Clinical Safety Case Report – Social Prescribing

Professional Standards Records Body

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Document Management

Revision History

Version	Date	Summary of Changes
V0.1	09/02/2022	First Draft
V0.2	03/03/2022	Second Draft
V0.3	08/04/2022	Third Draft
V1.0	29/04/2022	Final revision
V1.1	10/05/2022	Revisions in readiness for approval
V1.2	27/05/2022	Minor revisions post initial review by NHSD CSG
V1.3	08/06/2022	Updated to show NHSD CSG approval

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Dr John McGuiness	Social Prescribing Clinical Lead	12/04/2022	1.0
Jeremy Wilkinson	Clinical Safety Officer	12/04/2022	1.0
NHS Digital Clinical Safety Group	Clinical Safety Officers and Engineers	08/06/2022	1.2

Related Documents

These documents provide additional information and are specifically referenced within this document.

Ref	Doc Reference Number	Title	Version	Status
1	DCB 0129	Clinical Risk Management: its Application in the Manufacture of Health IT Systems - Specification	4.2	Approved
2	DCB 0160	Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - Specification	3.2	Approved
3	Appendix 2	Social Prescribing Standard	2.0	Approved
4	Appendix 3	Developing an information standard for Social Prescribing - Final Report	1.0	Approved
5	Appendix 4	Social Prescribing Survey Report	1.3	Approved
6	Appendix 5	General implementation guidance for ALL PRSB standards (Detailed guidance, specific to the sections and elements of the standard, are included in the standard)	1.0	Approved
7	Appendix 6	Link to the PRSB Social Prescribing Standard web page		Live

Contents

Executive summary and safety statement

This document provides a clinical safety case for the social prescribing standard project. The project has delivered information models and implementation guidance which will be used by IT suppliers and healthcare organisations to develop technical standards for structuring, coding, and sharing social prescribing information, with a view to incorporating it into standard clinical IT contracts to facilitate better access and interoperability.

4 potential hazards were identified and mitigated and 3 deemed implementation issues. The other related to the system supplier's capability to display sex and gender being recorded together. The mitigated hazards include information that should be addressed by implementers. All hazards were identified through the consultation steps carried out to develop these standards. The consultations consisted of a multidisciplinary workshop, online survey, review of draft information models and implementation guidance (by clinical informaticians and system suppliers) and an expert user group meeting. These workshops, surveys and communications included patient representatives as well as professionals from Royal Colleges, specialist societies, social care, allied health professions, health informatics professionals and IT vendors (see Appendix B).

At each step of the consultation hazards were identified, reviewed and mitigations/actions considered. Nevertheless, some risk is inherent in the standards, but most has been:

(A) mitigated by the development of the standards

(B) or the residual risk has been transferred (with guidance) to the implementers.

Certain hazards were deemed system implementation matters. The hazard log (embedded within this document) provides guidance for system developers and implementers. It is important that this guidance in relation to these hazards become requirements for implementation.

N.B: This clinical safety report is necessarily limited in its scope because it is neither directly related to software development nor to deployment. Suppliers developing software to implement these standards will therefore still be expected fully to apply DCB0129. Organisations involved in the deployment of such software will still be expected fully to apply DCB0160.

Introduction

The National NHS England and Improvement social prescribing team worked with the Professional Records Standards Body (PRSB) to develop a social prescribing information standard for health and social care providers and IT suppliers.

The Social Prescribing Standard V0.2 has been co-produced with a wide range of stakeholders, the Royal College of General Practitioners (RCGP), citizens, healthcare professionals, suppliers, and public health professionals to ensure that the standard meets their needs – see 'Developing an information standard for Social Prescribing - Final Report' in the appendices.

The following approach was taken to develop the project deliverables:

- NHS E& I conducted a small-scale pilot to test the feasibility of a minimum data set (MDS) for use by Social Prescriber link workers, health coaches and care co-ordinators. The MDS looked at the social prescribing categories, existing and new SNOMED coding required for the MDS, the level of burden on the MDS being collected in GP IT systems and how the MDS can be used to measure benefits. The outcomes of the NHS E&I MDS pilot were used to inform the further development of the PRSB Social Prescribing standard.

- 3 multidisciplinary consultation workshops were held with key stakeholders, including patients and carers, front line health and care professionals, 2 workshops with informaticians and industry representation to review the draft requirements. Outputs from the meeting were used to inform an updated version of the draft deliverables.

- An online survey was used to seek wider consultation and to obtain the views of frontline clinicians, patients, and carers on a number of identified issues. The report was compiled of the results called 'developing an information standard for social prescribing survey results and analysis v1.1 December 2021' and can be found in the appendices.
- Outstanding issues were consulted on by the social prescribing working group. The outputs of this meeting informed the final draft deliverables.
- Final draft deliverables were disseminated to the social prescribing project board for their official sign off on the 21st of January 2022.

The Social Prescribing User journey:

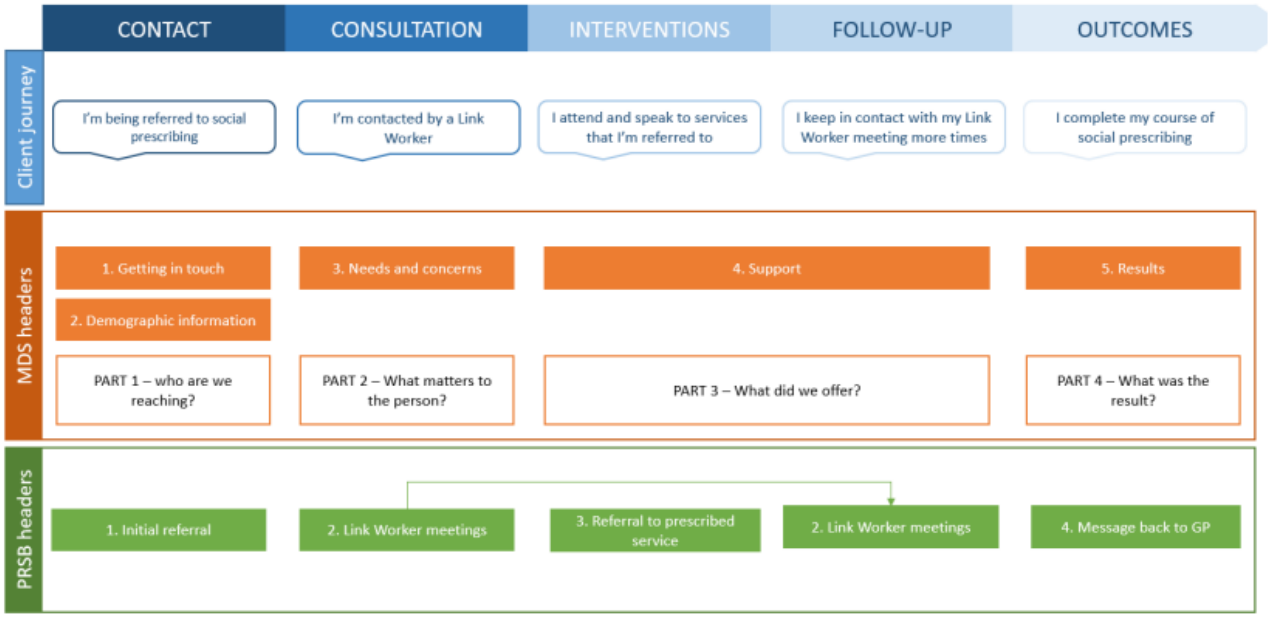

Table 1 The social prescribing user journey

The scope of the social prescribing information standard:

To support the full information journey, from referral to the end of the Social Prescribing intervention, the standard has been separated in to three distinct sections.

i. The referral to Social Prescribing (initial referral)

ii. The Social Prescribing conversation (link worker meetings including referral to social prescribing service)

iii. The message back to the referrer and GP (message back to GP)

Below are the data items for the 'Referral to Social Prescribing:

- Patient Demographics
- GP Practice detail
- Consent
- Pregnancy Status
- Safeguarding
- About Me
- Individual Requirements (Reasonable Adjustments)

- Referral Details
- Presenting Complaints and issues
- Problem List
- Social Context
- Services & Care
- Assessments
- Risk
- Care and Support Plan

Below are the data fields for The Social Prescribing conversation:

- Patient Demographics
- GP Practice details
- About Me
- Individual Requirements (Reasonable Adjustments)
- Safeguarding
- Consent
- Clinical Summary
- Social Context
- Pregnancy Status
- Assessments
- Risk
- Plan and requested Actions
- Care and Support Plan
- Referral Details
- Presenting Complaints and issues
- Problem List
- Services & Care
- Contact with professionals
- Signposting Details

Below are the data fields for the Message back to Referrer and GP:

- Patient Demographics
- GP Practice details
- About Me
- Individual Requirements (Reasonable Adjustments)
- Safeguarding
- Consent
- Clinical Summary
- Social Context
- Pregnancy Status
- Assessments
- Risk
- Plan and requested Actions
- Care and Support Plan

Out of scope

It is recognised that Adult Social Services providers and IT suppliers whilst involved in the creation of the social prescribing information standard are not currently in scope.

Clinical Risk Management System

The NHS Digital Clinical Safety Group (CSG) operates a full Clinical Safety Management System (CSMS) that encompasses integration with Health Organisations and professional bodies. The CSMS gives particular consideration to the integration with the Information Standards Board and the process in which professional standards are developed in the CSMS framework. The Clinical Safety Management System has been applied throughout all phases of the PRSB social prescribing standard. This Clinical Safety Case has been developed in accordance with the requirements of DCB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Specification [Ref1] and DCB0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - Specification [Ref. 2].

The essential structures of a CSMS have been implemented in this project by engagements with the following organisations:

- Royal College of Physicians
- Royal College of General Practitioners
- Royal College of Nursing
- National Academy for Social Prescribing
- The Social Prescribing Network
- National Association of Link Workers
- Association of Directors of Adult Social Services
- Council for Voluntary Services
- Social Prescribing project board
- Social Prescribing expert user group
- Joint GP IT Committee
- NHS E&I
- NHS Digital terminology team
- NHS Digital messaging team
- NHS Digital clinical safety group
- Other Royal Colleges and specialist societies
- The professional bodies of nursing, midwifery, and the Allied Health Professions
- Health & Social Care Alliance Scotland
- Digital Health & Care Wales
- RCP Patient and Carer Network

- The Patient Information Forum
- National Voices

However, it should be noted that this clinical safety report is necessarily limited in its scope because it is neither directly related to software development nor to deployment. Suppliers developing software to implement these standards will therefore still be expected fully to apply DCB0129 [Ref1]. Organisations involved in the deployment of such software will still be expected fully to apply DCBI0160 [Ref2].

Safety organisation structure

Clinical oversight was carried out throughout by RCCP Colleague Dr John McGuiness and Jeremy Wilkinson as the acting Clinical Safety Officer. The CSO should monitor the execution of the Clinical Safety Case and ensure that clinical safety obligations are being discharged in line with the latest Clinical Safety Management policy and processes.

Clinical Risk Analysis

A total of 4 hazards and their mitigations were identified via consultation and the formal hazard workshops, which are summarised in Table 1 below.

The table shows the total number of risks, and their associated initial and residual risk ratings.

The mitigated hazards should be considered and addressed in local implementations of the Social Prescribing Standard.

Initial	Residual	Risk rating	Definition
0	0	5	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
1	0	4	
2	0	3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
1	3	2	Acceptable where cost of further reduction outweighs benefits gained.
0	1	1	Acceptable, no further action required

Table 2: Summary of social prescribing hazard risk scores

As well as the 3 formal hazard workshops between December 2021 and January 2022, hazards were also identified during the wider consultation on the standard. The consultations consisted of multidisciplinary workshops, an online survey, a review of information models and implementation guidance and via the social prescribing project team.

The workshops, surveys and communications included patient representatives as well as UK wide professionals from, medical and other Royal Colleges, specialist societies, National Association of Link Workers, Community Voluntary Sector, MIND, social care, allied health professions, health informatics professionals and vendors.

It is expected that social prescribing software suppliers and healthcare organisation will consider and review these hazards and their mitigations within their own internal clinical safety management processes.

Clinical Risk Evaluation

Hazards were identified using the SWIFT (Structured 'What If' Technique) method of hazard identification during the hazard workshops. This entailed description of potential hazard, patient safety consequences, explanation of hazard causes, identification of existing controls, an estimation/rating of clinical risk and suggested further mitigations.

Hazard Workshop		
Date	Attendees	Role
12/10/21	Dr John McGuiness Jeremy Wilkinson Sharon Hanley Jules Ford	Clinical Lead Clinical Safety Officer Nonclinical Informatician NHS E/&I Senior Lead Social Prescribing

Hazard Workshop		
Date	Attendees	Role
19/10/21	Dr John McGuiness Jeremy Wilkinson Sharon Hanley Sarah Moreton Rob Moriarty	Clinical Lead Clinical Safety Officer Nonclinical Informatician Clinical informatician / Link Worker Person with lived experience

Clinical Safety Case Workshop		
Date	Attendees	Role
21/01/22	Jeremy Wilkinson Sharon Hanley	Clinical Safety Officer Nonclinical Informatician

Clinical Risk Control

Four hazards were identified, one was scored at level 4, two at level 3 and one at level 2, all of which required additional controls to reduce risk to an acceptable level. After the additional controls and mitigations were evaluated and verified during the hazard workshops the residual hazards are:

Three hazards were reduced to level 2 - *Acceptable where cost of further reduction outweighs benefits gained.*

The remaining hazard was reduced to level 1 - *acceptable, no further action is required.*

There are 3 Social Prescribing hazards with a residual risk of 2, which is *Undesirable level of risk, attempts should be made to eliminate or control to reduce risk to an acceptable level.*

Hazard Id:	1
Initial risk ranking	3
Hazard Name	Missing data (blank fields), incorrect, or corrupt data.
Hazard:	Data items that are important for the care of the individual maybe missing or incomplete

Hazard Causes:	1) Incorrect data entered in source system unable to be mapped into the receiving system. 2) Information model in source system is misinterpreted/not understood e.g. Family History recorded using Disorder Concept, misinterpreted as Disorder present or differential diagnosis thought to be a confirmed one 3) Logical data model is wrong leading to incorrect or missing data attributes. 4) Data processing and de-duplication loses important data item. 5) Headings have similar meanings, so users are unsure where to find the information they need e.g. About Me, Individual Requirements and Social Context. 6) Consequence of different professional groups with different roles and emphasis in creating electronic health and care records. 7) Semantics and language difference between the different professions. 8) Social Prescribing delivery model is inconsistent.
Potential patient safety impact description	Healthcare provider delivers inappropriate care based on absent / incorrect information which could lead to an absence or delay to care, which could result in patient harm.
Dependencies & assumptions	1. Suppliers implement the standard in accordance with the PRSB guidance provided. 2. Supplier systems are able to configure their system to support recommended conformance.
Mitigation:	**Existing controls / Mitigation** Existing organisational policies and process in place are fully embedded and adhered to **Mitigations** 1) Data standard has been designed to ensure conformance criteria is clear (2 &3) Testing of standards and templates to inform Information model 4) Design Assurance/ compliance processes already published for system suppliers / implementers 5)Training to support end users accessing information in receiving systems 6) Training on use of standards and templates for users to improve data quality. 7) Training for H&SC staff to understand terminology across different professions
Residual risk:	2

Hazard Id:	2
Initial risk ranking	3
Hazard Name	Incorrect mapping / transcription of data items from source systems (including paper /excel) into receiving system.
Hazard Description:	Data items that are important for the care of the individual maybe incorrect

Hazard Causes:	1) Recommended coding not available in supplier system. 2) Suppliers map incorrect codes or data. 3) Incorrect transcription of handwritten information
Potential patient safety impact description	Incorrect treatment or advice given by the HCP which could lead to an absence or delay to care, which could result in patient harm.
Dependencies & assumptions	1. Supplier systems can implement the 111-standard using the recommended coding via HL7 and/or FiHR for input and extract. 2. Sending of paper-based information includes list of appropriate codes to enter into electronic systems when possible
Mitigation:	**Existing controls / mitigations** Existing organisational policies and process in place are fully embedded and adhered to. **Mitigations** 1 & 2) Mapping of data sets to existing SNOMED coding to support implementation of standard data set 3) Training on use of standards and templates for users to improve data quality when entering data into source systems 3) Business Processes to be followed by social prescribers to ensure development of standard social prescribing business model using electronic / coded data
Residual risk:	2

Hazard Id:	3
Initial risk ranking	2
Hazard Name	Ambiguity with regards to the data standard data items
Hazard Description:	Differences in healthcare and social care terminology i.e. a 'problem' in health data is different to a 'problem' is social care
Hazard Causes:	Terminology used in social care settings are not always used or have the same meaning in health settings
Potential patient safety impact description	Use of health terminology for social prescribing may confuse the individual and make them feel less positive. This may cause the individual to disengage from the social prescribing service and their situation and/or health may deteriorate
Dependencies & assumptions	1. Requests for new data / reference sets to include appropriate social care terminology for Social Prescribing 2. Suppliers will be able to implement the new social prescribing data / ref sets when available
Mitigation:	**Existing controls / mitigations** PRSB carry out wide consultations to agree standard headings through all of the PRSB standards to ensure consistency, comprehension, and usability. **Mitigations** PRSB Headings use terms that are comprehensible to health and social case and the individual. Additional SNOMED terms expected with new SNOMED Ref sets (April 2022)

	Workshops and focus groups with individuals identified where terminology could be improved for social prescribing, which informed the new data / ref sets. Training on use of standards and templates for users to improve data quality when entering data into source systems
Residual risk:	1

Hazard Id:	4
Initial risk ranking	4
Hazard Name	Disclosure of Gender reassignment without the individual's consent/knowledge
Hazard Description:	Accidental disclosure of gender reassignment, without consent,
Hazard Causes:	The two data items 'Sex' and 'gender' recorded as part of the Social Prescribing Standard, where they do not match, could indicated gender reassignment.
Potential patient safety impact description	Disclosure of a person's gender reassignment without their consent could impact the individual psychologically and may lead to harm of the individual
Dependencies & assumptions	Conversation will be had with individuals about the recording of 'sex' and 'gender' either to gain their consent or to agree not to record specific information System suppliers will be able to configure their system to prevent sex and gender being recorded together without gaining the individual's consent
Mitigation:	**Existing controls / mitigations** GDPR **Mitigations** Both Sex and gender are 'required' fields NOT 'mandatory'. these fields can be left blank System suppliers to follow business rule to ensure a person's protected characteristics are not disclosed without the individual's consent. Implementation guidance to clearly explain impact of recording sex and gender together. With recommendation to prompt for patient consent if entered into the vendors system Suppliers to implement system processes that disallow the recording of both Sex and gender where they are different. Unless consent has been given and recorded in the sending system
Residual risk:	2

Hazard Log

The Social Prescribing hazard log is embedded below.

Social%20Prescribing%20Hazard%20log

Please note: The mitigations we have taken to address clinical safety risks are largely in relation to the transmission of data between software suppliers' systems. Further mitigations will be required when the headings are implemented in electronic health record systems. We have flagged some risks relating to implementation in this report but expect that further mitigations will be identified as clinical risk assessments and safety cases are developed by vendors and sites during the implementation.

Test Issues

As this Clinical Safety Case report pertains to an information standard rather than a clinical IT system, live testing was not undertaken.

Summary Safety Statement

The clinical safety statement is based on the safety argument below, based on two of the following criteria: -

1. Demonstration of adherence to a fit for purpose clinical safety process: The Clinical Safety process described in Section 4 has been carried out and is consistent with the NHS Digital's Clinical Safety Management System (CSMS) and DCB 0129 outlined in reference 2.

2. The mitigation is deemed to be appropriate and commensurate with the scale of risk. Risk is deemed to be acceptable in most cases and tolerable in others.

All risks identified within the hazard log have been managed via their associated controls to either an 'Acceptable' or 'Tolerable' level, in line with the identified risk tolerance levels.
As previously stated, this clinical safety report is not directly related to software development or deployment. It has been designed to look at the clinical safety hazards and mitigate the risks in the creation and production of the social prescribing information standard itself. Suppliers developing software to implement these standards, will therefore need to undertake their own DCB0129 Clinical Safety Case and healthcare organisations involved in the deployment of such software will still be expected to apply DCB0160. From this perspective the Clinical Safety Officer considers the Social Prescribing v0.2 standard safe to deploy.

Quality Assurance & Document Approval

All PRSB standards and associated documents undergo a formal internal assurance process and full approval by the board before any standard is released for public use.

Configuration Control / Management

Future governance of the development and maintenance of the Social Prescribing Standard is the responsibility of the PRSB.
All reviews and changes are fully documented and recorded via the version control processes within the software hosting the social prescribing standard.

Appendices

1. Project Board Members:

Role	Organisation
Project Sponsor & Chair	NHSE
NHSE commissioners	NHSE NHSE / Project CSO
Senior Project Manager	PRSB
Business Analyst	PRSB
MDS Lead Early Adopter Lead	NHSE Southwest Academic Health Science Network
People representative	PRSB Non-Exec
Link Worker Lead GP Lead Person Lead	Sefton Council for Voluntary Service (CVS) One Lewisham Patient with lived experience
PRSB Exec	PRSB Communication Lead

2. Social Prescribing Standard V2

Social prescribing standard v2.0 (Release date: 2022-03-08 16:35:16)

Social Prescribing
Version 0.2

Search By Item | Filter By | Reset all

MRO	Information Type	Name	Description	Value Sets	Implementation Guidance	Cardinality
M		Person demographics	The person's details and contact information.	-	• For the implementation of this ... Read more >	1 ... 1
M		GP practice	Details of the person's GP practice.	-	This section contains details of t... Read more >	1 ... 1
R		About me	About me	-	This is a record of the things tha... Read more >	0 ... 1
R		Individual requirements	The individual requirements of the person.	-	This is not mandatory for providin... Read more >	0 ... 1
R		Safeguarding	The safeguarding details of the person.	-	This is not mandatory for providin... Read more >	0 ... 1
R		Consent	Legal information captured relating to patient care, such as consent.	-	This is not mandatory for providin... Read more >	0 ... 1
M		Referral details	The details of the referral.	-	This section includes a record of ... Read more >	1 ... 1
R		Contacts with professionals	The details of the person's contact with a professional.	-	This section captures details of t... Read more >	0 ... 1
R		Presenting complaints or issues	Presenting complaints or issues	-	This concept is used in multiple l... Read more >	0 ... 1
		Problem list	A summary of the problems that require investigation or treatment.	-	T his section allows for all relev... Read more >	0 ... 1
M		Clinical Summary	Clinical Summary	-	The Clinical / professional summar... Read more >	1 ... 1

	▸ Social context	The social setting in which the person lives, such as their household, occupational history, and lifestyle factors.	-	This section includes information ... Read more >	0 ... 1
R	▸ Services and care	The services and care provided for the person.	-	The system should be able to capt... Read more >	0 ... 1
R	▸ Signpost details	Details of signpost	-	These are the details of any servi... Read more >	0 ... 1
R	▸ Pregnancy status	Pregnancy status of the person.	-	This is to share if someone is cur... Read more >	0 ... 1
	▸ Assessments	Details of the person's assessments	-	This section includes details of a... Read more >	0 ... 1
M	▸ Risks	Details of any risks related to the person.	-	Risks are likely to fall into the ... Read more >	1 ... 1
R	▸ Plan and requested actions	The details of planned investigations, procedures and treatment, and whether this plan has been agreed with the person or their legitimate representative.	-	To ensure the referrer and or GP i... Read more >	0 ... 1
R	▸ Care and support plan	This records the decisions reached during conversation between the individual and health and care professional about future plans and also records progress.	-	This section replicates the sectio... Read more >	1 ... 1

3. Social Prescribing Final Report

To view the Social Prescribing Final Report please visit https://theprsb.org/ and navigate to:

Standards/Social Prescribing Standard v0.2/supporting Documentation / Final report

4. Social Prescribing Survey Results

To view the Social Prescribing Survey Results please visit https://theprsb.org/ and navigate to:

Standards/Social Prescribing Standard v0.2 /supporting Documentation /Survey Results

5. General Implementation Guidance for all PRSB Standards

To view the Social Prescribing Final Report please visit https://theprsb.org/ and navigate to:

Standards/Social Prescribing Standard v0.2/ supporting Documentation / General Implementation Guidance for all PRSB Standards

6. Link to the PRSB Social Prescribing Standard

To view the Social Prescribing Final Report please visit https://theprsb.org/ and navigate to:

Standards/Social Prescribing Standard v0.2/ supporting Documentation / view the standard