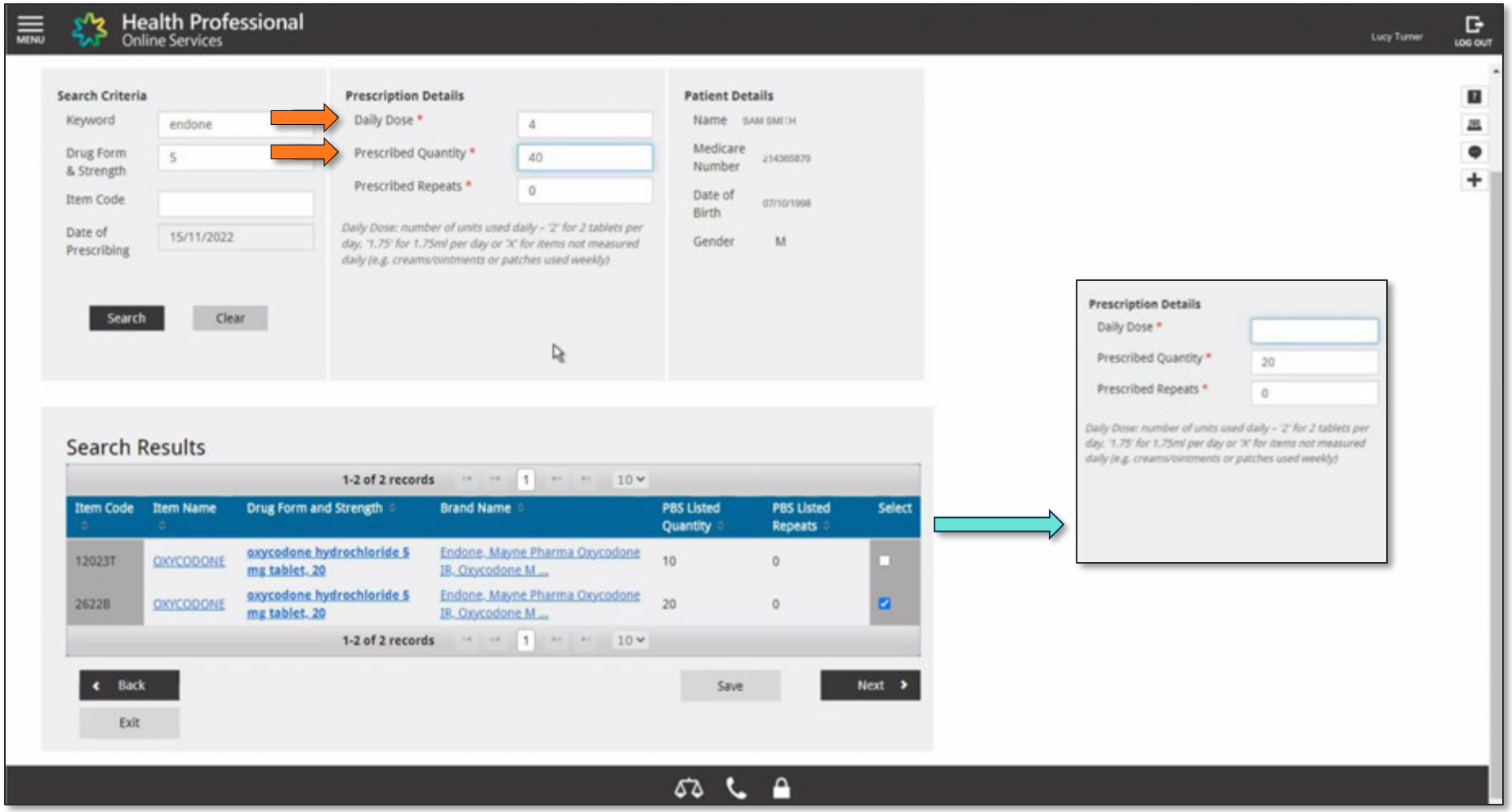
Step 19: Enter unique daily dose and quantity (duplicated as per CIS)



Overview

- Enter daily dose
- Change "Prescribed Quantity" to match the quantity being requested in the CIS
- Click 'Next'.

Pain points and potential solutions continued next slide

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Pain points

- Need to remember medicine details and dosage from CIS
  - These details must be correct, or the request fails
  - In that case, you would need to begin to process again
- Entering duplicate data from CIS – manually repeated.

Potential solution

✓ Have medicine information and dose automatically transcribe from CIS to HPOS.

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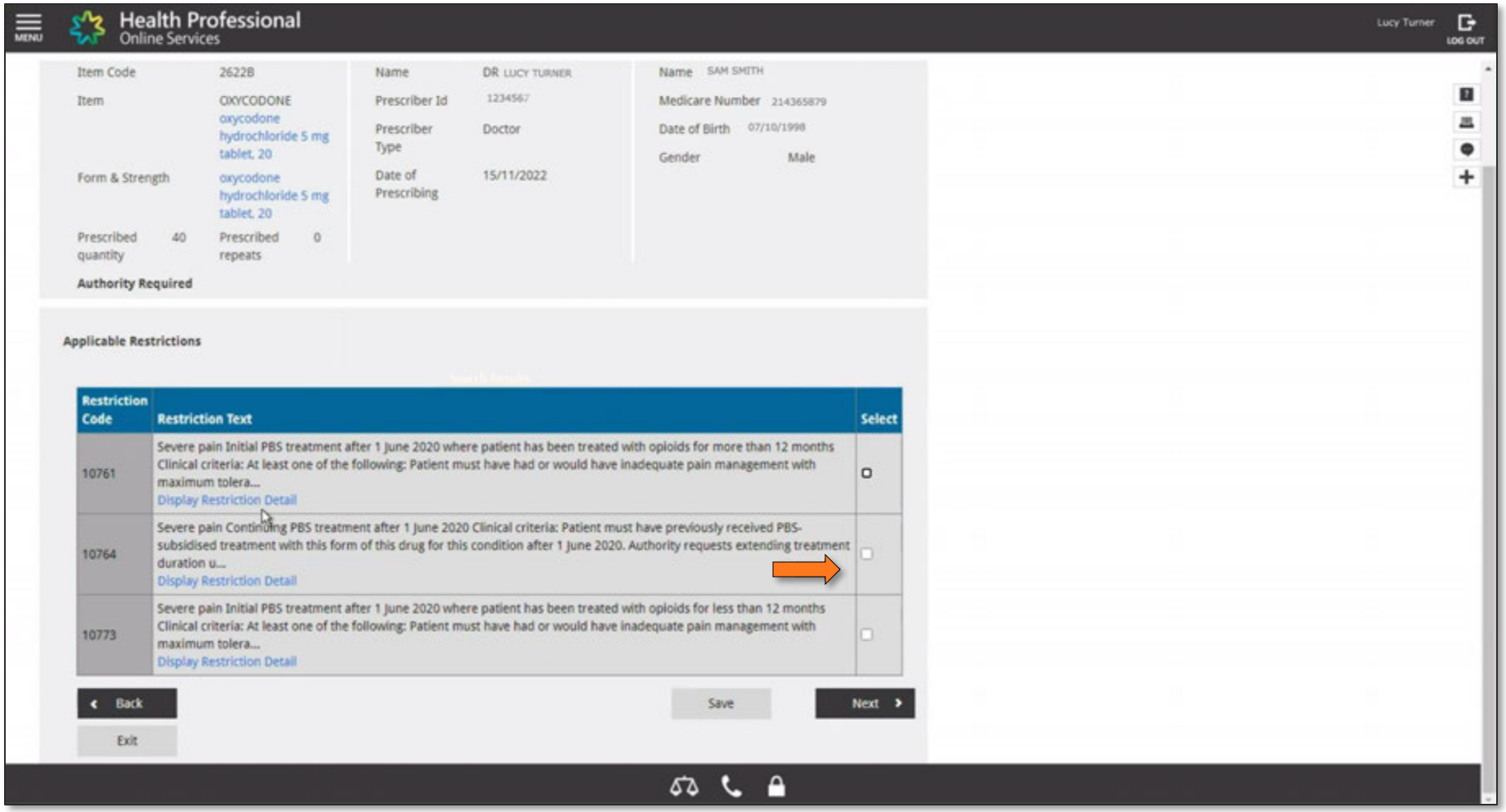
Step 20: Select reason for prescription (as per CIS)



Overview

- Select reason from prescription
  - Must match information in CIS
- Click 'Next'.

Pain point

- Need to remember reason for prescription from CIS.

Potential solution

✓ Automatically populate reason for prescription from CIS into HPOS.

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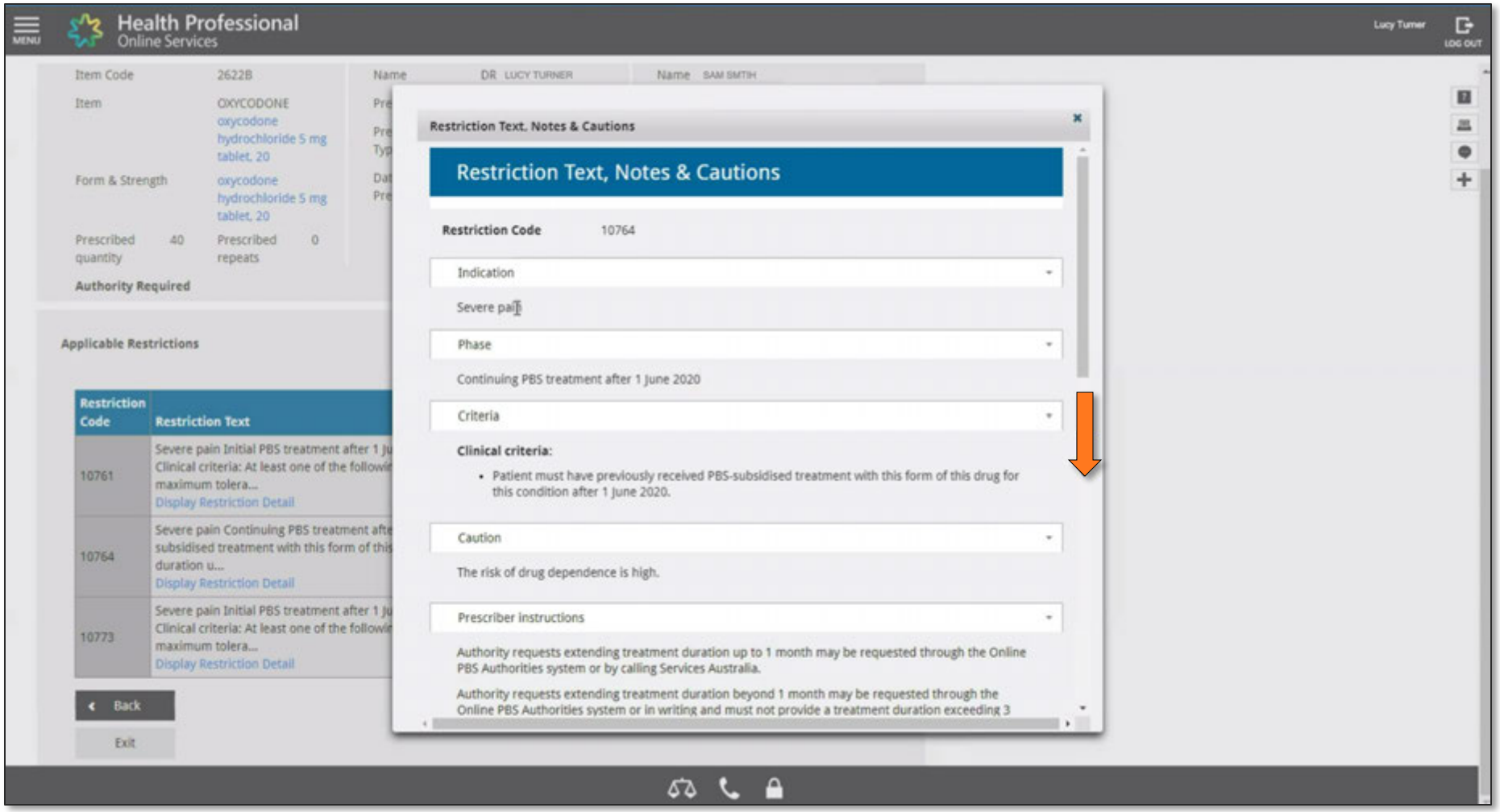
Step 21: Review restriction notes



Overview

- Read and review restriction notes along with cautions as per protocol.

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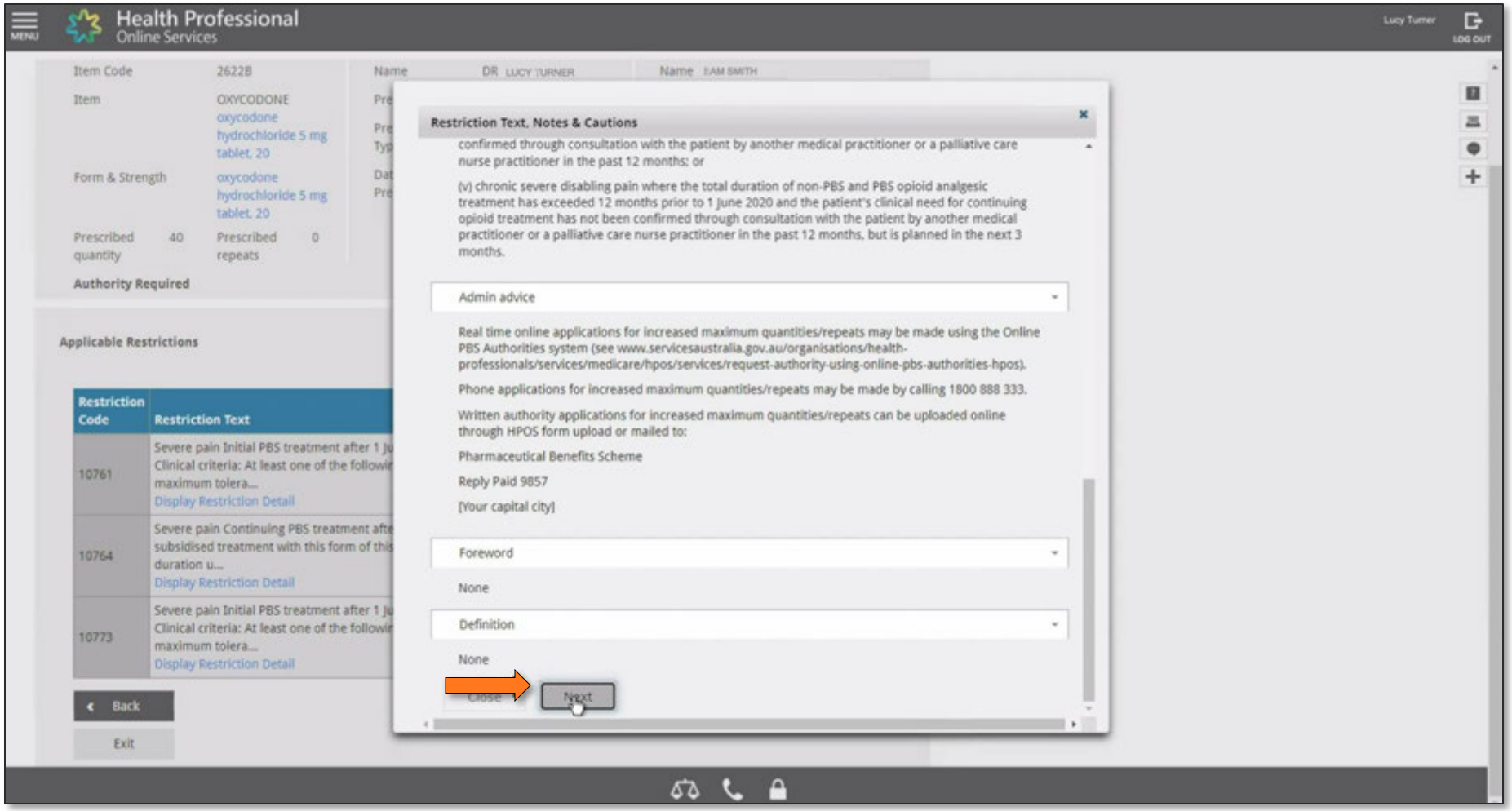
Step 22: Scroll to read and review further restriction notes



Overview

- Scroll down
- Read rest of prescription notes
- Click 'Next' once the medicines restriction and caution text is reviewed and confirmed.

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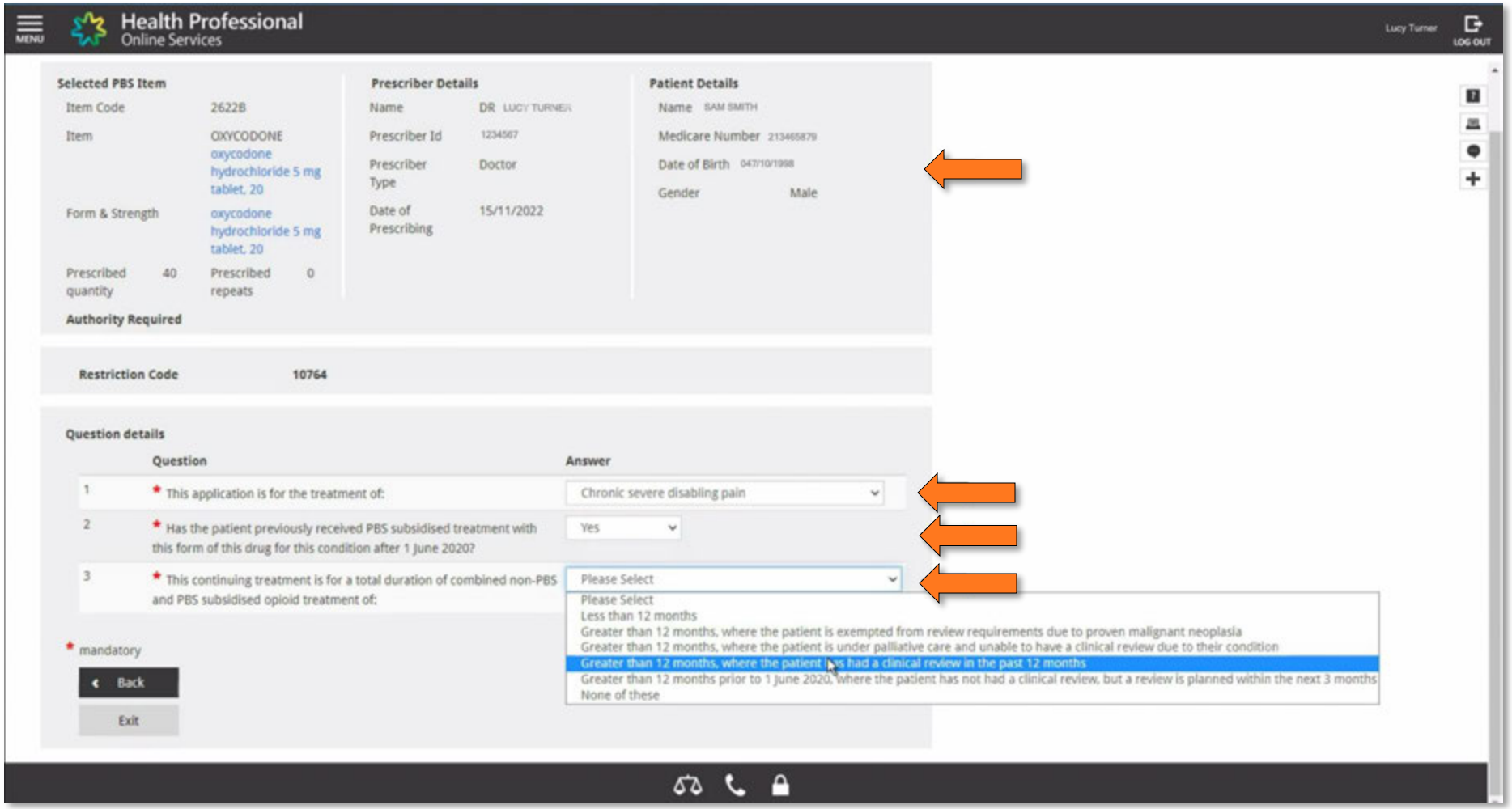
Step 23: Answer prescription questions



Overview

- Review details
- Answer all three questions via the drop-down menus
- Click 'Next'.

Pain point

- Reviewing data again
- Must select correct line or request will be rejected.

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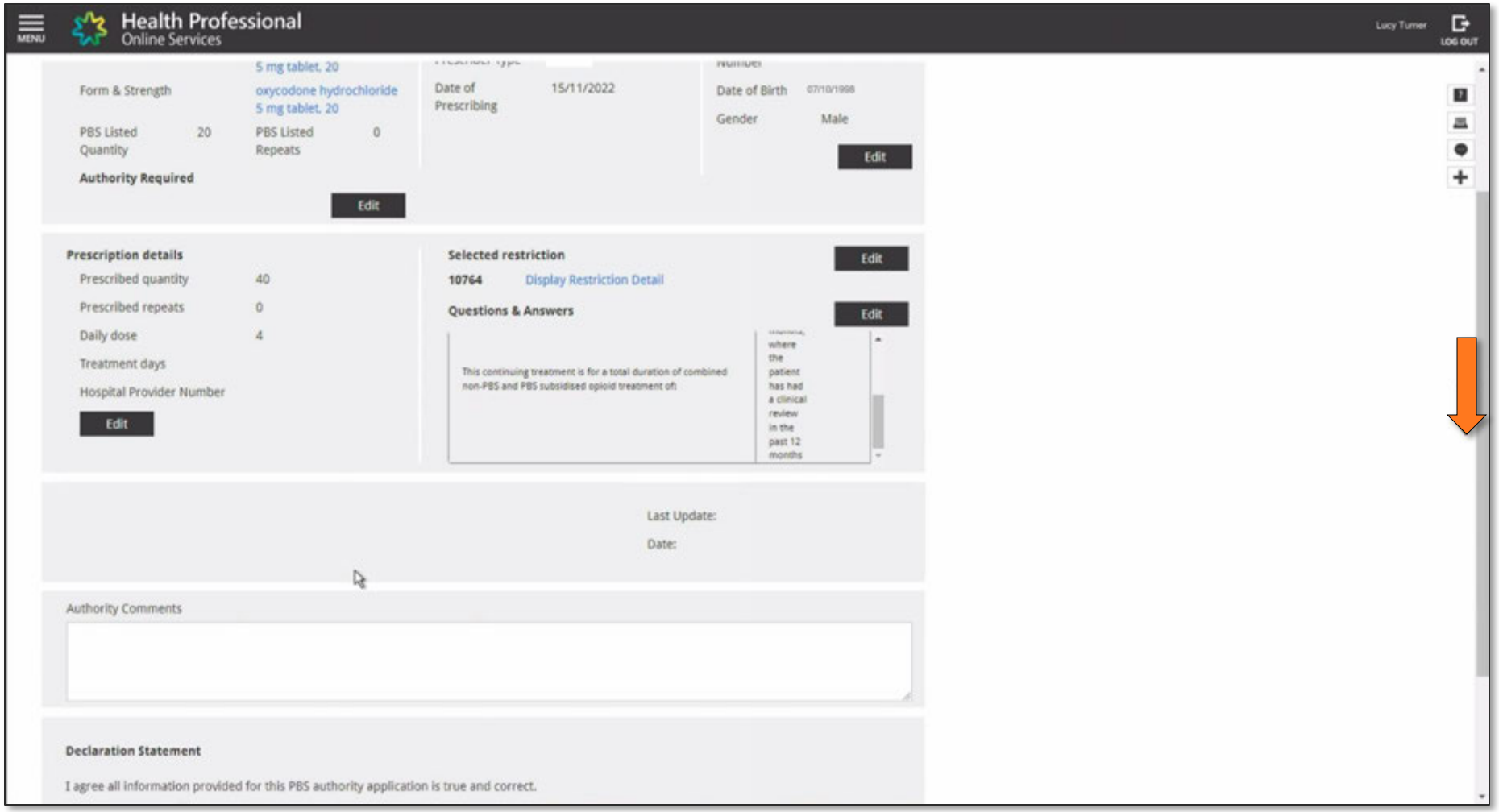
Step 24: Opportunity to review individual pages and make edits if required



Overview

- Review information
- Make any edits if required
- Scroll down.

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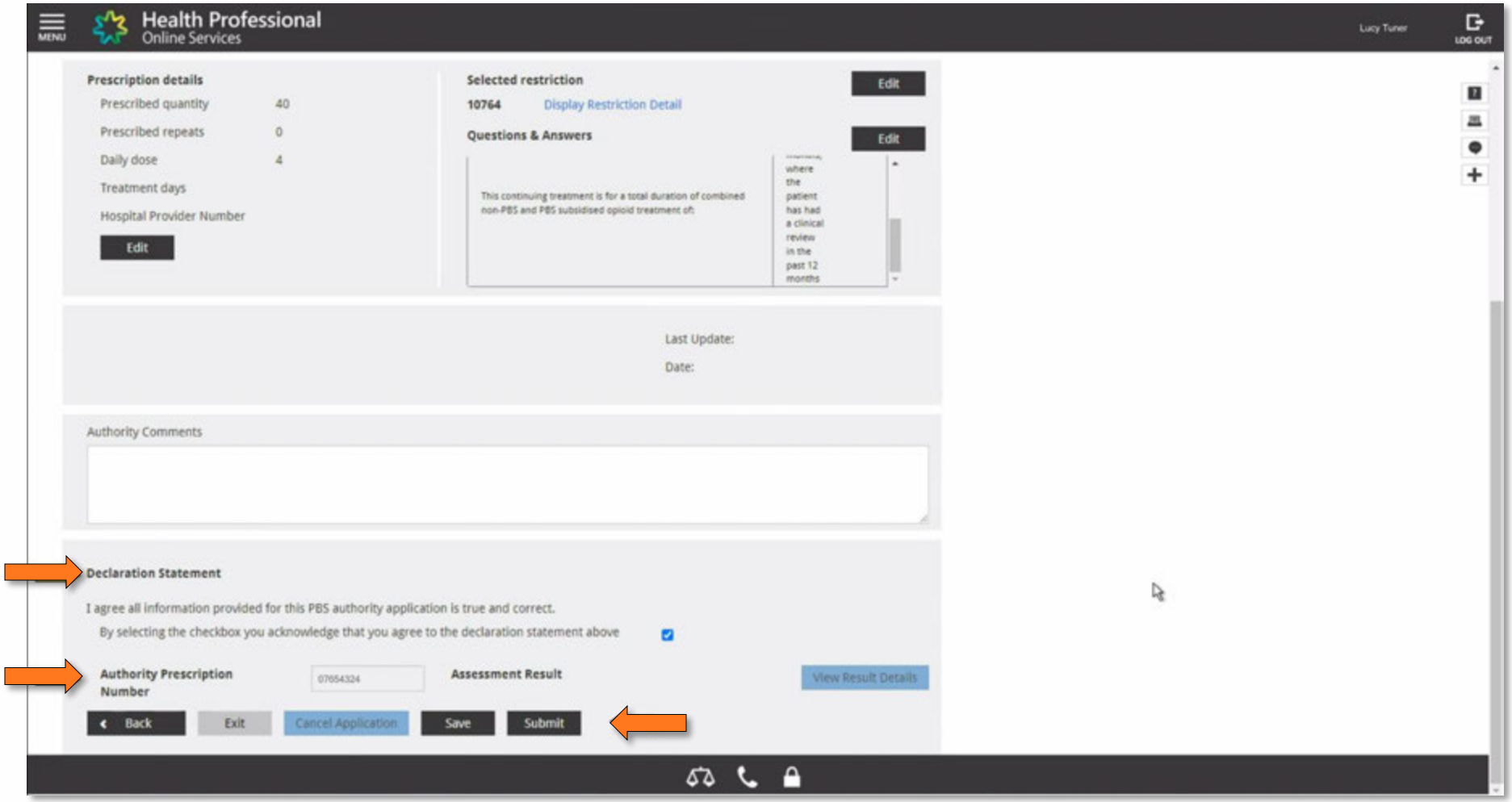
Step 25: Review data, agree to declaration and submit



Overview

- Click to 'Agree' to Declaration Statement
- Review and edit Authority Prescription Number information if required
- Click 'Submit'.

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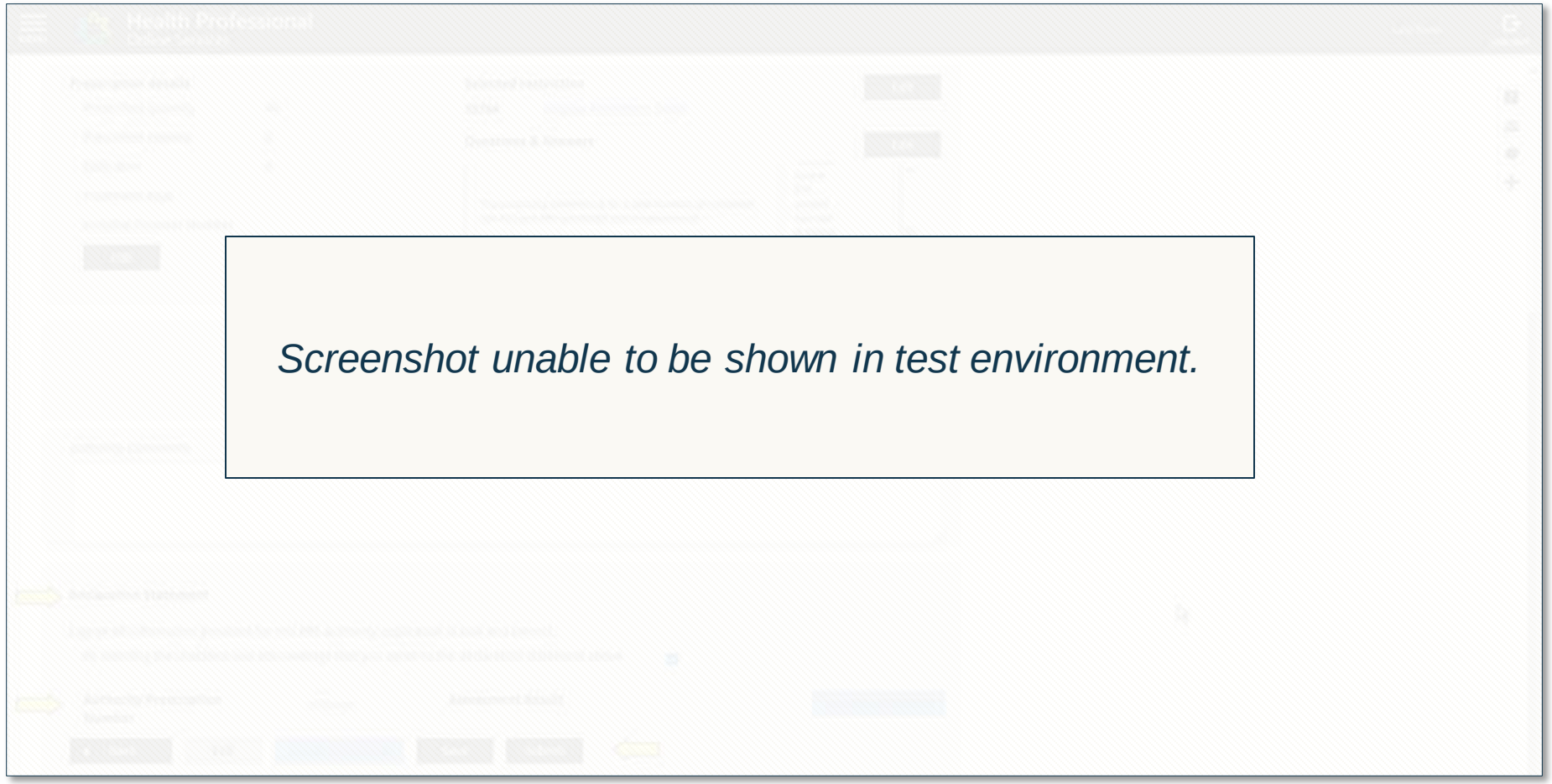
Step 26: Approval number is provided



Overview

- If all is correct, Authority Approval Number is created by system
- Authority Approval Number can (and must be) copied
- Then return to CIS to input number to complete prescription.

Pain point

- Need to switch back to CIS to complete prescription
- If authority prescription is rejected, the reason is unclear and need to restart the whole process again.

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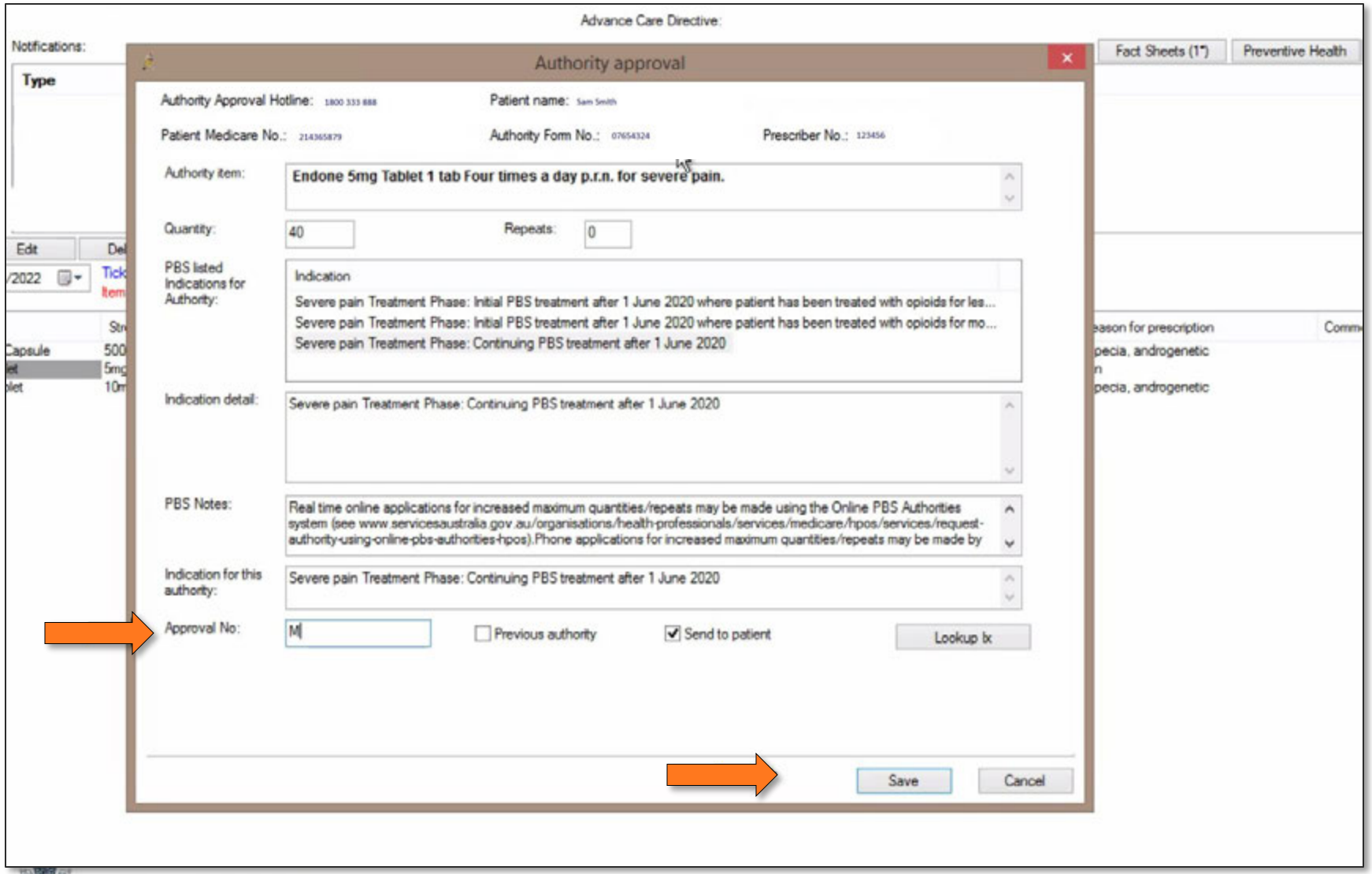
Step 27: Go back into CIS to enter approval number and complete script



Overview

- Paste approval number
- Click ‘Save’
- After 'Save', then print script or send via eScript system to patient or delegate.

Pain point

- Need to switch back to CIS to complete prescription.

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Safe Script process

Victorian system

Highlights potential opportunities for PBS Authorities:

- ✓ Streamlined
- ✓ Integrated with CIS
- ✓ Intuitive for GPs to use

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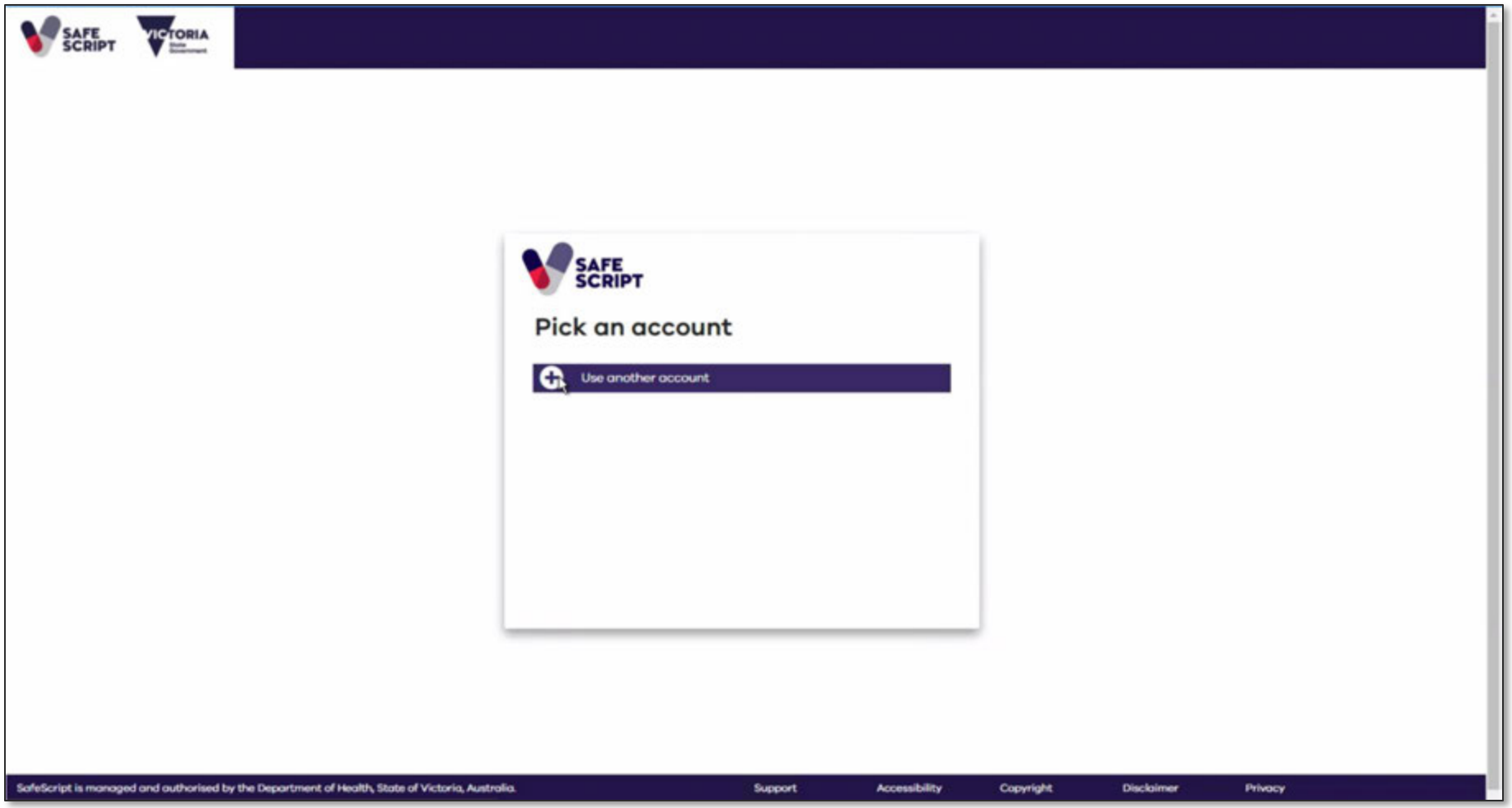
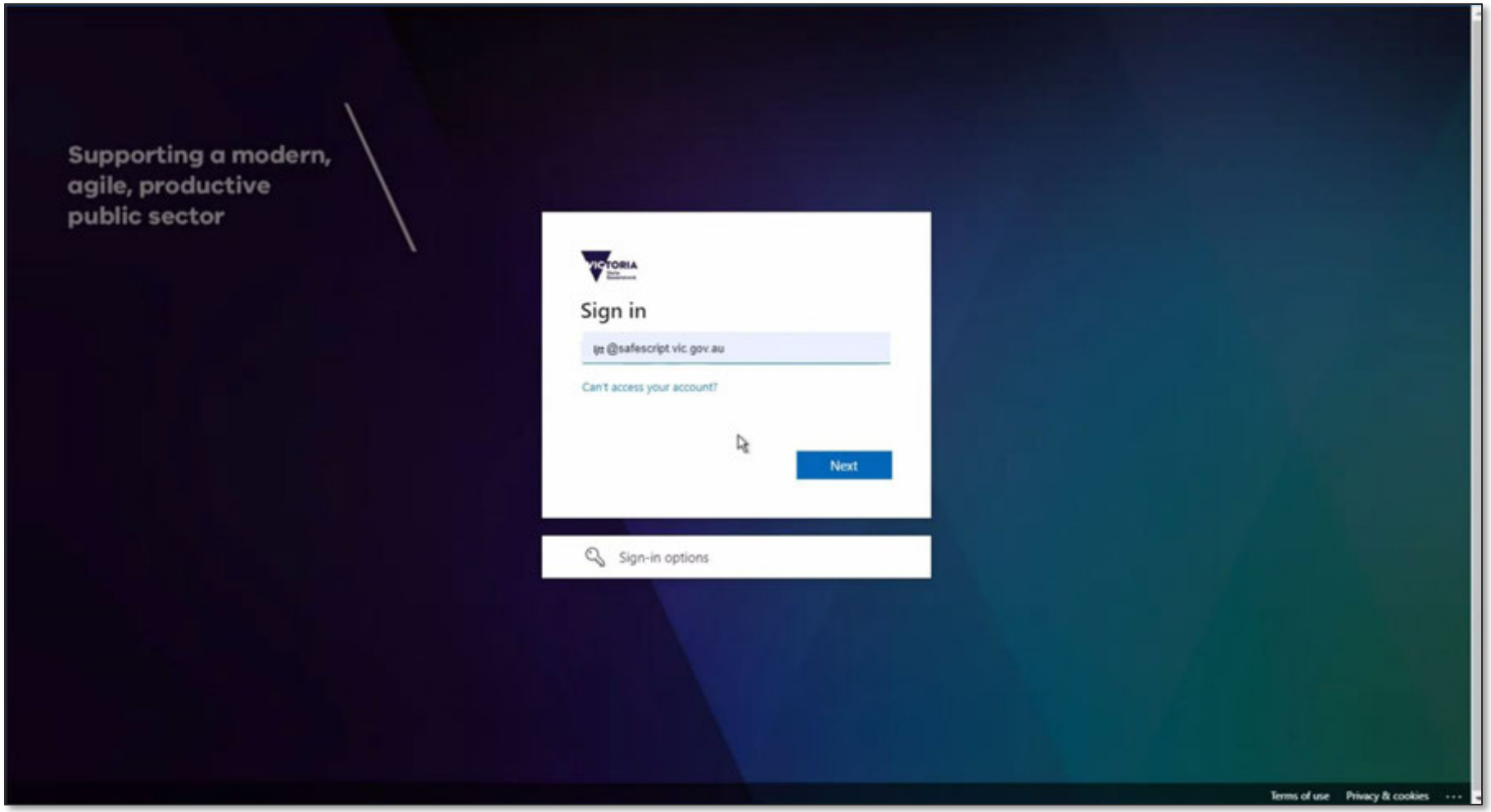
Step 1: Login process via CISS



Overview

- Load up Safe Script via CIS (Vic System)
- Note, you must review Safe Script and open it up if you have a **red flag notification** in the CIS.

Step 2: Enter user details



Overview

- Sign in via Safe Script login details

Pain point

- Separate login details are required.

Potential solution

✓ The system should automatically recognise the doctor, since already connected via CIS.

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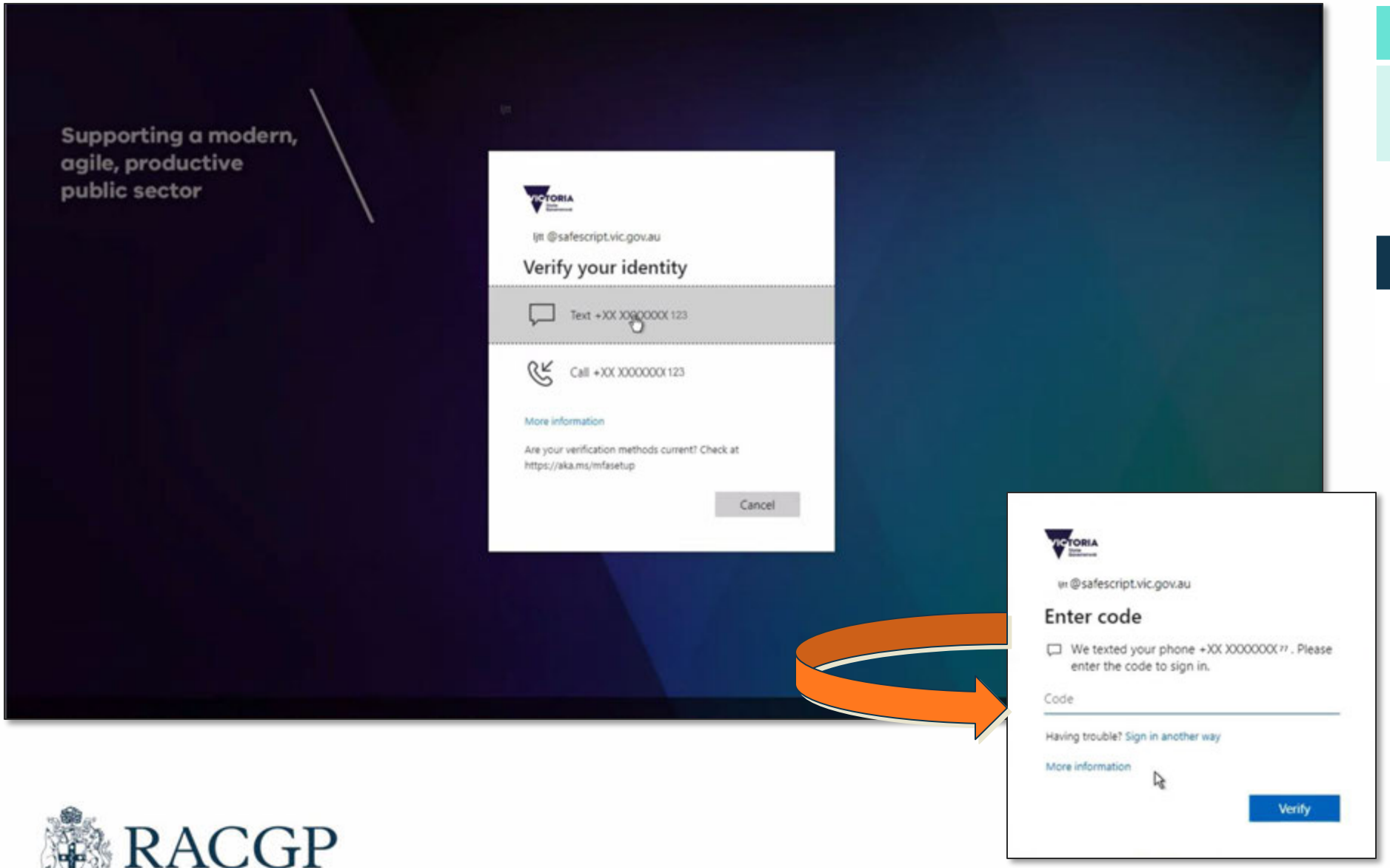
Step 3: 2-Step verification process



Overview

- Click to verify via phone

Pain point

- Need to take out phone to get verification.

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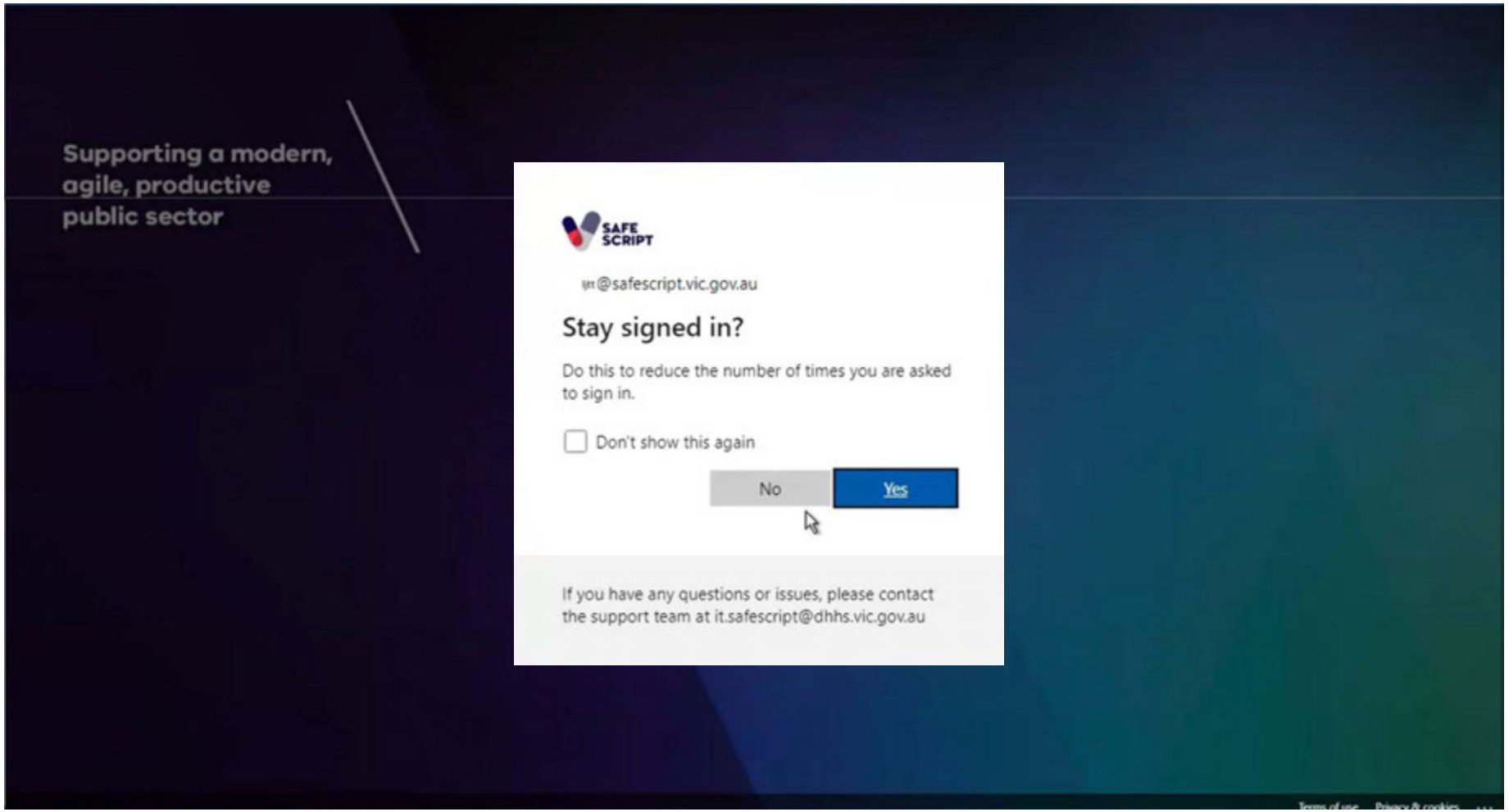
Step 4: ‘Remember details’ option



Overview

- Click 'Yes' to ‘Stay signed in’.

Pain points and potential solutions continued next slide

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Pain points

- This option does not keep you signed in, as stated
- Tedious to get into even with CIS use details already authenticated.

Potential solutions

✓ This system models a more seamless connection than PBS Authorities via HPOS. Although this system could also be integrated directly to CIS for Authentication.

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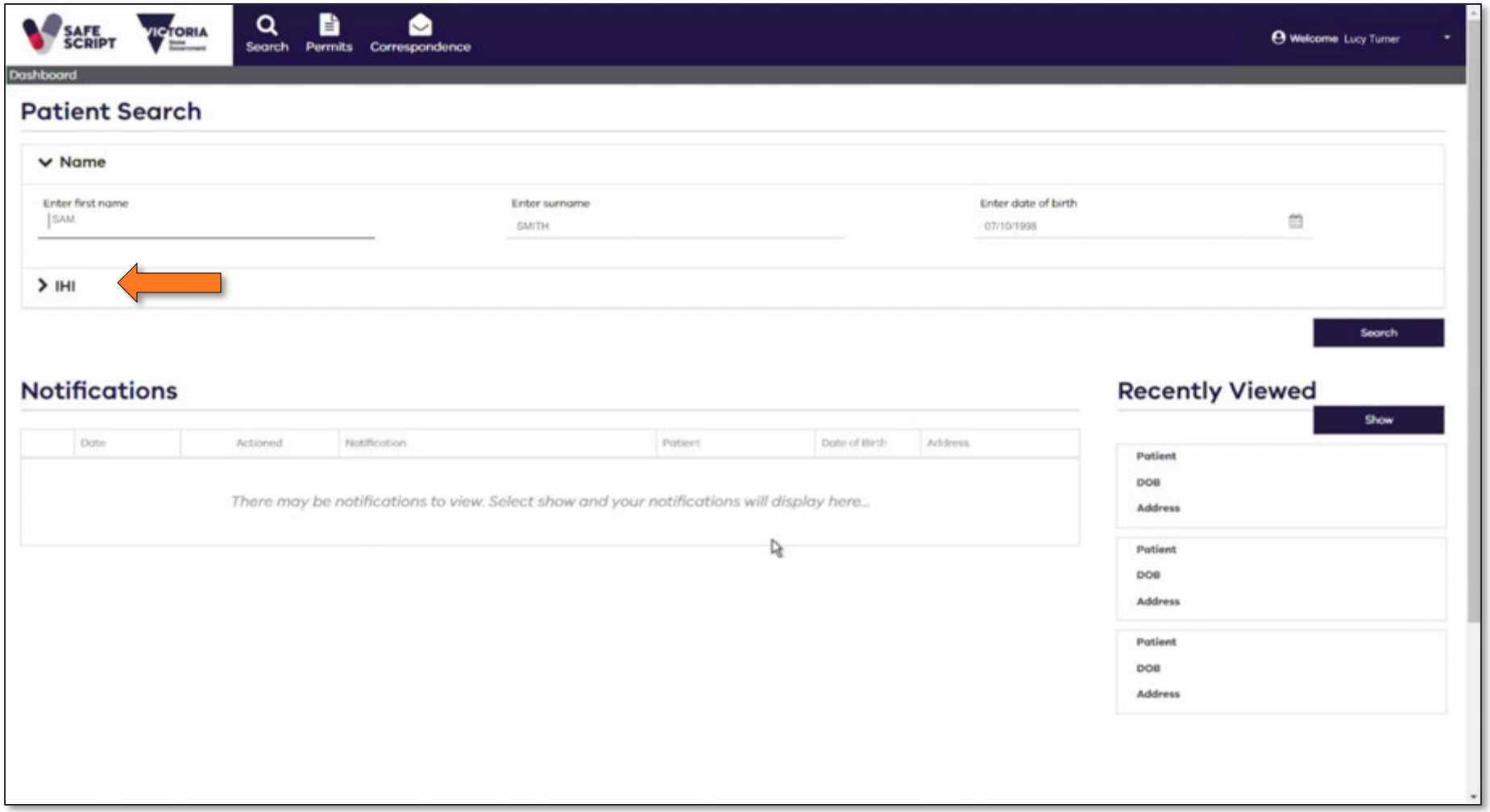
Step 5: Search for patient details



Overview

- To search for patient details you can use IHI
- Go back into CIS (if not using the connection from a patient record within CIS)

Pain points and potential solutions continued next slide

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Safe Script allows the use of IHI number

Pain points (using Medicare number in PBS Authorities)

- Why not use IHI's in PBS Authorities process also?
- Medicare no. is not used for most health applications
  - People have more than 1 Medicare number
  - Cannot use for Safe Script
  - Cannot use for e-script
  - Cannot use for MHR.

Potential solutions (for using IHI's in PBS Authorities

Benefits of IHI's

✓ IHIs as provide greater certainty that the right information is attributed to the right individual than the use of Medicare numbers

✓ Other benefits of using IHI:

- ❑ **Can** use IHI to access MHR, Safe Script and also e-script
- ❑ People only have one IHI
- ❑ IHI's are available for people who are not eligible for Medicare therefore are a universal identifier for all healthcare consumers.

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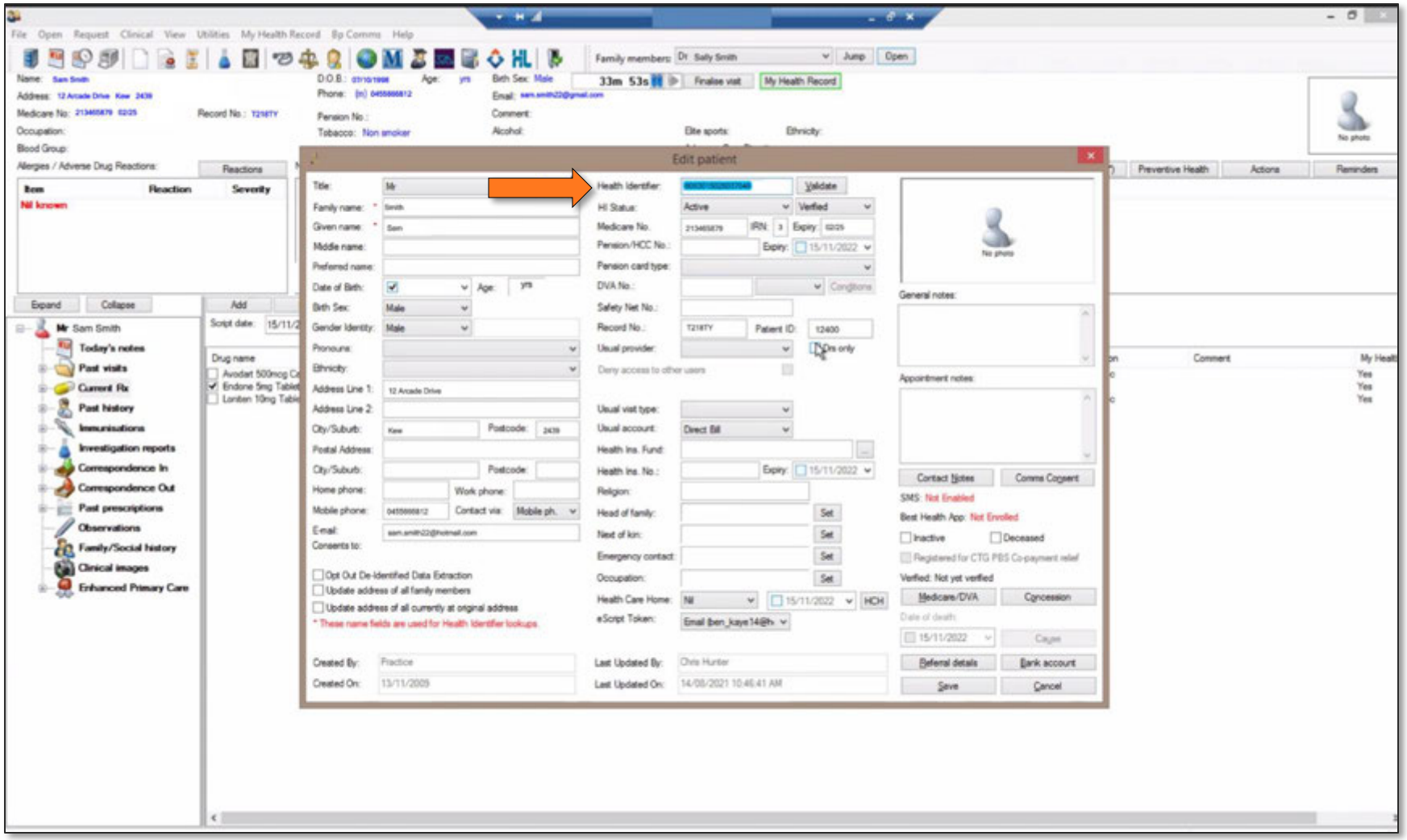
Step 6: Copy IHI from CISS



Overview

- Click on ‘Patient demographics’
- Copy IHI number.

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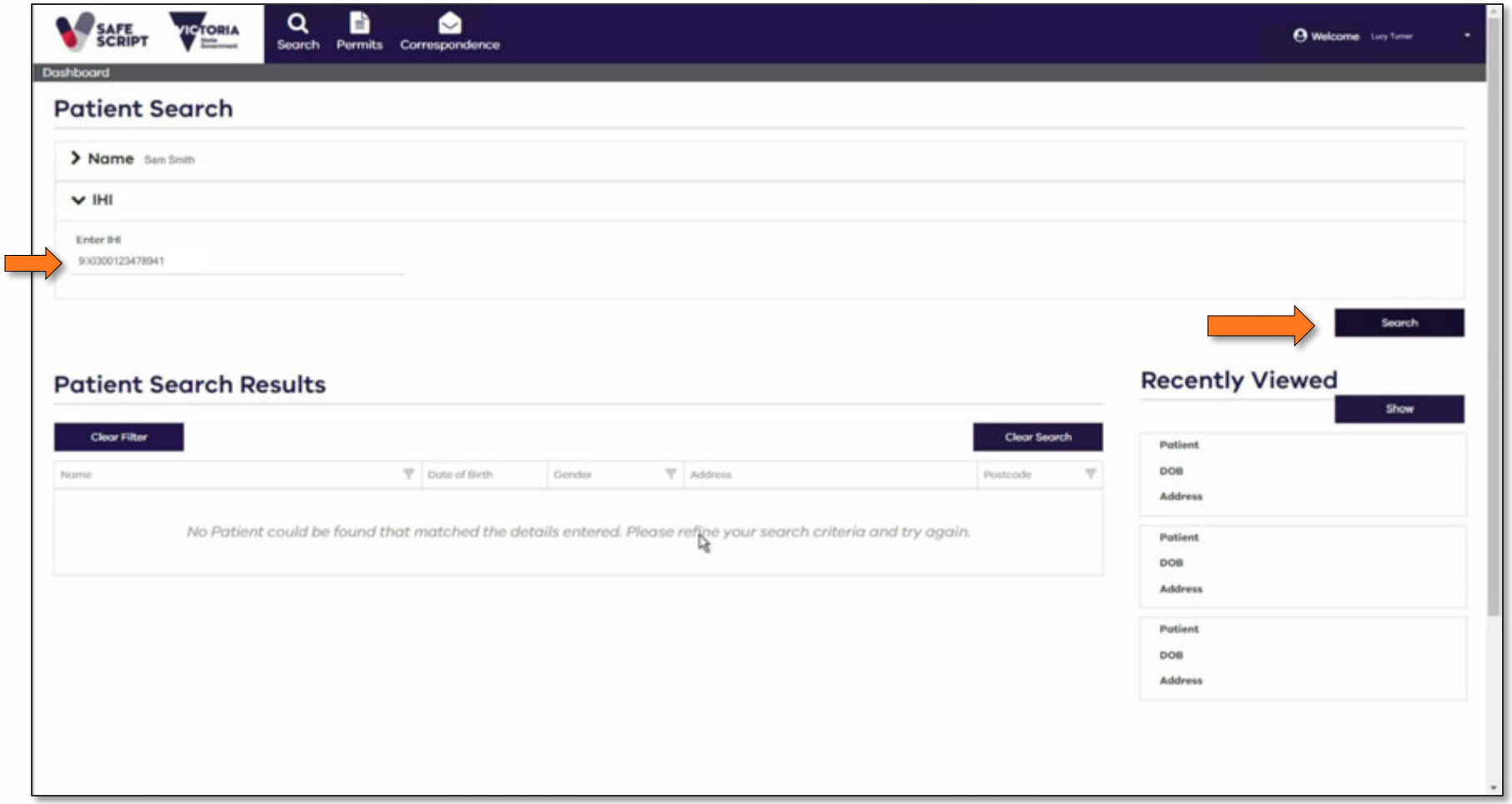
Step 7: Paste IHI number into patient search in Safe Script



Overview

- Go back to Safe Script screen
- Paste IHI number
- Then click ‘Search’.

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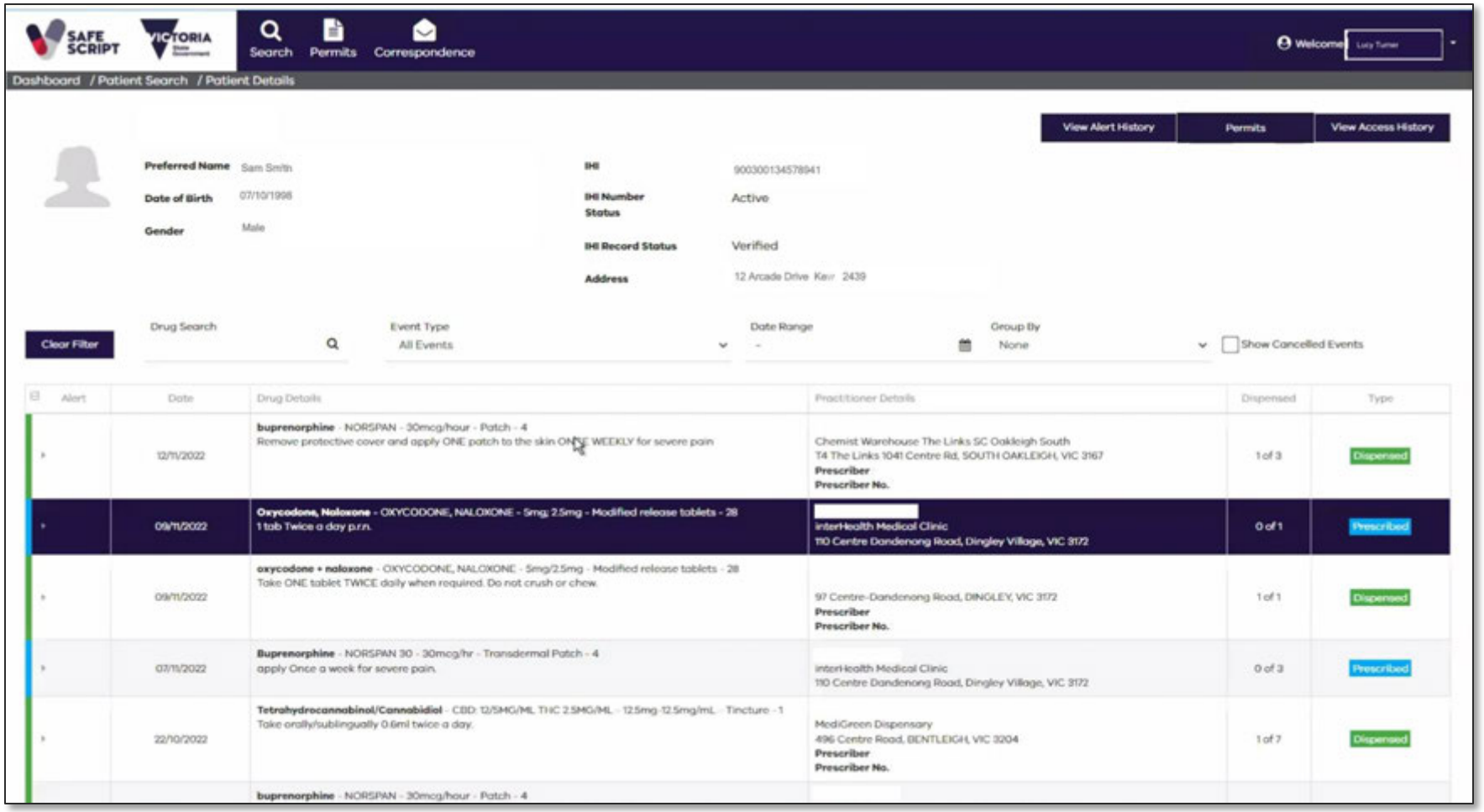
Step 8: Review results



Overview

- Review results of all narcotics prescribed
- Proceed with medicine order prescription in CIS if appropriate
- Displays potential red flags, prescriber habits, (ie. where and what) over a long period of time
- Displays what medicine was dispensed and where.

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PBS Authorities Streamlined process

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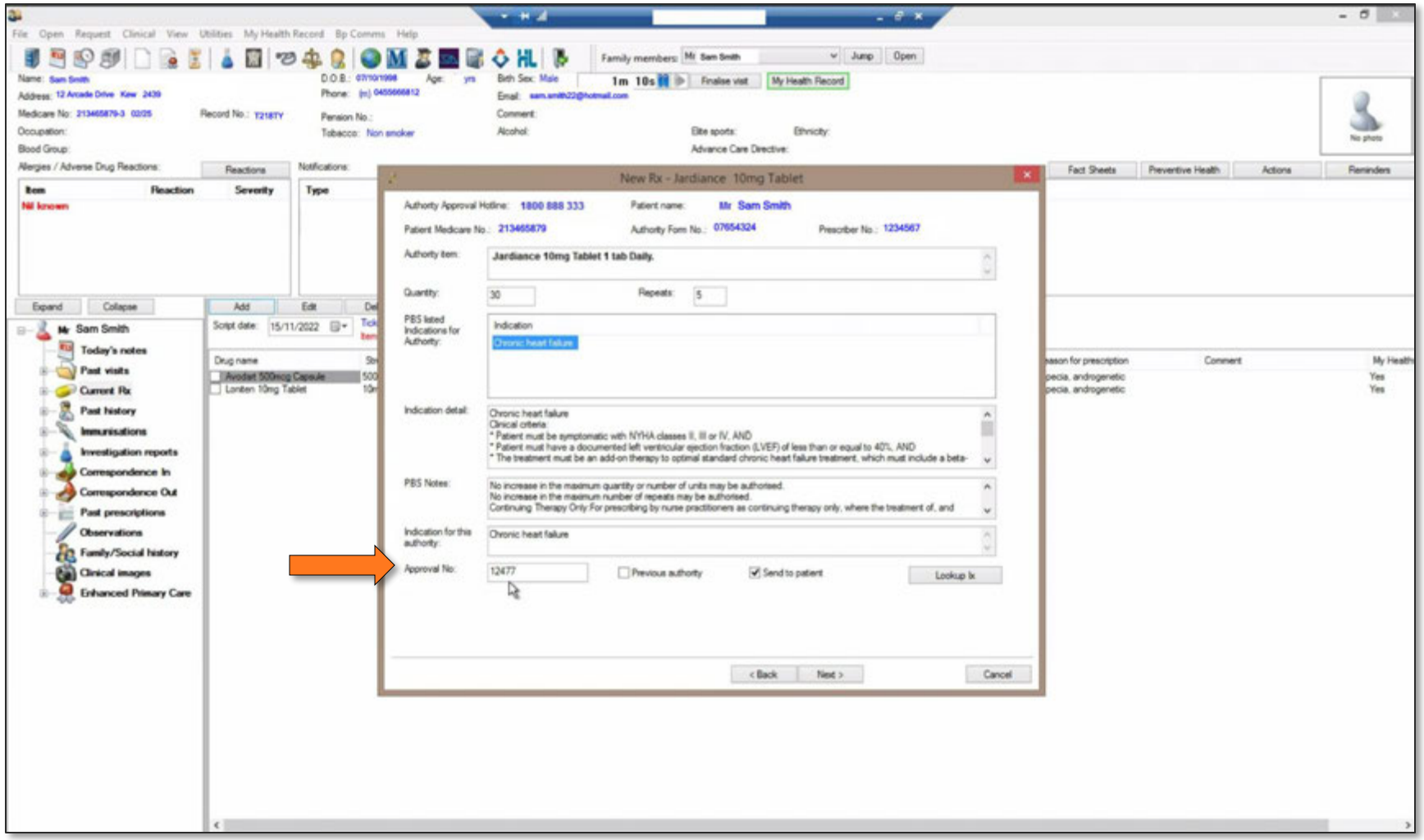
Overview: Approval number is generated within the CIS



Overview

- Approval number appears within CIS for medications with streamlined authorities

✓ Ease of use for workflow of GPs.

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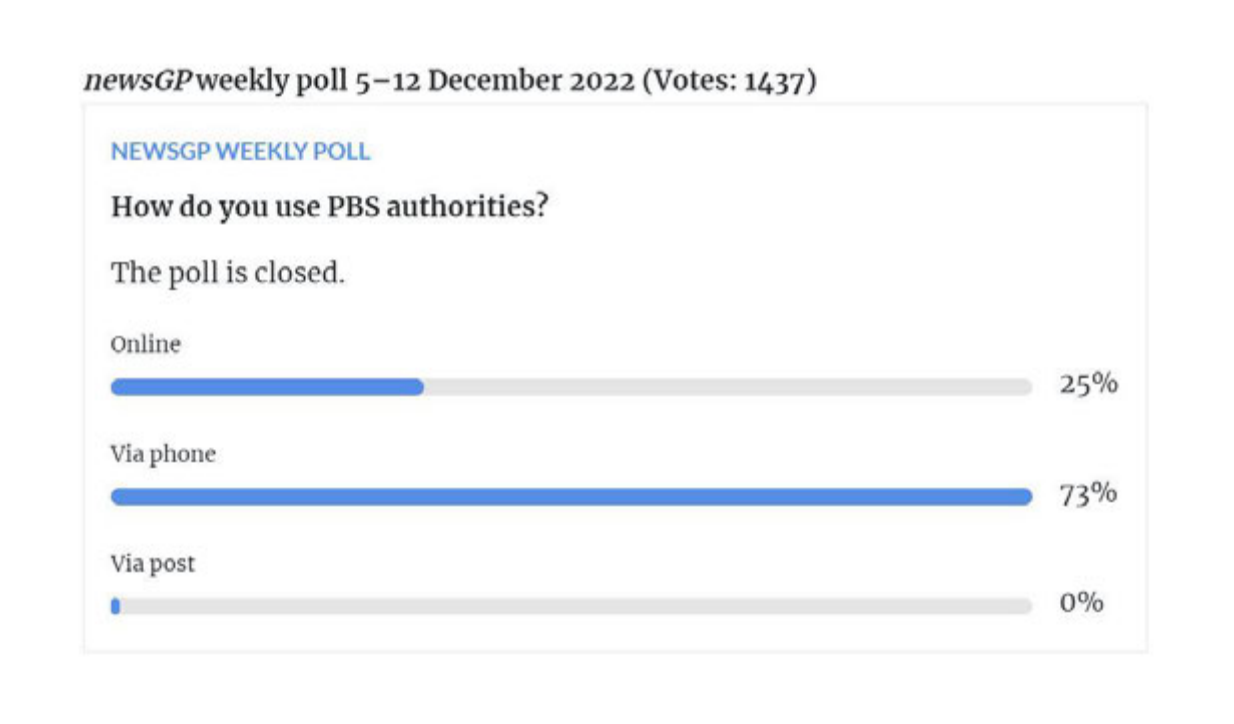
Current state



- Currently 73% of GPs surveyed use PBS authorities via phone
- Only 25 % of GPs surveyed use PBS authorities online

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Thank you

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Cover sheet: Supporting document #3

2025 Incoming Government Brief for Productivity

48th Parliament of Australia

Powering Australia's healthcare for all Australians wherever they are. #thegoodtech

MSIA
MEDICAL SOFTWARE INDUSTRY ASSOCIATION

Acknowledgment of Country

The Medical Software industry of Australia acknowledges traditional custodians of country throughout Australia and recognises the continuing connection to lands, waters and communities. We pay our respects to Aboriginal and Torres Strait Island cultures and to Elders past and present.

Contents

Congratulations on your second term, working together for healthier, safer and more productive Australia.

The Medical Software Industry Association congratulates the Albanese Government on its re-election. We stand ready to partner with you to lift health, disability and aged care outcomes and national productivity for every Australian.

Why this Briefing matters

Our 140-plus member companies supply the world-class software running public and private healthcare across Australia. They already enable millions of telehealth consultations each year and underpin hundreds of millions of secure clinical transactions — the digital backbone of connected care, Closing the Gap for First Nations Peoples and ensuring equitable access for rural, remote and vulnerable communities.

MSIA has a proven record of constructive co-design with government, from the My Health Record secure-messaging mandate to standards-based e-referrals in aged care. These same frameworks can accelerate reforms across Medicare, the PBS, the NDIS and foundational supports within the expanded Department of Health, Disability and Ageing.

Delivering on the Albanese Government's priorities

Productivity
The Productivity Commission's 2024 Report estimates digital efficiency could save $5 billion a year in public-hospital costs alone — gains our members can unlock for Treasurer Chalmers

Health, Disability & Ageing
MSIA members software hold the digital tools to strengthen Medicare, deliver generational aged-care reform and future-proof the NDIS. Our members can achieve Minister Butler's generational reform.

Aged Care & Seniors
Minister Rae is embracing this challenging portfolio of reform for Australia. Provider and software readiness for the 1 July 2025 aged-care reforms is a shared goal to ensuring no Australian is left behind. Our industry is doing what it takes.

Cyber Security
Our sector secures Australia's most sensitive information and can fast-track implementation of the 2025-30 Cyber Security Strategy. We are working across Department's to achieve Minister Burke's chief objectives which can be realised through collaboration with our industry.

Digital Government and Service Delivery
Whole-of-government platforms that lift productivity and citizen experience depend on seamless MSIA integration. Virtually every MBS and PBS claim is made on our members systems which can be improved for Minister Gallagher through our industry.

This paper sets out the key issues and MSIA recommendations for each portfolio. We would welcome the opportunity to brief you or your senior advisers over the next fortnight.

Emma Hossack
CEO
Medical Software Industry Association

The MSIA supports Australia's health software industry for equitable access to healthcare & productivity.

MSIA Priority Actions:

Cost, Budget Impact, Benefits & Timeline

Action	Indicative Cost to Government	Net Budget Impact	Patient-centred Benefit	Timeline / Milestones
Targeted Interoperability Acceleration Program	Funded via 0.15 % micro-levy on MBS/PBS outlays (~A$95 m p.a.)	Levy-financed (budget-neutral); unlocks Productivity Commission-modelled $5 bn p.a. hospital efficiency dividend	Real-time data at point-of-care; fewer duplicate tests/faxes; lower medication-error risk	Levy enacted 2025-26 Budget; vendor certification aligned to 1 Jul 2025 aged-care & Cyber Strategy milestones
Fair-Go Procurement Renewal	≈A$1 m one-off White Paper; credit-guarantee fee-funded (cost-neutral)	Lower tender prices; wider bidder pool; risk underwritten without cash outlay	Faster access to innovative local tools; more choice for rural & aged-care services	White Paper Q1 FY 25-26; SourceIT-Lite & guarantee pilot live 1 Jul 2026
Implementation & Training Partnership Fund	Pilot envelope A$21.225 m (Apr 2025-Jun 2026)	Prevents failed roll-outs; earlier reform benefits	Rapid, consistent uptake of mandated features; clinicians trained by software vendors	Fund opens Jul 2025; vouchers acquitted within 12 months of go-live
OPA Connect Gateway for Online Prescription Authorities	One-off build < A$10 m plus integration grants (from DOP pool)	Removes > 4 m GP calls; billions in PBS workflow savings	30-second digital approvals; faster dispensing; safer aged-care prescribing	Gateway live within 12 months; 98 % authority items digital by Q4 FY 25-26
National Data-Governance Unification	< A$5 m to consolidate frameworks & sandbox	Cuts SME compliance spend; faster procurements	Consistent privacy & security boost patient trust; quicker tool roll-out	Framework legislated FY 25-26; GovData-Ready certificate by 2026
Digital Outcomes Payment (re-cast ePIP)	Re-allocates existing ePIP pool (no new spend)	Redirects funds to proven outcomes; stops leakage	Clinician time freed; automated reporting; aligns with OPA/FHIR mandates	Blueprint mid-2025; first metrics funded 1 Jul 2026
Efficiency-First Conformance Package	Sandbox & voucher scheme scoped with Interoperability Fund (moderate)	Avoids duplicate testing; lowers regulatory cost	Faster access to safe AI & SaMD; SMEs stay in market	Sandbox live Q2 FY 25-26; mutual-recognition regime fully adopted 2027

Priorities for a smarter, safer, more productive Australian health system.

Powered by digital innovation that improves patient outcomes, empowers clinicians, and secures national data.

Facilitate the Speed of Health Interoperability

Through resourcing health software companies to educate and implement their solutions which would dramatically increase productivity.

Procurement Reform

Creating a fair, SME-friendly, IP-smart and competitively-neutral market.

Implementation & Training Support

Funding the change-management “last mile” after every digital-health reform.

AI Regulation

Toward a principles-based, risk-proportionate and SME-friendly framework.

Conformance Versus Efficiency

Ensuring regulation is proportionate, risk-based and innovation-friendly.

Online Prescription Authorities (OPA)

Turning a $19 billion process from “partly effective” to seamless, data-rich and doctor-friendly.

Health-Software Accelerators

From “scatter-gun” funding to a focused, challenge-driven pipeline for innovation at scale.

Data Governance

Moving from many overlapping frameworks to one clear, risk-based system.

Medicare Digital Incentives

Advance from activity-based payments to outcome-driven, vendor-enabled reform.

Facilitate the Speed of Health Interoperability

Through resourcing health software companies to educate and implement their solutions which would dramatically increase productivity.

Every month up to 7 million patient results fail to flow between clinics because legacy systems still can't talk FHIR—costing Australia $420 million in repeat tests and preventable admissions. Many clinical systems struggle to exchange data seamlessly because vendors lack the bandwidth – people, cash and sand-boxed test environments – to fast-track implementation of evolving national standards (FHIR-based APIs, secure-messaging, e-referrals, e-prescribing). Delays keep duplicative manual workflows in place, create safety risks when information is missing at the point of care, and slow progress on priority reforms across Medicare, PBS, NDIS and aged care. The 2020 ANAO audit response confirms that higher-assurance, ISM-aligned security controls must now also be built into all connecting software, adding further effort for already-stretched vendors.

This slows the progress across Medicare, PBS, NDIS and aged care – costing the Budget millions the Treasurer can allocate to savings.

SOLUTION
Establish a Targeted Interoperability Acceleration Program

Directly funds vendor implementation. Competitive grants or outcome-based vouchers for software companies to build, test and deploy priority interoperability use-cases (e.g., event summary, discharge summary, e-referral) and the security controls mandated in the ANAO assurance framework.

Provides national sandboxes & conformance labs. Cloud test beds, reference APIs and automated test suites run by ADHA/MSIA so every vendor can prove compliance once and connect everywhere.

Delivers practical workforce training. Subsidised micro-credentials and vendor-to-vendor "code camps" so SMEs and large vendors alike can skill up quickly on FHIR, SNOMED CT, OWASP-aligned secure coding and ISM Essential Eight practices.

Aligns incentives & deadlines. Tie program milestones to upcoming policy drivers (e.g., 1 July 2025 aged-care reforms, Cyber Security Strategy 2025-30) and make certification a pre-requisite for claiming modernised MBS/PBS items.

Include a $20 Million Interoperability Acceleration Fund in the October 2025 Budget.

BENEFITS

Productivity dividend. Removes duplicate data entry and faxes, cuts $5 billion annually in hospital waste, per Productivity Commission (2024). Practices that adopt SmartForm e-referrals typically cut fax usage by 70–90 per cent within the first quarter, according to PHN rollout data.

Better, safer care. Clinicians gain real-time, complete patient data, reducing medication misadventures and supporting continuity of care for First Nations, rural and vulnerable Australians.

Cyber-resilience by design. Embeds ISM-mapped security controls across the vendor ecosystem, reducing breach risk and supporting the 2025-30 Cyber Security Strategy.

Economic growth. Accelerates time-to-market for Australian health-tech, boosting exports and high-skill jobs while attracting private investment into the sector.

Government reform enabler. Provides the digital plumbing that Ministers Butler, Rae, Chalmers, Gallagher and Burke need to deliver generational change in Medicare, aged-care, NDIS, cyber security and whole-of-government service delivery.

Procurement Reform

Creating a fair, SME-friendly, IP-smart and competitively-neutral market.

Capital-barrier "glass ceiling." Many RFTs insist on multi-million-dollar turnover tests or unlimited parent guarantees, benchmarks few Australian digital-health SMEs can meet. SME's make up 97% of Australian businesses but win only 11% of procurement value. MSIA's 2025-26 Budget submission calls this the key barrier and proposes that government underwriting "level the playing field" so innovators can bid with confidence.

Competitive-neutrality breaches. PHNs have used Commonwealth grants to build and distribute software such as Primary Sense and HealthPathways, directly competing with commercial vendors despite the Commonwealth Competitive Neutrality Policy Statement's requirement that publicly funded entities not distort markets. Complex, inconsistent rules. More than 120 entities overlay bespoke conditions on the Commonwealth Procurement Rules (CPRs); the July 2024 update lifted SME targets to 25 % (< A$1 bn) and 40 % (< A$20 m) and raised the direct-buy threshold to A$500k, yet compliance and transparency remain patchy.

Paperwork & legacy IP clauses. SourceIT-Plus contracts still run past 100 pages and vest all foreground IP in the Crown, ignoring the Attorney-General's 2012 IP Manual that advises licence-back, not acquisition.

Insurance. The current insurance requirements for contracts in public and state RFTs are often not fit for purpose requiring cover in excess of the value of the contract and not matched to the risk. This disincentivises smaller innovative companies which lack the bargaining power with insurers.

Transparency of Procurement success. The ANAO reports on large procurements e.g. Defence ands MyHR. Trust, accountability and improvements to process are necessary to drive return on investment are all procurements were flagged for annual updates on how they are meeting objectives or not.

SOLUTION
Fair-Go Health-ICT Procurement Renewal Package

Commonwealth SME Credit-Guarantee Facility.

- Treasury, Export Finance Australia and MSIA co-design a pilot guarantee that tops up performance bonds or provides partial contract-value guarantees for qualifying Australian vendors.
- Fund an initial **White Paper (2025-26 Budget Submission to include this measure in Budget Paper No.2 under treasury/ Finance)** to scope parameters, risk pricing and governance.
- Limit individual exposures (e.g., A$5 m) and charge a modest fee so the scheme is fiscally neutral over time.

Unified rules & 20-page "SourceIT-Lite".

- Finance publishes a live register of CPR deviations and issues a plain-English modular contract that:
  – defaults IP ownership to the supplier with a perpetual, royalty-free government licence;
  – caps liability at proportionate fault;
  – embeds outcome-based milestones.
- Any true IP assignment must be CIO-approved and logged on AusTender with a short justification tag.

SME-First pathways.

- Default to CPR **Exemption 17** for procurements < A$500 k; mandate an SME weighting in the "broader economic benefit" assessment for contracts > A$1 m and publish progress towards the 25 %/40 % targets.

Always-open digital-health panel + "try-before-buy". Quarterly refresh; require at least one SME on every shortlist and allow A$200 k rapid proofs-of-concept using the Commonwealth Contracting Suite.

Accredited "IP-Smart Buyer" program. MSIA/Finance micro-credential covering FHIR, cyber-risk, agile contracting and the 2012 IP Manual; graduates flagged on AusTender.

Competitive Neutrality Enforcement Stream.

- Mandatory CN test for any entity (PHNs, hospitals, agencies) proposing new software development; they must publish evidence that no suitable commercial alternative exists.
- Empower the Productivity Commission's Competitive Neutrality Complaints Office to initiate investigations, issue binding directions and levy penalties within 90 days.

Live performance dashboards. AusTender displays cycle-time, SME share, IP-ownership status, CN compliance and delivery outcomes—driving continuous improvement.

Transparency of Procurement process and Value. Drive trust accountability and process uplift by annual l publication of status of procurement, variations, ROI and timelines.

BENEFITS

Level playing field & sovereign capability. Government underwriting plus slimmer templates let Australian SMEs go head-to-head with multinationals, keeping more of the A$70 bn federal spend in local IP and high-skill jobs.

More innovation at lower cost. Wider bidder pools, "try-before-buy" pilots and outcome-based contracts sharpen price tension and speed delivery of cutting-edge digital-health tools.

Reduced project risk. Credit guarantees tackle solvency hurdles without forcing SMEs into risky unlimited indemnities; balanced IP/ licence clauses ensure products can evolve post-implementation.

Market integrity. Enforcing competitive neutrality stops publicly funded bodies crowding out private R&D and focuses PHNs on their commissioning mandate rather than product development.

Transparency & trust. Public dashboards and empowered CN oversight show taxpayers that government buying is fair, efficient and aligned with the Buy Australian Plan and "Future Made in Australia" agenda.

Implementation & Training Support

Funding the change-management "last mile" after every digital-health reform.

Australia repeatedly mandates new digital-health functions (e.g., aged-care star-ratings, e-prescribing updates) yet **offers no dedicated funding to roll them out in clinics, hospitals or pharmacies.** Vendors shoulder the R&D cost, then must also bankroll site-by-site implementation, change-management and staff training — often > 20 % of the original development bill.

When money is available, it is paid to **generic consulting firms with limited product knowledge** or direct to providers, producing slow uptake and fragmented help-desk support.

The result is delayed policy impact, inconsistent cyber-security posture and reform fatigue among clinicians.

SOLUTION
Implementation & Training Partnership Fund

Dedicated funding stream. Establish a competitive grants program tied to each major policy change (e.g., eNRMC, aged-care digital reforms). Vendors apply for **per-site or per-user "implementation vouchers"** that cover training, data migration, workflow redesign and first-line support.

Pay-on-adoption model. Grants are acquitted only when the vendor demonstrates the site is live and clinicians are using the new functionality — aligning spend with real outcomes.

Vendor-led training mandate. Funding flows to the companies that built and already support the software, not to third-party consultants or the end user, ensuring content accuracy and trusted relationships.

Cyber uplift baked-in. Each voucher includes a checklist of Essential-Eight controls; implementation funding can be used for patching, identity management and staff phishing drills alongside functional training.

BENEFITS

Faster, cleaner rollouts. Policy reforms land in months, not years, because the people who wrote the code also manage the go live.

Lower total cost & higher ROI. Government pays once, directly linked to successful adoption, avoiding the "consultants first, fix later" cycle highlighted in previous national programs.

Stronger cyber posture. Embedding security tasks in every funded implementation lifts baseline protection across thousands of small providers.

Clinician trust & efficiency. Training by familiar vendor teams boosts uptake, reduces helpline calls and frees clinicians to focus on care.

Stimulated local innovation. Reliable post-reform funding signals to Australian SMEs that their investment in new features will be supported, sustaining a vibrant home-grown digital-health ecosystem.

AI Regulation

Toward a principles-based, risk-proportionate and SME-friendly framework.

Regulatory sprawl & confusion. Three parallel consultations (Health, DISR, TGA) show the same pain-point: overlapping laws and talk of a brand-new AI Act risk duplicating what already works and slow clinical adoption.

One-size-fits-all guardrails could over-shoot. Mandating every proposed control on every model would burden low-risk uses (scribes, workflow bots) and create a consultancy "tick-box" market, while still leaving gaps for genuinely high-risk diagnostic AI.

SME cost squeeze. Testing, accreditation and documentation land hardest on Australian innovators; without help they may exit or never enter the market.

Fragmented trust signals. Clinicians and consumers lack a simple way to see whether an AI tool is regulated, exempt or proven safe, eroding confidence.

Australian innovation and productivity. Australia's workforce deserves world-class tools to improve their job satisfaction and output. Lack of knowledge breeds fear doubt and uncertainty impeding uptake of useful safe AI solutions.Industry also needs assurance that our regulation is consistent where appropriate and possible with international markets or investment will dry up.

SOLUTION
Calibrated AI Guardrail Package

Adopt "Option 2" across portfolios. Keep TGA software-as-medical-device rules, privacy law and safety standards, but add a short, technology-agnostic AI Principles Act that tells each existing regulator what to clarify — not a brand-new mega-regulator.

Tiered guardrails & sandboxes. Map the ten proposed controls to risk classes; fund national sandboxes/ conformance labs so vendors can self-test once, prove once, and publish the results.

SME Support Fund. Provide vouchers covering up to 80 % of first-time conformance, safety studies and post-market monitoring for Australian SMEs, paralleling the underwriting model proposed for procurement.

Trusted-AI "mark" & open register. A single public database (and symbol for labels/UI) shows whether a tool is: regulated (ARTG number), exempt but conformant to principles, or pending assessment.

Continuous education loop. Resource TGA, ADHA and peak bodies (MSIA, AAAiH) to co-publish plain-English explainer sheets, podcasts and CPD modules, keeping pace with fast-moving models. Ensure workforces are properly resourced for this revolution.

Global harmonisation default. Align definitions and evidence thresholds with IMDRF, ISO 42001 and FDA practice; any Australian divergence requires a regulatory-impact statement up front.

National Trust to pass the "Pub Test". Leverage and support resourcing of the University of Melbourne Law School Centre for AI and Digital Ethics which socialises ideas, canvases opinions and technical and ethical approaches to address public distrust of new technologies.

BENEFITS

Safe innovation. High-risk diagnostic AI stays under tight, updated SaMD rules, while low-risk productivity tools face proportionate checks — reducing both patient harm and red tape.

Faster market entry & lower costs. One sandbox, one badge and targeted vouchers cut compliance time for SMEs, keeping Australian IP onshore and competitive.

Clinician & consumer trust. A visible Trusted-AI mark plus open registry makes it obvious which tools meet the rules, boosting uptake and informed choice.

Regulator efficiency. Clarifying roles lets TGA focus on health-specific evidence, OAIC on privacy and DISR on cross-sector AI principles, avoiding duplicated audits.

International credibility. A harmonised, principles-first system attracts global investment and ensures Australian patients access world-class AI solutions first.

Conformance Versus Efficiency

Ensuring regulation is proportionate, risk-based and innovation-friendly.

"Gold-plated" compliance creep. Agencies routinely mandate UI details, exhaustive documentation or advanced interoperability that add little safety value but absorb upwards of **30–40% of staff time** in some Australian health-software companies. Conformance profiles must be used to address risks but not product design which the marketplace is best suited to address.

Unfunded mandates. Governments require new features or standards yet provide no implementation funding, forcing SMEs either to cross-subsidise public policy or exit the market.

Ambiguous, drawn-out approval pathways. Vague guidance and repeated design reviews delay launches; EU MDR and recent TGA reclassifications have already driven smaller developers from those markets.

Productivity drag & reduced competition. Excessive conformance tasks shrink R&D budgets, slow product cycles and thin the vendor pool, ultimately dampening innovation and raising costs for providers and patients.

SOLUTION
Efficiency-First Conformance Package

Risk-proportionate tiers. Calibrate evidence and documentation to true patient- or user-risk; low-risk tools can self-declare to a core checklist, while high-risk AI/diagnostic software stays under full SaMD rules. Similar risk-based approaches should be deployed for all digital health software verticals including ePrescribing and MyHR connectivity.

Regulatory sandboxes & "test-once, accept-many". Fund national sandboxes where vendors prove security, privacy and interoperability once; results are mutually recognised by TGA, ADHA and state regulators. Testing should be nuanced so it is not required for full features previously tested, but only newly developed discrete features.

Implementation vouchers. Mirror MSIA's training-support proposal: per-site funding that vendors redeem only when new functions are live, covering change-management and cyber-uplift costs.

Streamlined documentation & harmonisation. Adopt common templates, accept international evidence (e.g. IMDRF, ISO 42001) where available and appropriate, and retire duplicative national forms; publish decision timelines to cut re-work.

SME impact test. Any new conformance requirement above a cost threshold must include a Productivity Commission analysis and offsetting funding if compliance costs fall disproportionately on SMEs.

BENEFITS

Faster innovation cycles. Risk-based tiers and test-once sandboxes cut months of re-engineering and paperwork, getting safe tools to clinicians sooner.

Stronger competition & sovereign capability. SMEs stay in the market instead of exiting under compliance pressure, keeping Australian IP and jobs onshore.

Lower whole-of-life cost & higher ROI. Government funds only successful rollouts; providers avoid duplicate consultant spend and gain productivity sooner.

Regulator efficiency & trust. Clear tiers, shared evidence and published timelines focus regulators on true high-risk areas, increasing transparency and confidence among clinicians and consumers.

Online Prescription Authorities (OPA)

Turning a $19 billion process from "partly effective" to seamless, data-rich and doctor-friendly.

$19.5 billion PBS workflow still phone bound. Nearly 7 million "authority-required" prescriptions a year (≈30 % of all PBS lines) still need doctors to phone Services Australia — 54.5 % of requests in 2023-24 — because only one clinical system has built the complex web-service interface.

Prescriber productivity drain. RACGP polls show 75 % of GPs spend 3-10 minutes per call, often while frail aged-care residents wait.

ANAO (Jan 2025) rates PBS administration "partly effective". It flagged OPA as the key bottleneck; Services Australia rejected the recommendation to report against its own 30-second online-approval target.

Services Australia have not adopted the FHIR standards supported by the Department of Health, Disabilities and Ageing interoperability strategy.

SOLUTION
OPA Connect implementation package

Fund & stand-up OPA Connect, a single, vendor-neutral gateway that converts the existing Services Australia web services into a light-touch REST/FHIR* style API. Vendors pass core prescription data, OPA Connect handles all authority questions and returns the approval number.

Stage 1 roll-out (covers > 98 % of authority items) within 12 months; later stages add chemotherapy, complex CAR items, RPBS, etc.

Competitive grant vouchers for software companies to integrate the new API and update customers; pay on proof of live use to align spend with outcomes.

Tight ANAO-aligned KPIs: 30-second median response-time, public dashboard, and inclusion in Services Australia's Annual Performance Statement — fixing the sole ANAO recommendation they declined.

BENEFITS

Billions in system savings. Eliminating 4 + million annual call-centre interactions and duplicated data entry slashes labour costs across prescribers, Services Australia and aged-care facilities.

Doctor time back to patients. RACGP's 3-10 minutes per approval returns to consultations, improving care quality and access.

Faster, safer dispensing. Instant authority numbers reduce prescription errors and delays in starting critical therapies.

Rich, real-time data. Digital submissions feed analytics for PBS utilisation, inappropriate prescribing flags and fraud detection.

Regulatory credibility restored. Measurable, public KPIs move PBS administration from "partly" to fully effective and align with the Productivity Commission's digital-health efficiency agenda.

Health-Software Accelerators

From "scatter-gun" funding to a focused, challenge-driven pipeline for innovation at scale.

Fragmented public investment. Canberra and the states now fund at least six separate health-tech accelerators (e.g., ANDHealth+, MTPConnect's TTRA, state hubs) through the MRFF and jurisdictional grants. Each runs its own intake, mentors and admin team, spreading scarce dollars thinly and duplicating overheads.

Mismatch with market traction. Much of the money targets very early "blue-sky" concepts; fewer resources flow to companies that already have clinically validated products and just need scale support. MSIA's 2025-26 Pre-Budget submission notes that many smaller, lightly connected hubs "have less ability to deliver Government policy and reform" than industry-wide bodies with an established customer footprint.

Weak accountability for return on investment (ROI). Current grants often stop at project completion, with limited visibility of downstream adoption, jobs created or export sales.

SOLUTION
Challenge-Based Accelerator Consolidation Package

Define national "missions". Each Budget cycle, the Department of Health & Aged Care publishes 3-4 priority challenges (e.g., digitally enabled aged-care reform, AI-driven chronic-disease management).

Competitive, winner-takes-most funding. Instead of seeding many hubs, allocate a single, milestone-based grant to one or two lead organisations (accelerators, peak bodies or consortiums) that:

- already support a portfolio with proven clinical use and paying customers; and
- commit co-investment from industry and states.

90 : 10 split between "traction" and "blue-sky". At least 90 % of program funds go to companies that can demonstrate early revenues/clinical adoption; up to 10 % supports horizon-three ideas.

Hard ROI and health-impact KPIs. Lead accelerators must report quarterly on jobs, private capital attracted, export sales, patients reached and clinician productivity gains. Funding tranches are released only on KPI achievement.

Independent productivity audit. The Productivity Commission reviews outcomes two years post-grant and can recommend clawbacks or bonus pools to reward exceptional performance.

BENEFITS

Higher productivity, faster. Concentrating dollars on solutions already gaining traction shortens the path from lab to clinic, freeing clinicians from manual work and lifting system efficiency. Industry investment will grow.

Better health outcomes. Proven tools scale nationally sooner, improving care quality, access and safety across metropolitan and regional settings.

Stronger sovereign industry. Milestone-tied grants leverage private co-investment and export growth, amplifying every taxpayer dollar and anchoring high-skill jobs in Australia.

Reduced administrative overhead. Fewer, larger programs cut duplicated back-office costs and let public servants focus on strategic oversight or working in privately funded organisations, instead of micro-managing many small grants.

Transparent value for money. Public KPI dashboards and independent PC audits demonstrate clear ROI, boosting public trust in innovation funding.

Data Governance

Moving from many overlapping frameworks to one clear, risk-based system.

Fragmented rules cause cost and confusion. Each tier of the health system has its own framework: the Australian Digital Health Agency's corporate "Data & Information Governance" model Digital Health Australia; the RACGP's practice-level security handbook RACGP; state and Commonwealth health departments' frameworks Health and Aged Care Australia; plus the Finance-led whole-of-government framework now under development Department of Finance. Vendors must map to—and insure against—several sets of principles, inflating procurement paperwork and premium costs and slowing adoption of new software.

SOLUTION
National Data-Governance Unification Package

Single over-arching framework. Finish Finance's APS-wide Data Governance Framework and legislate it as the baseline; all sector-specific guides (health, GP, AIHW) become "implementation handbooks" that can add nuance but **may not contradict** the core controls.

National Data Governance Council. Co-chaired by Finance and Health with ADHA, AIHW, OAIC, Peak industry and professional representatives and state CDOs to maintain the common core, approve sector add-ons and publish a living glossary.

One certification, many uses. Create a single "GovData-Ready" conformance assessment (built on the Five Safes, ISO 27001 and the FAIR principles); agencies accept it in lieu of bespoke questionnaires.

Harmonised contract clauses. Insert identical data-governance wording into SourceIT-Lite and state purchasing templates so suppliers don't renegotiate terms agency-by-agency.

Public guidance & sandbox. Fund the University of Melbourne Validitron -run sandbox where vendors can test once against security, privacy and interoperability requirements and publish their pass result in an open registry aligned with the Data & Digital Government Strategy's "Mission 5 – Data Foundations.

BENEFITS

Lower compliance costs. One audit instead of four+ saves SMEs tens of thousands in assessment and insurance fees, freeing capital for R-&-D.

Faster procurement & uptake. Purchasers can rely on the common certificate, cutting tender cycle-time and accelerating clinician access to new tools.

Improved data quality & transparency. A harmonised standard lets AIHW aggregate national datasets more quickly and publish clearer insights for funding and policy.

Greater investor confidence. Clear, stable rules de-risk scale-up capital, boosting domestic innovation and export potential.

Stronger public trust. Consistent privacy and security settings across jurisdictions make it easier to explain protections to patients and clinicians, supporting wider data sharing and AI adoption.

Medicare Digital Incentives

From activity-based payments to outcome-driven, vendor-enabled reform.

Inputs, not outcomes. Medicare's fee-for-service streams and the eHealth Practice Incentive Payment (ePIP) pay clinicians for having capability (e.g., a secure-messaging certificate) rather than proving it is used for safer, faster care. The 2022 Strengthening Medicare Taskforce called for blended, performance-linked funding.

Low digital yield. ANAO's 2024–25 audit found PBS administration only "partly effective"; 29 % of authority scripts still need phone calls, draining 3-10 min per GP per approval.

Provider grants bypass builders. Aged-care "digital-uplift" grants ($10 k per provider) left software companies unfunded for the change-management that decides success—risk flagged in MSIA's March 2025 submission.

Clinician burden & resistance. RACGP and AMA say ePIP rules are paperwork-heavy; AMA warned that "meaningful-use" quotas punish GPs for infrastructure they don't control.

In short, tying incentives to measurable digital outcomes and paying the people who actually write the code and educate the users during implementation turns Medicare's transaction spend into a lever for safer care, clinician productivity and a stronger Australian health-software industry.

Fragmented overseas evidence. Nations that pay vendors for outcomes—e.g., the UK catalogue—report quicker interoperability gains and lower practice overheads.

SOLUTION
Outcome-based Digital Enablement Package

Re-cast ePIP → "Digital Outcomes Payment (DOP)". 70 % of the pool is released only when software auto-reports agreed metrics (e.g., percentage of scripts sent via online authority, secure-message volumes, data-quality score). Part of the funding to be directed to industry to deploy the software services

Vendor-direct vouchers. Practices nominate their accredited software; a Medicare Digital Voucher is paid to the vendor once the outcome metric is met. First three mandates: online prescription authority (OPA Connect), FHIR event summaries, aged-care Support-at-Home claiming.

Shared national APIs & sandbox. Services Australia/ ADHA host open FHIR and security test beds; "test once, accept many" mirrors the UK NHS GP IT Futures model that funds suppliers directly via a buying catalogue.

Public dashboards & claw-back. Quarterly adoption and uptime statistics for each vendor; suppliers that miss service levels lose voucher eligibility, redirecting funds to high performers.

Fund with a micro-levy. Hypothecate 0.15 % of MBS/ PBS outlays (~A $95 m/yr) to sustain vouchers without new Budget spending.

BENEFITS

Faster national rollouts. One conformance tick suffices for every player, slashing vendor re-work and getting new features into clinics sooner.

Transparent accountability. Live data links every public dollar to digital performance, addressing ANAO's oversight concerns and boosting public trust.

Sovereign tech lift. Predictable, milestone-tied revenue lets Australian vendors scale and export—echoing the innovation surge seen under GP IT Futures.

Conclusion

Australia's 140-plus MSIA companies already run the nation's digital pulse. They run the large majority of all hospital EMRs, GP and specialist platforms, aged-care and disability systems, radiology and pathology PACS/RIS, pharmacy dispensing, telehealth and the secure-messaging rails that move almost every Medicare and PBS claim. Our members export world-class code, yet billions in productivity, safety and cyber-resilience gains remain locked behind sprawling procurement red tape, overlapping data rules, unfunded mandates and a call-centre era prescription-authority process that still steals minutes from every consultation.

The incoming Government can release this value by super-charging interoperability through vendor acceleration grants, national FHIR sandboxes and ISM-aligned certification; replacing hundred-page contracts with a 20-page SourceIT-Lite while underwriting SME bids and enforcing competitive neutrality. Initiatives including directing funding to industry when mandated features are live and clinicians trained; installing risk-proportionate AI guard-rails; adopting "test-once, accept-many" conformance sandboxes with an SME-impact lens; converting phone-bound prescription authorities to a single secure API; consolidating scatter-gun accelerator funding into mission-driven programs that back solutions with proven uptake; unifying data-governance into one national certificate; and shifting ePIP from input grants to outcome payments.

The MSIA looks forward to realising the benefits of these initiatives to achieve the Governments vision now.

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The Medical Software Industry Association of Australia (MSIA) powers healthcare in Australia.

We welcome this opportunity to provide a submission to the Department for consideration in the framing of its Budget.

MSIA members enable MBS and PBS, and vital systems including GP and Specialist systems, Pharmacy systems, ePrescribing infrastructure, Hospital systems, Pathology, Radiology, Telehealth/virtual care, Aged Care, Indigenous care, Palliative Care. bookings and payment platforms as well as Australia's Bowel and Breast screening Registers. The Australian Immunisation register and MyHR need information from our members systems to function.

Our members systems make equity of access a reality or possibility for all Australians. Our members make the efficiency and productivity of healthcare possible, but there is much more that could be done today.

The MSIA exists to enable this market to thrive and facilitate more effective and efficient healthcare. In line with the 2025-2026 Federal Budget, this submission highlights key funding priorities essential to supporting the continued growth of the medical software industry and improving healthcare outcomes across Australia.

Our success in these areas is detailed in our

2024 MSIA Annual Report

Cover sheet: Supporting document #4

Submission to the Productivity Commission

Pillars 1, 3 & 4

MSIA
MEDICAL SOFTWARE INDUSTRY ASSOCIATION

Date: 8 June 2025

Acknowledgment of Country

The Medical Software industry of Australia acknowledges traditional custodians of country throughout Australia and recognises the continuing connection to lands, waters and communities. We pay our respects to Aboriginal and Torres Strait Island cultures and to Elders past and present.

The MSIA supports Australia's health software industry for equitable access to healthcare & productivity.

About MSIA Members combined workforce, exports and capability.

MSIA is Australia's peak body for digital-health software, analytics and cloud vendors, representing more than 140 member companies. These companies design, build, maintain and implement the digital foundations of our health system—electronic medical records, prescribing and dispensing platforms, imaging and pathology interfaces, aged-care resident systems, virtual-care hubs and advanced analytics. Collectively our members employ well over 25,000 Australians, export to 40+ countries[1] and process over 95% of Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) transactions daily.

Productivity is at the heart of our purpose: each line of code our members deploy aims to eliminate waste and rework, maximise clinical interactions and reduce processing burdens for administrative staff and clinicians. This enables more focused time with patients and less workers burn out to enable more time with patients. The evidence in this response to the Productivity Commission demonstrates just some of the concrete returns.[2]

We therefore welcome the Productivity Commission's five-pillar agenda and respond specifically to Pillars 1; 3 and 4 where digital health can move the national needle the fastest. We ask Government to grasp three over-arching levers: proportional regulation, outcome-based funding, and system-wide interoperability.

[1] Conservative total derived from large employers plus SME cohort: Sonic Healthcare careers page (accessed 8 Jun 2025) – ">10 000 people nationally". Telstra Health Benefits Brochure 2023, p. 1 – "1,500+ employees, 15 locations". InterSystems "About Us" page – 2 000 global staff; Sydney is APAC dev hub (~250). Dedalus "Global Footprint" – 8 000 staff, including Australian engineering centre. 100+ SMEs averaging 25 staff ≈ 2 500 (10–50 range). Total >25 000.Telstra Health Benefits Brochure 2023, p. 1. InterSystems global footprint (80+ countries) and Dedalus (40); plus, member export case-studies.

[2] The MSIA will have a complete list following the Interim Report.

Creating a Dynamic & Resilient Economy

Digital health is dominated by small-to-medium Australian innovators who carry a disproportionately high compliance and procurement burden. Under the current monolithic accreditation pathways, a start-up clinical decision-support vendor faces the same evidentiary demands as a multi-national cloud host. The result is capital drag and negative impact to innovation and competition.

1. What areas of regulation do you see as enhancing business dynamism and resilience? What are the reasons for your answer?

Tiered accreditation models that calibrate the risk- to benefit.

1. The work by the Department of Health, Ageing and Disabilities provides the possibility of fit for purpose regulation. It is being developed with input from industry and end users in a genuine co-design. The net effect will be reduced procurement red tape and cost to government and industry. It will also increase certainty and confidence for users of health systems.

2. The current Software as a Medical Device (SaMD) regulatory scheme by the TGA provides a harmonized framework which assists in the reduction of red tape by industry exporting overseas because of the Therapeutic Goods Administration (TGA) involvement with the International Medical Device Reform Forum (IMDRF). It also maps to the 11 proposed mandatory Guardrails proposed by the Department of Industry Science and Resources. Risk-based regulation which is supplemented by Essential Principles is an excellent example regulation providing appropriate safety and security without stifling business sustainability and innovation.

2. How has your regulatory burden changed over time?

The MSIA is currently finalising a member survey which demonstrates that the requirements for industry have grown from approximately 20% of resources being allocated to government compliance to 80%. The survey will be available following release of the PC interim report.

3. What regulations do you find time-consuming, overly complex or otherwise constraining business dynamism and resilience? What are the reasons for your answer?

There are three good examples.

1. **Privacy and Security Regulation** - Currently multiple and various security and privacy regulations from Commonwealth and Jurisdictions mean that companies are compelled to conform to varying standards which could be harmonised for a better result for industry, health care providers and consumers. Procurement would be improved and KPMG modelling for the Australian Digital Health Agency (2023) found that every month shaved from procurement lead-time in clinical software equates to AU$50 million in earlier benefits. A risk-tiered accreditation process alone is expected to remove four to six months from 70 % of first-time deployments, implying a net present value of AU$1.2 billion over ten years.

2. **Schedule 8 Medications** - Similarly each Jurisdiction has its own Schedule 8 drug list which means companies must code for safety in several different ways which is illogical, inconsistent and inefficient.

3. **Online Prescription Authorities** - Finally, the regulation of Online Prescription Authorities which account for over $5B of PBS medications per annum have been found to be poorly executed by the ANAO which found Services Australia delivery only “partly effective”.

Key facts & findings from the 2025 ANAO Report on the Delivery of the PBS:

1. As of 30 June 2023, there were 928 medicines (across 5,261 brands) listed on the Schedule of Pharmaceutical Benefits.

2. Budgeted expenditure for the PBS for 2024–25 was **$19.5 billion** (excluding recovery revenue).

3. In 2022–23, there were 223.1 million over co-payment PBS prescriptions (67.9 per cent) and 105.6 million under co-payment PBS prescriptions (32.1 per cent) dispensed in Australia.

The ANAO found arrangements to manage the delivery of PBS services and payments are *partly effective.* Deficiencies related to ensuring legislative requirements for certifying claims are met and performance reporting.

There were seven recommendations to improve the administration of the PBS — three to Health, two to Services Australia and two to both entities. Services Australia did not agree to one recommendation. [*This was the one on OPA- which the MSIA has recommended a solution for years ago*].

29.4% of PBS medicines require prescribers to gain authority approval from Services Australia prior to prescribing. These are the OPA which account for **$5.733B.**

The Australian National Audit Office (ANAO) report on the administration of the Pharmaceutical Benefits Scheme (PBS) scrutinized the processes surrounding online prescription authorities, focusing on the efficiency and effectiveness of authority approvals. The report identified significant concerns regarding the timeliness of these approvals, which are essential for patient access to certain medications.

Key Findings:

Timeliness of Authority Approvals: The ANAO observed that the existing performance measures for authority approvals were not aligned with the agreed targets. Specifically, the report highlighted that Services Australia's performance metrics did not reflect the goal of issuing authority approvals within 30 seconds, as stipulated in bilateral agreements.

Surge in Online Authority Requests: There has been a notable increase in the use of the Online PBS Authorities system, accessed via Health Professionals Online Services (HPOS). This shift indicates a preference among healthcare providers for digital channels over traditional phone-based methods, likely due to efficiency and convenience.

Recommendations:

To address these issues, the ANAO made specific recommendations:

Performance Reporting Alignment: Services Australia should align its reporting on the timeliness of issuing authority approvals with the agreed performance measures and targets. This alignment would ensure transparency and accountability in meeting established service standards.

Inclusion in Annual Performance Statements: The timeliness of authority approvals should be included in Services Australia's annual performance statements. This inclusion would provide stakeholders with a clear understanding of the agency's efficiency in processing these approvals.

Implications:

The misalignment between performance targets and reporting can lead to inefficiencies in processing authority approvals, potentially delaying patient access to necessary medications. The increasing **reliance on online systems underscores the need for robust digital infrastructure and responsive service delivery to meet healthcare providers' expectations.**

Addressing these recommendations is crucial for enhancing the efficiency of the PBS and ensuring timely access to medications for patients.

The MSIA submission to the Services Australia and Department of Health suggest a fully integrated OPA. Just as online PBS was not fully embraced in 2006-2007 until it was fully integrated, so too should the OPA be integrated with each provider system using internationally adopted standards like SMART on FHIR.

Adopting this recommendation would enable Services Australia to achieve the timeline and reporting targets recommended by the ANAO, improve productivity of the health sector, and most importantly, improve the timeliness of medication to Australians.

Harnessing data and digital technology

The health sector produces roughly 30 % of the world's data yet struggles to appropriately manage it for better outcomes. Two issues dominate: fragmented privacy rules that create

Privacy reform

1. How is the Privacy Act operating to balance consumer privacy consideration while supporting the benefits associated with data sharing? Is the balance right?

The Privacy Act is principles based which is good, but there are areas which are confusing to users which reduces trust in appropriate sharing of data. Having Jurisdictional legislation further confuses the population. Harmonisation would be beneficial.

One area for immediate improvement could be to embed an outcomes-based "fair and reasonable" test in the Privacy Act and deem data sharing that complies with the Data Availability and Transparency Act (DAT Act) to meet that test by default. (See our uploaded submission on the Data Availability Transparency Act to the Department of Finance.

2. Are there any changes you would like to see to privacy legislation in Australia? Please provide details below.

Allow accredited health-techs to lodge a single digital services statement that satisfies OAIC, Therapeutic Goods Administration and Australian Digital Health Agency requirements. Again, reduce the duplication and increase harmonization.

Enable AI's productivity potential

1. How are you currently using AI? Please provide details of the context and uses.

Our membership is using AI for Administrative and clinical purposes. Prospection's real-world analytics returned a 419 % ROI and AU$1.19 million NPV in three years; Alcidion's Patientrack reduced cardiac arrests by 76 % at NHS Fife; Heidi Health's AI scribes shrank GP documentation load by 70 %. These examples—and many in Annex A—confirm that well-governed data and interoperable APIs unlock measurable productivity dividends.

Details of the uses and benefits and suggestions for reform are encapsulated in our 3 submissions in 2024 the TGA, Department of health Ageing and Disabilities and Department of industry Science and Resources. These are all uploaded for the TGA and can be found here:

30/10/2024 - DoHAC: Safe and Responsible Artificial Intelligence in Health Care – Legislation and Regulation Review

30/10/2024 - TGA: Clarifying and strengthening the regulation of Artificial Intelligence (AI)

04/10/2024 - DISR: Introducing mandatory guardrails for AI in high-risk settings: proposals paper

2. What challenges do you face in accessing or using AI? How can these challenges be overcome?

Ensuring access to a reliable legally usable body of data is a Stand-up a national sandbox operated by ADHA and CSIRO where vendors can complete "test-once, accept-many" validation for cybersecurity, bias and SaMD performance, underwritten by vouchers covering 80 % of first-time test costs for SMEs.

Delivering quality care more efficiently

Quality improvement is fundamentally a data problem: clinicians cannot manage what they cannot measure. Yet clinical-safety regulation remains disparate and process-heavy, while funding rarely pays for the digital "last-mile" integration that turns raw data into actionable insight. Transactions and not outcomes are rewarded under Medicare Benefits items, and neither the Commonwealth nor Jurisdictions are willing to shoulder the cost of using digital health for preventative care despite the research demonstrating the safety, cost and productivity benefits.

1. To what extent do differences in quality and safety regulation make it costly or complex to provide or access care services?

To a great extent.

Offering levels of comprehension in the health workforce make the varying regulations challenging for part timers who could otherwise mobilise their skills more easily. Less workforce + less access to care.

Harmonisation of standards through a single National Clinical Safety Framework recognised by all jurisdictions and anchored in ACSQHC or ISO 14971 could improve this. Obviously, the federated nature of Australia brings challenges here without a corollary benefit, particularly given the fluidity of the population.

2. To what extent should quality and safety regulations be more aligned across the different care service sectors and jurisdictions?

To a great extent.

Fundamentally quality and safety are national imperatives. The workforce is mobile. Having various regulations, when the same outcome of quality safe patient care is the goal for all, makes no logical sense.

3. What is your experience with collaborative commissioning?

Our membership responds to RFTs and collaborative commissioning.

Make interoperability KPIs—real-time discharge summaries, pathology events, medication-summary completeness—explicit eligibility criteria in pooled-fund pilots.

Although there is not a detailed report available yet, the recent commission by Defence for the shared care record appears to have been effective.

4. What are the main barriers to governments investing in evidence-based prevention programs across the care economy?

The responsibility of the Commonwealth Govt for primary health care and the Jurisdiction responsibility for Hospitals mean that there is rarely agreement on funding preventative help in primary care. It is called the blame game and has been called out by The Grattan Institute.

What are some examples of successful prevention programs (this could include discontinued programs)?

The National Health Roundtable estimates that preventable hospital readmissions cost AU$1.5 billion annually. Digital early-warning systems such as Alcidion's and AI-enabled rehab platforms such as Cardihab's have already demonstrated double-digit reductions in readmissions, pointing to at least AU$450 million in potential savings if deployed nationally.

How can governments better support investment in prevention activities that have broad and long-term benefits for the Australian community?

- Reward outcomes not transactions via Medicare.
- Consider the legalisation of primary care rebates/ preventative health through private health insurance.
- Harmonise regulations for certainty and investment.
- Provide funding for software companies to educate and implement their products to give consumers more autonomy and information so they can observe and measure their health.

Proposed Implementation Road-Map for consideration incorporating responses to Pillars 1, 3 and 4

The reform package is designed to be budget-neutral within four years by redirecting existing digital-health funds and leveraging private capital. Key milestones are shown in Table 1.

Quarter	Deliverable	Lead
Q4 FY 24-25	Legislate SourceIT-Lite; launch SME Credit-Guarantee pilot	Finance / Treasury
Q1 FY 25-26	Issue Tiered Accreditation Rules & National Data-Governance Certificate criteria	Health / ADHA / OAIC
Q2 FY 25-26	National data & AI sandbox operational; first GovData-Ready certificates issued	ADHA / CSIRO
Q3 FY 25-26	Care-Quality Data Incentive payments commence; outcomes dashboard live	Health / Services Australia

Conclusion

Digital health is not a cost centre; it is the principal enabler of a safe, sustainable and patient-centred health system.

By adoption of the proportional, outcome-driven reforms set out above, Government will liberate billions in productivity gains, strengthen sovereign capability and position Australia as the safest, fastest place to turn health data into public good.

MSIA and its members stand ready to co-design, deliver and evaluate each element of the roadmap. Our productivity Survey and Productivity Capability Schedule will be provided following the Interim Report by the Productivity Commission.

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Annexure A

Annexure A will be completed in full following the interim Report and formal consultation by the Productivity Commission.

Company	Evidence	Link
Acredia	Signature Care eNRMC rollout reports cost savings versus multiple systems.	https://insideageing.com.au/signature-care-rolls-out-acredia-enrmc/
AlayaCare	Visit Optimizer AI scheduling cut admin 98 %, lifted fulfilment 35 %.	https://alayacare.com/press-release/home-based-care-providers-see-98-productivity-increase-with-visit-optimizer-from-alayacare/ https://alayacare.com/en-au/press-release/client-intelligence-suite-australia/ https://alayacare.com/en-au/press-release/alayacare-interoperability/ https://alayacare.com/revolutionizing-home-care-alayacare-launches-layla-an-ai-powered-assistant/ https://www.youtube.com/watch?v=BqAMh5FsO9M
Alcidion	Monash University and Digital Health CRC implementation at Alfred Health with significant benefits	https://www.alcidion.com/news/an-independent-study-shows-the-ripple-effect-of-benefits-from-adopting-a-patient-flow-management-solution/
Altura Health	Doctors on Demand platform delivered 700 k virtual GP visits, slashing waiting-room time.	https://www.doctorsondemand.com.au/online-doctors/
Avant	PracticeHub digital governance reduces policy admin; clinics report hours saved weekly.	
Best Practice	Bp Premier efficiency toolbar lets GPs finish notes within consult, reducing overtime.	https://bpsoftware.net/blog/bp-premier-efficiency-features/
Bestmed	BESTMED PMS automates chronic-disease plans; clinics see 30 % admin reduction.	[link coming]
Cardihab	Digital cardiac-rehab improves completion & trims readmissions; PC cites ‘significant cost savings’.	https://www.pc.gov.au/research/completed/digital-health
Carelink	CarelinkPlus schedules 3 000 carers in minutes vs hours, streamlining home-care rostering.	[link coming]
Cerner Oracle Health	Oracle Health Clinical AI Agent reduced physician documentation time by ~30 % across 30+ specialties.	https://www.oracle.com/news/announcement/physicians-reduce-documentation-time-with-oracle-health-clinical-ai-agent-2025-03-04/

Chamonix	Chamonix partners with government to enhance safety, productivity, and efficiency through secure, cloud-first solutions, collaborative co-design, and modern delivery techniques.	https://www.chamonix.com.au/government
Cubiko	Maple St Surgery uncovered AU$100 k unbilled items in 10 minutes via Cubiko dashboards.	https://www.commbank.com.au/business/insights/touchstone-cubiko-case-study.html
Dedalus	Lorenzo EPR paper-lite rollout cut MRSA cases from 22 → 4 per year at UHMBT.	https://www.digitalhealth.net/2012/10/think-again-about-lorenzo/
Doctors on Demand	Virtual GP & prescription service rated 4.7★ (218 k reviews); delivers same-day scripts & referrals.	https://www.doctorsondemand.com.au/online-doctors/
Edify	Immersive VR training replaces scarce sim labs, accelerating clinical competency uptake.	https://www.edify.ac/solutions/healthcare
Eucalyptus	Patient Adherence Loop automates outreach across 1 M+ telehealth consults, boosting adherence.	https://eucalyptus.vc/blog/how-pal-improves-patient-adherence
Foxo	Secure messaging delivered significant workflow efficiencies within 30 days for radiology groups.	https://foxo.com
Genomical	GIMS pipelines cut pathologist interpretation ~30 min/test across 22 k genomic tests.	[link coming]
Halo Connect	Integration pipes pathology results direct into GP software; reduces result-turnaround delays.	https://haloconnect.com.au/pathology-integration-for-gps/
HealthTeams	Remote-care hub consolidates tele-consults, vitals & comms, slashing GP travel and phone tag.	https://healthteams.com.au/
Heidi Health	AI scribe reduced charting time 70 %, freeing 100 clinician-hours in 14 weeks; 600 % ROI.	https://www.heidihealth.com/customers/priority-physicians
HotDoc	Online bookings cut reception phone workload by ~30 %.	[link coming]
iCare	iCareHealth eNRMC saves 45 minutes per medication round in aged-care.	[link coming]
InfoMedix	Digital medical record scanning delivers ~10-second retrieval vs paper file searches.	[link coming]
InterSystems	TrakCare unified record eliminates faxed notes & duplicate tests across NT Health.	https://www.intersystems.com/anz/customers/nt-health-single-digital-record/

Kestral	Auslab LIMS rollout improved lab turnaround times by 25 %.	[link coming]
Leecare / SimpleMed	Mobile audits & SimpleMed eNRMC cut med rounds 40 % at Amana Living.	https://leecare.co.uk/wp-content/uploads/2022/09/Leecare-Platinum5-Brochure.pdf
Magentus	Evolution vLab will manage 100 M tests/year, connecting 93 labs & wiping duplicate orders.	https://digitalhealth.net/2024/02/magentus-to-provide-lims-for-nhs-scotland/
MedAdvisor	Script reminder app raises adherence by ~20 %.	[link coming]
MIMS	Real-time interaction alerts reduce prescribing errors & downstream re-work.	https://cds.mims.com/hospitals-healthcare-systems
Minfos	POS-dispense sync speeds checkout and inventory reconciliation for pharmacies.	[link coming]
Modeus	MethDA compliance app digitises narcotics register, removing paper handling.	[link coming]
Montu	Digital telehealth & logistics scaled workforce 15× in 18 mo; serves 150 k patients/yr.	https://blog.hibob.com/case-studies/montu/
MPS Connect	e-meds platform integrates charts & pharmacy for 500+ aged-care homes, reducing errors.	https://mpsconnect.com.au/aged-care/
Oracle Health	See Cerner Oracle Health entry.	https://www.oracle.com/industries/health/
Orion Health	Amadeus shared-care record saves clinicians ~30 min searching disparate systems.	[link coming]
Packapill	On-demand pharmacy delivery within 3 h lowers abandoned prescription rates.	[link coming]
PalCare	Palliative EMR auto-generates ACC reports, saving nurses hours weekly.	[link coming]
Person Centred Software	Mobile Care Monitoring saves carers 90 min/day & nurses 4 h/day.	https://personcentredsoftware.com/au/case-studies/handsale-care-homes/
Prospection	Real-world evidence analytics delivered 419 % ROI and $1.19 m NPV in 3 yrs.	https://prospection.com/case-study/tei/
Qscan	Foxo integration lets referrers contact radiologists instantly, speeding reports.	https://www.qscan.com.au/foxo

RLDatix	DCIQ boosted incident reporting 16 % & near-miss capture 11 % at JH Aramco.	https://resources.rldatix.com/case-studies/johns-hopkins-aramco-healthcare-case-study
S4S Touchstone	Audit4 extracts automate CKD registry reporting, avoiding manual chart audits.	https://kidney.org.au/CKD-surveillance-project-audit4
Scrypt	Mobile e-script wallet forwards scripts direct to pharmacy, cutting queues.	https://scrypt.com.au/pharmacy
Silknote	Speech-to-text saves clinicians ~2 h/ day on documentation.	https://silknote.com/
Telstra Health	51% reduction in hospital readmission risk, a 3.2-day decrease in average length of stay, and an average saving of $3,698 per admission through virtual care technology. 40% reduction in medication round times and 10 hour reduction per day on documentation via our aged care solutions. A 30% drop in unexpected readmissions and a 10% increase in NEAT compliance through ourPatient Flow Manager solution. Replacing 17 separate billing systems with one enterprise-wide platform to enhance efficiency and consistency with PowerHealth's PBRC solution.	
Tyro Health	Integrated claims processing speeds rebate reconciliation & cash-flow.	[link coming]
Visual Outcomes	Automated KPI emails replace manual spreadsheets for multi-site clinics.	https://visualoutcomes.com/news/
VitalHub	SHREWD Vantage dashboards provide real-time demand views, reducing ED handover delays.	https://uk.vitalhub.com/products/shrewd-vantage/
Webstercare	MedsPro® blister-packing robot lifts pharmacy productivity 70 % & cuts overtime 11 %.	https://www.webstercare.com.au/products/medspro/

The Medical Software Industry Association of Australia (MSIA) powers healthcare in Australia.

2025 Brief to Incoming Government