

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

NATIONAL OPT-OUT MODEL**PART 1: BULK OPT-OUT REGISTRATION****1. Outline**

Bulk opt-out registration is the roll-out of a national opt-out My Health Record system whereby all eligible individuals will be registered for a My Health Record unless they opt-out. It will be conducted by jurisdiction, with opt-out deadlines for to each jurisdiction. This is known as *phased opt-out*. It will commence no earlier than February 2018 and be complete by December 2018.

2. Selection of eligible individuals

Individuals whose personal postal address held in the Medicare system (Medicare address) is situated in Australia immediately before commencement of bulk opt-out registration will be selected as potential subjects for the bulk opt-out registration.

These potential subjects will be eligible to participate in the bulk opt-out registration whether or not they continue to reside at the same Medicare address after that time. Individuals who are born in Australia, or new immigrants who register with Medicare, after this time will not be eligible to participate in the bulk opt-out registration. These individuals will be recognised in the ongoing opt-out registration (see Part 2).

Individuals meeting the following criteria will be eligible to participate in the bulk opt-out registration:

- (a) individuals whose Medicare address is situated in Australia are eligible to participate in the bulk opt-out registration if they have a verified IHI record unless they:
 - (i) have an IHI record status of deceased, retired or resolved; or
 - (ii) have an administrative alert in the Medicare system that the person is no longer contactable at that address; or
 - (iii) have an administrative alert in the Medicare system that the person is the subject of a fraud investigation; or
 - (iv) have an IHI record flagged as being an intertwined record or possible duplicate record; or
 - (v) have a Medicare or DVA end date recorded in the Medicare system; or
 - (vi) have a IHI that has a status of suppressed; or
 - (vii) have an active or suspended My Health Record; or
 - (viii) have a cancelled My Health Record; or
 - (ix) were a participant in the opt-out trials and opted out.

Information regarding the My Health Record system and the bulk opt-out registration arrangements will be included on the My Health Record website, including a facility to access

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

to the online opt-out service. Individuals will be made aware of and directed to the My Health Record website for further information through communications activities.

3. Opt-out channels

During the opt-out period, an individual will be able to choose not to be registered for a My Health Record via the following channels:

- (a) online via the online opt-out service. The online out-out service will be hosted by the System Operator (DHS) but will be accessible via a link on the My Health Record website which is hosted by the Department on behalf of the System Operator;
- (b) over the telephone with the System Operator (DHS) – i.e. via a DHS Customer Service Operator; and
- (c) in person via the System Operator (DHS) – i.e. face-to-face at a DHS service centre offering Medicare services.

4. Opt-out period

The opt-out period will begin on the “commencement date” (to be determined) and will end on a date specific to the jurisdiction in which an individual’s Medicare address was situated on the eligibility date.

The end dates for each jurisdiction are yet to be determined.

Individuals will need to know in which jurisdiction their Medicare address was situated immediately before commencement in order to know what their opt-out period is.

5. Exercising the opt-out choice

During the opt-out period, all eligible individuals aged 14 and over will be able to opt-out of the My Health Record system via the opt-out channels.

Individuals under the age of 14 who are able to demonstrate their capacity and satisfy the current requirements for independent minors will also be able to opt-out, but only through the face-to-face channel.

An individual (e.g. parent or guardian) will be able to opt-out his or her dependants where:

- (a) the dependant is listed on the individual's Medicare card; and
- (b) the dependant is under 18 years of age.

Where an individual (the first individual) wishes to opt-out another individual (the second individual) who is:

- (a) under 18 years of age and is not listed on the first individual's Medicare card; or
- (b) over 18 years of age and lacks capacity to make decisions for themselves,

the first individual will be unable to opt-out the second individual via the online opt-out service or telephone channel (except where the first individual is listed as the group contact for

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

that Medicare card and is able to answer security questions, in which case, the first individual will be able to use the telephone channel).

An individual will be able to opt-out another person without having to opt-out themselves, and will be able to opt-out themselves without having to opt-out another person.

Individuals whose Medicare address is situated outside Australia may still opt out another person whose Medicare address is situated in Australia.

If a My Health Record already exists in relation to an individual at the time that individual seeks to opt-out, the individual will be advised that a My Health Record exists and they will be given an opportunity to cancel their record should they wish to do so.

6. Opt-out confirmation

Individuals opting out will receive notification confirming that they have been opted out. The type of notification will depend on the opt-out channel they use. The notification will be provided to the individual opting out, including to independent minors who opt-out. Where a parent/guardian has opted out a dependant, the parent/guardian will receive the notification.

7. Record creation

At the end of the opt-out period in a jurisdiction, My Health Records will be created for all eligible individuals in that jurisdiction unless they opted out during the opt-out period. The My Health Records will be available to registered healthcare provider organisations at that time subject to any access controls set by the individual.

8. Setting access controls

Individuals will be able to set the access controls to their My Health Record at the end of the opt-out period when their record has been created.

An individual can choose to set their access controls during the opt-out period. To do so, they would opt-in and have their My Health Record created (thereby becoming subject to existing arrangements, including making their record immediately available to healthcare provider organisations subject to any access controls set by the individual).

9. Medicare information

At the end of the opt-out period, Medicare information will be included in a My Health Record upon first access (by the individual or registered healthcare provider organisation), unless the individual has elected not to include this information. When individuals set up their access controls, they will be able to elect not to include this information.

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

NATIONAL OPT-OUT MODEL**PART 2: ONGOING OPT-OUT REGISTRATION****1. Outline**

Ongoing opt-out registration is the implementation of ongoing arrangements for individuals who become eligible after roll-out and who will be registered for a My Health Record unless they opt-out. It will be implemented by the time roll-out concludes.

2. Selection of eligible individuals

From a specified date (to be determined), any individual who becomes eligible (see section 2(a), Part 1) will be registered for a My Health Record unless they opt-out.

Note: If this commencement date does not coincide with the commencement of bulk opt-out registration, any people who may subsequently (but before ongoing commencement) become eligible will not be registered.

3. Opt-out channels

In ongoing opt-out, an individual will be able to choose not to be registered for a My Health Record by completing one of the following applications:

- (a) the Medicare enrolment (including those for newborns);
- (b) the application to create an individual healthcare identifier; or
- (c) the application to register a pseudonym individual healthcare identifier record.

4. Opt-out period

An individual will be able to opt-out at the time they complete one of the above applications.

5. Exercising the opt-out choice

If one of the applications at section 2 provides for the entry of multiple individuals, opt-out will be available in respect of each person.

An individual will be able to opt-out another person without having to opt-out themselves, and will be able to opt-out themselves without having to opt-out another person.

6. Opt-out confirmation

Individuals opting out will receive notification confirming that they have been opted out. The notification will be provided to the individual opting out, including to independent minors who opt-out. Where a parent/guardian has opted out a dependant, the parent/guardian will receive the notification.

7. Record creation

A My Health Record will be created for each eligible individual soon after an application of the type described in section 2 has been submitted, unless their opted out. The My Health

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

Record will be available to registered healthcare provider organisations at that time subject to any access controls set by the individual.

8. Setting access controls

Individuals will be able to set the access controls to their My Health Record when their record has been created.

9. Medicare information

Medicare information will be included in a My Health Record upon first access (by the individual or registered healthcare provider organisation), unless the individual has elected not to include this information. When individuals set up their access controls, they will be able to elect not to include this information.

BULK OPT-OUT REGISTRATION

Step	Particulars	Timing	Other Information
1-3	<i>Creation of shell My Health Record</i>		
1	System Operator (NIO) collects: <ul style="list-style-type: none"> from HI Service Operator – the list of all individuals who have an active verified IHI; and from Chief Executive Medicare – the list of all individuals indicating who should not have a record because the individual fits within one of the exceptions described in section 2(a) of Part 1. 	X December 2017	
2	System Operator (NIO) creates shell records for all eligible individuals. System Operator (NIO) will continue to collect the information identified at step 2 in order to update the list of eligible individuals (and update shell records accordingly) to reflect changes to information and eligibility.		A shell record is not a My Health Record. It is the collection of identifying information about an individual. Health information is not associated with the shell record. The collection of this information allows an individual to opt-out of participation and for a My Health Record to be created for the individual upon registration. The shell record is not accessible to individuals or their healthcare providers.
3	System Operator (NIO) finalises the list of eligible individuals (and corresponding shell records).	X February 2017	
4-5	<i>Opt-out period</i>		
4	Individuals notify the System Operator (DHS) of their decision to opt-out.	Within the opt-out period specific to the jurisdiction in which their Medicare address was situated immediately before commencement	The information will be collected through various channels. Individuals who want to opt-out must do so by the end of the opt-out period. If an individual wants to opt-out after the end of the opt-out period, they will need to cancel

National opt-out model: 14 March 2017

ATTACHMENT 1

Step	Particulars	Timing	Other Information
			their My Health Record.
5	System Operator (DHS) notifies the individual that they have been opted out.		The type of notification will depend on the opt-out channel used.
6-9	<i>Creation of My Health Records</i>		
6	System Operator (NIO) collects: <ul style="list-style-type: none"> from System Operator (DHS) – the list of individuals who opted out; from HI Service Operator – an update of the list of individuals who have an IHI; from Chief Executive Medicare – an update of the list of all individuals indicating who should not have a record because the individual fits within one of the exceptions described in section 2(a) of Part 1. 	Steps 6-9 will occur after the end of each jurisdiction's opt-out period and the activities will relate only to individuals whose Medicare address was, immediately before commencement, situated in that jurisdiction.	
7	System Operator (NIO) uses the My Health Record system to determine which individuals have or had a My Health Record, or previously opted out of the opt-out trials.		
8	System Operator (NIO) uses the information obtained in steps 6 and 7 to determine who should and should not be registered for a My Health Record.		
9	System Operator (NIO) registers the eligible individuals and creates My Health Records for them. The System Operator deletes shell records for ineligible individuals.		
10	The My Health Records created in step 9 become accessible to individuals and registered healthcare provider organisations.		
11-13	<i>Setting access controls</i>		
11	Individual may create and access their myGov account, and link their myGov account to their My Health Record.	Steps 11 to 13 are available as soon as the individual's My	

Step	Particulars	Timing	Other Information
		Health Record has been created	
12	<p>Individual may access their My Health Record through myGov, and set their access and content preferences as follows:</p> <ul style="list-style-type: none"> access preferences – if the individual wishes to limit the access by healthcare provider organisations to their My Health Record, they can set a Record Access Code (RAC) which healthcare provider organisations must input into the My Health Record system in order to view the individual's My Health Record, or a Limited Document Access Code (LDAC) to restrict access to certain documents; and content preferences – the individual's preferences for the inclusion of the individual's Medicare Benefits Schedule (MBS – future and past two years), Department of Veterans' Affairs (DVA – future and past two years), Pharmaceutical Benefits Scheme (PBS – future and past two years), Repatriation Pharmaceutical Benefits Scheme (RPBS – future and past two years), Australian Childhood Immunisation Register (ACIR – all) and Australian Organ Donor Register (AODR – all) records into the individual's My Health Record. 		Medicare information will be made available to the individual's My Health Record upon first access (by the individual or registered healthcare provider organisation) unless the individual chooses not to include it.
13	If the individual does not set access controls the System Operator (NIO) will apply the default access and content control settings for each individual's My Health Record.		An individual can change their access controls and content settings at any time.
14-20	Medicare data flow		
14	When either the individual or a registered healthcare provider organisation accesses the individual's My Health Record for the first time after it has been created (in step 9), this sets off a trigger to upload the two years of retrospective MBS/DVA/PBS/RPBS/AODR/ACIR data (Medicare Repository Data) to the individual's My Health Record (unless the individual opted out of this when setting their access controls – see step 12). (In the case of the healthcare provider, the type of 'access' would	Upon first access (by the individual or registered healthcare provider organisation)	<p>Steps 15 to 20 describe the information flows following the trigger set off in this step.</p> <p>In opt-out registration, the default position is that the Medicare Repository Data will be included in the My Health Record unless the individual opted out of this when setting their access controls.</p>

National opt-out model: 14 March 2017

ATTACHMENT 1

Step	Particulars	Timing	Other Information
	be a user viewing the My Health Record.)		
15	An electronic notification is sent from the System Operator (NIO) to Chief Executive Medicare to request that Medicare Repository Data be made available in the My Health Record system. The request will include the individual's IHI, whether they have a My Health Record, and the Medicare Repository Data to be made available (as set in step 12, if applicable).		
16	Chief Executive Medicare as registered repository operator identifies the Medicare record for the individual in the Medicare/DVA claims database, PBS/RPBS claims database and ACIR and AODR (the live system) using the IHI.		
17	Chief Executive Medicare as registered repository operator copies the individual's MBS/DVA claims records, PBS/RPBS records, ACIR records and AODR records from its live system to its My Health Record repository administration system.		
18	Chief Executive Medicare as registered repository operator attaches the individual's IHI to the individual's Medicare Repository Data in its My Health Record repository administration system.		
19	Chief Executive Medicare as registered repository operator sorts the records in its My Health Record repository administration system to match the automatic (default) uploading of Medicare Repository Data. Chief Executive Medicare as registered repository operator indexes the records for individuals who have not opted out of having their retrospective Medicare data from being uploaded.		
20	Chief Executive Medicare as registered repository operator makes the index available to the System Operator (NIO).		

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

ATTACHMENT 2**ONGOING OPT-OUT REGISTRATION**

Step	Particulars	Timing	Other Information
1-2	<i>Individual identified</i>		
1	Individual applies to enrol in Medicare, create an IHI or create a pseudonymous IHI. Individual indicates in the application if they want to opt-out of being registered for a My Health Record.		If an individual wants to opt-out after they make this application, they will need to cancel their My Health Record.
2	Application is processed by relevant entity (Chief Executive Medicare and/or HI Service Operator), then referred to the System Operator (NIO) to decide whether to register the individual.		
3-8	<i>Creation of My Health Records</i>		
3	System Operator (NIO) collects: <ul style="list-style-type: none"> from HI Service Operator – the individual's IHI information; and from Chief Executive Medicare – information about whether the individual fits within one of the exceptions described in section 2(a) of Part 1. 		
4	System Operator (NIO) uses: <ul style="list-style-type: none"> the application in received in step 2 to identify whether the individual opted out; and the My Health Record system to determine whether the individual has or had a My Health Record, or previously opted out of the opt-out trials. 		

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
5	System Operator (DHS) notifies the individual that they have been opted out.		
6	System Operator (NIO) uses the information obtained in steps 3 and 4 to determine whether the individual should be registered for a My Health Record.		
7	System Operator (NIO) registers the eligible individual and creates a My Health Record for them.		
8	The My Health Record created in step 7 becomes accessible to the individual and registered healthcare provider organisations.		
9-11	<i>Setting access controls</i>		
9	Individual may create and access their myGov account, and link their myGov account to their My Health Record.	Steps 9 to 11 are available as soon as the individual's My Health Record has been created	
10	Individual may access their My Health Record through myGov, and set their access and content preferences as follows: <ul style="list-style-type: none"> access preferences – if the individual wishes to limit the access by healthcare provider organisations to their My Health Record, they can set a Record Access Code (RAC) which healthcare provider organisations must input into the My Health Record system in order to view the individual's My Health Record, or a Limited Document Access Code (LDAC) to restrict access to certain documents; and content preferences – the individual's 		Medicare information will be made available to the individual's My Health Record upon first access (by the individual or registered healthcare provider organisation) unless the individual chooses not to include it.

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	preferences for the inclusion of the individual's Medicare Benefits Schedule (MBS – future and past two years), Department of Veterans' Affairs (DVA – future and past two years), Pharmaceutical Benefits Scheme (PBS – future and past two years), Repatriation Pharmaceutical Benefits Scheme (RPBS – future and past two years), Australian Childhood Immunisation Register (ACIR – all) and Australian Organ Donor Register (AODR – all) records into the individual's My Health Record.		
11	If the individual does not set access controls the System Operator (NIO) will apply the default access and content control settings for each individual's My Health Record.		An individual can change their access controls and content settings at any time.
12-18	Medicare data flow		
12	When either the individual or a registered healthcare provider organisation accesses the individual's My Health Record for the first time after it has been created (in step 7), this sets off a trigger to upload the two years of retrospective MBS/DVA/PBS/RPBS/AODR/ACIR data (Medicare Repository Data) to the individual's My Health Record (unless the individual opted out of this when setting their access controls – see step 10). (In the case of the healthcare provider, the type of 'access' would be a user viewing the My Health Record.)	Upon first access (by the individual or registered healthcare provider organisation)	Steps 13 to 18 describe the information flows following the trigger set off in this step. In opt-out registration, the default position is that the Medicare Repository Data will be included in the My Health Record unless the individual opted out of this when setting their access controls.
13	An electronic notification is sent from the System Operator (NIO) to Chief Executive		

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	Medicare to request that Medicare Repository Data be made available in the My Health Record system. The request will include the individual's IHI, whether they have a My Health Record, and the Medicare Repository Data to be made available (as set in step 10, if applicable).		
14	Chief Executive Medicare as registered repository operator identifies the Medicare record for the individual in the Medicare/DVA claims database, PBS/RPBS claims database and ACIR and AODR (the live system) using the IHI.		
15	Chief Executive Medicare as registered repository operator copies the individual's MBS/DVA claims records, PBS/RPBS records, ACIR records and AODR records from its live system to its My Health Record repository administration system.		
16	Chief Executive Medicare as registered repository operator attaches the individual's IHI to the individual's Medicare Repository Data in its My Health Record repository administration system.		
17	Chief Executive Medicare as registered repository operator sorts the records in its My Health Record repository administration system to match the automatic (default) uploading of Medicare Repository Data. Chief Executive Medicare as registered repository operator indexes the records of the individual if they have not opted out of having		

CONFIDENTIAL DRAFT

National opt-out model: 14 March 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	their retrospective Medicare data uploaded.		
18	Chief Executive Medicare as registered repository operator makes the index available to the System Operator (NIO).		

NATIONAL OPT-OUT MODEL

PART 1: BULK OPT-OUT REGISTRATION

1. Outline

Bulk opt-out registration is the roll-out of a national opt-out My Health Record system whereby all eligible individuals will be registered for a My Health Record unless they opt-out. It will be conducted by jurisdiction, with opt-out deadlines for to each jurisdiction. This is known as *phased opt-out*. It will commence no earlier than February 2018 and be complete by December 2018.

2. Selection of eligible individuals

Individuals whose personal postal address held in the Medicare system (Medicare address) is situated in Australia immediately before commencement of bulk opt-out registration will be selected as potential subjects for the bulk opt-out registration.

These potential subjects will be eligible to participate in the bulk opt-out registration whether or not they continue to reside at the same Medicare address after that time. Individuals who are born in Australia, or new immigrants who register with Medicare, after this time will not be eligible to participate in the bulk opt-out registration. These individuals will be recognised in the ongoing opt-out registration (see Part 2).

Individuals meeting the following criteria will be eligible to participate in the bulk opt-out registration:

- (a) individuals whose Medicare address is situated in Australia are eligible to participate in the bulk opt-out registration if they have a verified IHI record unless they:
 - (i) have an IHI record status of deceased, retired or resolved; or
 - (ii) have an administrative alert in the Medicare system that the person is no longer contactable at that address; or
 - (iii) have an administrative alert in the Medicare system that the person is the subject of a fraud investigation; or
 - (iv) have an IHI record flagged as being an intertwined record or possible duplicate record; or
 - (v) have a Medicare or DVA end date recorded in the Medicare system; or
 - (vi) have a IHI that has a status of suppressed; or
 - (vii) have an active or suspended My Health Record; or
 - (viii) have a cancelled My Health Record; or
 - (ix) were a participant in the opt-out trials and opted out.

Information regarding the My Health Record system and the bulk opt-out registration arrangements will be included on the My Health Record website, including a facility to access

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

to the online opt-out service. Individuals will be made aware of and directed to the My Health Record website for further information through communications activities.

3. Opt-out channels

During the opt-out period, an individual will be able to choose not to be registered for a My Health Record via the following channels:

- (a) online via the online opt-out service. The online out-out service will be hosted by the System Operator (DHS) but will be accessible via a link on the My Health Record website which is hosted by the Department on behalf of the System Operator;
- (b) over the telephone with the System Operator (DHS) – i.e. via a DHS Customer Service Operator; and
- (c) in person via the System Operator (DHS) – i.e. face-to-face at a DHS service centre offering Medicare services.

4. Opt-out period

The opt-out period will begin on the “commencement date” (to be determined) and will end on a date specific to the jurisdiction in which an individual’s Medicare address was situated on the eligibility date.

The end dates for each jurisdiction are yet to be determined.

Individuals will need to know in which jurisdiction their Medicare address was situated immediately before commencement in order to know what their opt-out period is.

5. Exercising the opt-out choice

During the opt-out period, all eligible individuals aged 14 and over will be able to opt-out of the My Health Record system via the opt-out channels.

Individuals under the age of 14 who are able to demonstrate their capacity and satisfy the current requirements for independent minors will also be able to opt-out, but only through the face-to-face channel.

An individual (e.g. parent or guardian) will be able to opt-out his or her dependants where:

- (a) the dependant is listed on the individual's Medicare card; and
- (b) the dependant is under 18 years of age.

Where an individual (the first individual) wishes to opt-out another individual (the second individual) who is:

- (a) under 18 years of age and is not listed on the first individual's Medicare card; or
- (b) over 18 years of age and lacks capacity to make decisions for themselves,

the first individual will be unable to opt-out the second individual via the online opt-out service or telephone channel (except where the first individual is listed as the group contact for

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

that Medicare card and is able to answer security questions, in which case, the first individual will be able to use the telephone channel).

An individual will be able to opt-out another person without having to opt-out themselves, and will be able to opt-out themselves without having to opt-out another person.

Individuals whose Medicare address is situated outside Australia may still opt out another person whose Medicare address is situated in Australia.

If a My Health Record already exists in relation to an individual at the time that individual seeks to opt-out, the individual will be advised that a My Health Record exists and they will be given an opportunity to cancel their record should they wish to do so.

6. Opt-out confirmation

Individuals opting out will receive notification confirming that they have been opted out. The type of notification will depend on the opt-out channel they use. The notification will be provided to the individual opting out, including to independent minors who opt-out. Where a parent/guardian has opted out a dependant, the parent/guardian will receive the notification.

7. Record creation

At the end of the opt-out period in a jurisdiction, My Health Records will be created for all eligible individuals in that jurisdiction unless they opted out during the opt-out period. The My Health Records will be available to registered healthcare provider organisations at that time subject to any access controls set by the individual.

8. Setting access controls

Individuals will be able to set the access controls to their My Health Record at the end of the opt-out period when their record has been created.

An individual can choose to set their access controls during the opt-out period. To do so, they would opt-in and have their My Health Record created (thereby becoming subject to existing arrangements, including making their record immediately available to healthcare provider organisations subject to any access controls set by the individual).

9. Medicare information

At the end of the opt-out period, Medicare information will be included in a My Health Record upon first access (by the individual or registered healthcare provider organisation), unless the individual has elected not to include this information. When individuals set up their access controls, they will be able to elect not to include this information.

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

NATIONAL OPT-OUT MODEL**PART 2: ONGOING OPT-OUT REGISTRATION****1. Outline**

Ongoing opt-out registration is the implementation of ongoing arrangements for individuals who become eligible after roll-out and who will be registered for a My Health Record unless they opt-out. It will be implemented by the time roll-out concludes.

2. Selection of eligible individuals

From a specified date (to be determined), any individual who becomes eligible (see section 2(a), Part 1) will be registered for a My Health Record unless they opt-out.

Note: If this commencement date does not coincide with the commencement of bulk opt-out registration, any people who may subsequently (but before ongoing commencement) become eligible will not be registered.

3. Opt-out channels

In ongoing opt-out, an individual will be able to choose not to be registered for a My Health Record by completing an application to enrol in Medicare (including for newborns) or an application to create an individual healthcare identifier.

4. Opt-out period

An individual will be able to opt-out at the time they complete one of the above applications.

5. Exercising the opt-out choice

If one of the applications at section 2 provides for the entry of multiple individuals, opt-out will be available in respect of each person.

An individual will be able to opt-out another person without having to opt-out themselves, and will be able to opt-out themselves without having to opt-out another person.

6. Opt-out confirmation

Individuals opting out will receive notification confirming that they have been opted out. The notification will be provided to the individual opting out, including to independent minors who opt-out. Where a parent/guardian has opted out a dependant, the parent/guardian will receive the notification.

7. Record creation

A My Health Record will be created for each eligible individual soon after an application of the type described in section 2 has been submitted, unless their opted out. The My Health Record will be available to registered healthcare provider organisations at that time subject to any access controls set by the individual.

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

8. Setting access controls

Individuals will be able to set the access controls to their My Health Record when their record has been created.

9. Medicare information

Medicare information will be included in a My Health Record upon first access (by the individual or registered healthcare provider organisation), unless the individual has elected not to include this information. When individuals set up their access controls, they will be able to elect not to include this information.

CONFIDENTIAL DRAFT

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

BULK OPT-OUT REGISTRATION

Step	Particulars	Timing	Other Information
1-3	<i>Creation of shell records</i>		
1	System Operator (NIO) collects: <ul style="list-style-type: none"> from HI Service Operator – the list of all individuals who have an active verified IHI; and from Chief Executive Medicare – the list of all individuals indicating who should not have a record because the individual fits within one of the exceptions described in section 2(a) of Part 1. 	1 December 2017 (TBC)	
2	System Operator (NIO) creates shell records for all eligible individuals. System Operator (NIO) will continue to collect the information identified at step 2 in order to update information for eligible individuals (and update shell records accordingly) to reflect changes to information and eligibility.		A shell record is not a My Health Record. It is the collection of identifying information about an individual. Health information is not associated with the shell record. The collection of this information allows an individual to opt-out of participation and for a My Health Record to be created for the individual upon registration. The shell record is not accessible to individuals or their healthcare providers.
3	System Operator (NIO) finalises the list of eligible individuals (and corresponding shell records).	TBA	
4-5	<i>Opt-out period</i>		
4	Individuals notify the System Operator (DHS) of their decision to opt-out.	Within the opt-out period specific to the jurisdiction in which their Medicare address was situated immediately before commencement	The information will be collected through various channels. Individuals who want to opt-out must do so by the end of the opt-out period. If an individual wants to opt-out after the end of the opt-out period, they will need to cancel

National opt-out model: 16 March 2017

ATTACHMENT 1

Step	Particulars	Timing	Other Information
			their My Health Record.
5	System Operator (DHS) notifies the individual that they have been opted out.		The type of notification will depend on the opt-out channel used.
6-9	<i>Creation of My Health Records</i>		
6	System Operator (NIO) collects: <ul style="list-style-type: none"> from System Operator (DHS) – the list of individuals who opted out; from HI Service Operator – an update of the list of individuals who have an IHI; from Chief Executive Medicare – an update of the list of all individuals indicating who should not have a record because the individual fits within one of the exceptions described in section 2(a) of Part 1. 	Steps 6-9 will occur after the end of each jurisdiction's opt-out period and the activities will relate only to individuals whose Medicare address was, immediately before commencement, situated in that jurisdiction.	
7	System Operator (NIO) uses the My Health Record system to determine which individuals have or had a My Health Record, or previously opted out of the opt-out trials.		
8	System Operator (NIO) uses the information obtained in steps 6 and 7 to determine who should and should not be registered for a My Health Record.		
9	System Operator (NIO) registers the eligible individuals and creates My Health Records for them. The System Operator deletes shell records for ineligible individuals.		
10	The My Health Records created in step 9 become accessible to individuals and registered healthcare provider organisations.		
11-13	<i>Setting access controls</i>		
11	Individual may create and access their myGov account, and link their myGov account to their My Health Record.	Steps 11 to 13 are available as soon as the individual's My	

Step	Particulars	Timing	Other Information
		Health Record has been created	
12	<p>Individual may access their My Health Record through myGov, and set their access and content preferences as follows:</p> <ul style="list-style-type: none"> access preferences – if the individual wishes to limit the access by healthcare provider organisations to their My Health Record, they can set a Record Access Code (RAC) which healthcare provider organisations must input into the My Health Record system in order to view the individual's My Health Record, or a Limited Document Access Code (LDAC) to restrict access to certain documents; and content preferences – the individual's preferences for the inclusion of the individual's Medicare Benefits Schedule (MBS – future and past two years), Department of Veterans' Affairs (DVA – future and past two years), Pharmaceutical Benefits Scheme (PBS – future and past two years), Repatriation Pharmaceutical Benefits Scheme (RPBS – future and past two years), Australian Childhood Immunisation Register (ACIR – all) and Australian Organ Donor Register (AODR – all) records into the individual's My Health Record. 		Medicare information will be made available to the individual's My Health Record upon first access (by the individual or registered healthcare provider organisation) unless the individual chooses not to include it.
13	If the individual does not set access controls the System Operator (NIO) will apply the default access and content control settings for each individual's My Health Record.		An individual can change their access controls and content settings at any time.
14-20	Medicare data flow		
14	When either the individual or a registered healthcare provider organisation accesses the individual's My Health Record for the first time after it has been created (in step 9), this sets off a trigger to upload the two years of retrospective MBS/DVA/PBS/RPBS/AODR/ACIR data (Medicare Repository Data) to the individual's My Health Record (unless the individual opted out of this when setting their access controls – see step 12). (In the case of the healthcare provider, the type of 'access' would	Upon first access (by the individual or registered healthcare provider organisation)	<p>Steps 15 to 20 describe the information flows following the trigger set off in this step.</p> <p>In opt-out registration, the default position is that the Medicare Repository Data will be included in the My Health Record unless the individual opted out of this when setting their access controls.</p>

National opt-out model: 16 March 2017

ATTACHMENT 1

Step	Particulars	Timing	Other Information
	be a user viewing the My Health Record.)		
15	An electronic notification is sent from the System Operator (NIO) to Chief Executive Medicare to request that Medicare Repository Data be made available in the My Health Record system. The request will include the individual's IHI, whether they have a My Health Record, and the Medicare Repository Data to be made available (as set in step 12, if applicable).		
16	Chief Executive Medicare as registered repository operator identifies the Medicare record for the individual in the Medicare/DVA claims database, PBS/RPBS claims database and ACIR and AODR (the live system) using the IHI.		
17	Chief Executive Medicare as registered repository operator copies the individual's MBS/DVA claims records, PBS/RPBS records, ACIR records and AODR records from its live system to its My Health Record repository administration system.		
18	Chief Executive Medicare as registered repository operator attaches the individual's IHI to the individual's Medicare Repository Data in its My Health Record repository administration system.		
19	Chief Executive Medicare as registered repository operator sorts the records in its My Health Record repository administration system to match the automatic (default) uploading of Medicare Repository Data. Chief Executive Medicare as registered repository operator indexes the records for individuals who have not opted out of having their retrospective Medicare data from being uploaded.		
20	Chief Executive Medicare as registered repository operator makes the index available to the System Operator (NIO).		

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

ATTACHMENT 2**ONGOING OPT-OUT REGISTRATION**

Step	Particulars	Timing	Other Information
<i>1-2</i>	<i>Individual identified</i>		
1	Individual applies to enrol in Medicare, create an IHI or create a pseudonymous IHI. Individual indicates in the application if they want to opt-out of being registered for a My Health Record.		If an individual wants to opt-out after they make this application, they will need to cancel their My Health Record.
2	Application is processed by relevant entity (Chief Executive Medicare and/or HI Service Operator), then referred to the System Operator (NIO) to decide whether to register the individual.		
<i>3-8</i>	<i>Creation of My Health Records</i>		
3	System Operator (NIO) collects: <ul style="list-style-type: none"> from HI Service Operator – the individual's IHI information; and from Chief Executive Medicare – information about whether the individual fits within one of the exceptions described in section 2(a) of Part 1. 		
4	System Operator (NIO) uses: <ul style="list-style-type: none"> the application in received in step 2 to identify whether the individual opted out; and the My Health Record system to determine whether the individual has or had a My Health Record, or previously opted out of the opt-out trials. 		

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
5	System Operator (DHS) notifies the individual that they have been opted out.		
6	System Operator (NIO) uses the information obtained in steps 3 and 4 to determine whether the individual should be registered for a My Health Record.		
7	System Operator (NIO) registers the eligible individual and creates a My Health Record for them.		
8	The My Health Record created in step 7 becomes accessible to the individual and registered healthcare provider organisations.		
9-11	<i>Setting access controls</i>		
9	Individual may create and access their myGov account, and link their myGov account to their My Health Record.	Steps 9 to 11 are available as soon as the individual's My Health Record has been created	
10	Individual may access their My Health Record through myGov, and set their access and content preferences as follows: <ul style="list-style-type: none"> access preferences – if the individual wishes to limit the access by healthcare provider organisations to their My Health Record, they can set a Record Access Code (RAC) which healthcare provider organisations must input into the My Health Record system in order to view the individual's My Health Record, or a Limited Document Access Code (LDAC) to restrict access to certain documents; and content preferences – the individual's 		Medicare information will be made available to the individual's My Health Record upon first access (by the individual or registered healthcare provider organisation) unless the individual chooses not to include it.

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	preferences for the inclusion of the individual's Medicare Benefits Schedule (MBS – future and past two years), Department of Veterans' Affairs (DVA – future and past two years), Pharmaceutical Benefits Scheme (PBS – future and past two years), Repatriation Pharmaceutical Benefits Scheme (RPBS – future and past two years), Australian Childhood Immunisation Register (ACIR – all) and Australian Organ Donor Register (AODR – all) records into the individual's My Health Record.		
11	If the individual does not set access controls the System Operator (NIO) will apply the default access and content control settings for each individual's My Health Record.		An individual can change their access controls and content settings at any time.
12-18	Medicare data flow		
12	When either the individual or a registered healthcare provider organisation accesses the individual's My Health Record for the first time after it has been created (in step 7), this sets off a trigger to upload the two years of retrospective MBS/DVA/PBS/RPBS/AODR/ACIR data (Medicare Repository Data) to the individual's My Health Record (unless the individual opted out of this when setting their access controls – see step 10). (In the case of the healthcare provider, the type of 'access' would be a user viewing the My Health Record.)	Upon first access (by the individual or registered healthcare provider organisation)	Steps 13 to 18 describe the information flows following the trigger set off in this step. In opt-out registration, the default position is that the Medicare Repository Data will be included in the My Health Record unless the individual opted out of this when setting their access controls.
13	An electronic notification is sent from the System Operator (NIO) to Chief Executive		

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	Medicare to request that Medicare Repository Data be made available in the My Health Record system. The request will include the individual's IHI, whether they have a My Health Record, and the Medicare Repository Data to be made available (as set in step 10, if applicable).		
14	Chief Executive Medicare as registered repository operator identifies the Medicare record for the individual in the Medicare/DVA claims database, PBS/RPBS claims database and ACIR and AODR (the live system) using the IHI.		
15	Chief Executive Medicare as registered repository operator copies the individual's MBS/DVA claims records, PBS/RPBS records, ACIR records and AODR records from its live system to its My Health Record repository administration system.		
16	Chief Executive Medicare as registered repository operator attaches the individual's IHI to the individual's Medicare Repository Data in its My Health Record repository administration system.		
17	Chief Executive Medicare as registered repository operator sorts the records in its My Health Record repository administration system to match the automatic (default) uploading of Medicare Repository Data. Chief Executive Medicare as registered repository operator indexes the records of the individual if they have not opted out of having		

CONFIDENTIAL DRAFT

National opt-out model: 16 March 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	their retrospective Medicare data uploaded.		
18	Chief Executive Medicare as registered repository operator makes the index available to the System Operator (NIO).		

NATIONAL OPT-OUT MODEL

PART 1: BULK OPT-OUT REGISTRATION

1. Outline

Bulk opt-out registration is the roll-out of a national opt-out My Health Record system whereby all eligible individuals will be registered for a My Health Record unless they opt-out. The opt-out period has not yet been determined, however it will not be less than three months, it will commence no earlier than May 2018 and be complete by December 2018.

2. Selection of eligible individuals

Individuals whose personal postal address held in the Medicare system (Medicare address) is situated in Australia immediately before commencement of bulk opt-out registration will be selected as potential subjects for the bulk opt-out registration.

These potential subjects will be eligible to participate in the bulk opt-out registration whether or not they continue to reside at the same Australian Medicare address after that time.

Individuals who are born in Australia, or new immigrants who register with Medicare, after this time will not be eligible to participate in the bulk opt-out registration. These individuals will be recognised in the ongoing opt-out registration (see Part 2).

Individuals meeting the following criteria will be eligible to participate in the bulk opt-out registration:

- (a) individuals whose Medicare address is situated in Australia are eligible to participate in the bulk opt-out registration if they have a verified IHI record unless they:
 - (i) have an IHI record status of deceased, retired or resolved; or
 - (ii) have an IHI record flagged as being an intertwined record or possible duplicate record; or
 - (iii) have a Medicare or DVA end date recorded in the Medicare system; or
 - (iv) have a IHI that has a status of suppressed; or
 - (v) have an active or suspended My Health Record; or
 - (vi) have a cancelled My Health Record; or
 - (vii) were a participant in the opt-out trials and opted out.

Information regarding the My Health Record system and the bulk opt-out registration arrangements will be included on the My Health Record website, including a facility to access to the online opt-out service. Individuals will be made aware of and directed to the My Health Record website for further information through communications activities.

3. Opt-out channels

During the opt-out period, an individual will be able to choose not to be registered for a My Health Record via the following channels:

CONFIDENTIAL DRAFT

National opt-out model: 12 April 2017

- (a) online via the online opt-out service. The online opt-out service will be hosted by the System Operator (DHS) but will be accessible via a link on the My Health Record website which is hosted by the Department on behalf of the System Operator;
- (b) over the telephone with the System Operator (DHS) – i.e. via a DHS Customer Service Operator;
- (c) in person via the System Operator (DHS) – i.e. face-to-face at a DHS service centre offering Medicare services; and
- (d) through special arrangements established to support hard to service groups who are unable to utilise the above channels, such as prisoners.

4. Opt-out period

The opt-out period will begin on the “commencement date” (to be determined). The end date, or the event by which opt-out will end, has yet to be determined.

5. Exercising the opt-out choice

During the opt-out period, all eligible individuals aged 14 and over will be able to opt-out of the My Health Record system via the opt-out channels.

Individuals under the age of 14 who are able to demonstrate their capacity and satisfy the current requirements for independent minors will also be able to opt-out, but only through the face-to-face channel.

An individual (e.g. parent or guardian) will be able to opt-out his or her dependants where:

- (a) the dependant is listed on the individual's Medicare card; and
- (b) the dependant is under 18 years of age.

Where an individual (the first individual) wishes to opt-out another individual (the second individual) who is:

- (a) under 18 years of age and is not listed on the first individual's Medicare card; or
- (b) over 18 years of age and lacks capacity to make decisions for themselves,

the first individual will be unable to opt-out the second individual via the online opt-out service or telephone channel (except where the first individual is listed as the group contact for that Medicare card and is able to answer security questions, in which case, the first individual will be able to use the telephone channel).

An individual will be able to opt-out another person without having to opt-out themselves, and will be able to opt-out themselves without having to opt-out another person.

Individuals whose Medicare address is situated outside Australia may still opt out another person whose Medicare address is situated in Australia.

CONFIDENTIAL DRAFT

National opt-out model: 12 April 2017

If a My Health Record already exists in relation to an individual at the time that individual seeks to opt-out, the individual will be advised that a My Health Record exists and they will be given an opportunity to cancel their record should they wish to do so.

6. Opt-out confirmation

It is uncertain whether individuals opting out will receive notification confirming that they have been opted out.

7. Record creation

At the end of the opt-out period, My Health Records will be created for all eligible individuals unless they opted out during the opt-out period. The My Health Records will be available to registered healthcare provider organisations at that time subject to any access controls set by the individual.

8. Setting access controls

Individuals will be able to set the access controls to their My Health Record at the end of the opt-out period when their record has been created.

An individual can choose to set their access controls during the opt-out period. To do so, they would opt-in and have their My Health Record created (thereby becoming subject to existing arrangements, including making their record immediately available to healthcare provider organisations subject to any access controls set by the individual).

9. Medicare information

At the end of the opt-out period, Medicare information will be included in a My Health Record upon first access (by the individual or registered healthcare provider organisation), unless the individual has elected not to include this information. When individuals set up their access controls, they will be able to elect not to include this information.

NATIONAL OPT-OUT MODEL**PART 2: ONGOING OPT-OUT REGISTRATION****1. Outline**

Ongoing opt-out registration is the implementation of ongoing arrangements for individuals who become eligible after roll-out and who will be registered for a My Health Record unless they opt-out. It will be implemented by the time roll-out concludes.

2. Selection of eligible individuals

From a specified date (to be determined), any individual who becomes eligible (see section 2(a), Part 1) will be registered for a My Health Record unless they opt-out.

Note: If this commencement date does not coincide with the commencement of bulk opt-out registration, any people who may subsequently (but before ongoing commencement) become eligible will not be registered.

3. Opt-out channels

In ongoing opt-out, an individual will be able to choose not to be registered for a My Health Record by completing an application to enrol in Medicare (including for newborns) or an application to create an individual healthcare identifier.

4. Opt-out period

An individual will be able to opt-out at the time they complete one of the above applications.

5. Exercising the opt-out choice

If one of the applications at section 2 provides for the entry of multiple individuals, opt-out will be available in respect of each person.

An individual will be able to opt-out another person without having to opt-out themselves, and will be able to opt-out themselves without having to opt-out another person.

6. Opt-out confirmation

Individuals opting out will receive notification confirming that they have been opted out. The notification will be provided to the individual opting out, including to independent minors who opt-out. Where a parent/guardian has opted out a dependant, the parent/guardian will receive the notification.

7. Record creation

A My Health Record will be created for each eligible individual soon after an application of the type described in section 2 has been submitted, unless their opted out. The My Health Record will be available to registered healthcare provider organisations at that time subject to any access controls set by the individual.

8. Setting access controls

Individuals will be able to set the access controls to their My Health Record when their record has been created.

9. Medicare information

Medicare information will be included in a My Health Record upon first access (by the individual or registered healthcare provider organisation), unless the individual has elected not to include this information. When individuals set up their access controls, they will be able to elect not to include this information.

CONFIDENTIAL DRAFT

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

BULK OPT-OUT REGISTRATION

Step	Particulars	Timing	Other Information
1-3	<i>Creation of shell records</i>		
1	<p>System Operator (NIO) collects:</p> <ul style="list-style-type: none"> from HI Service Operator – the list of all individuals who have an active verified IHI; and from Chief Executive Medicare – the list of all individuals indicating who should not have a record because the individual fits within one of the exceptions described in section 2(a) of Part 1. 	1 December 2017 (TBC)	
2	<p>System Operator (NIO) creates shell records for all eligible individuals.</p> <p>System Operator (NIO) will continue to collect the information identified at step 2 in order to update information for eligible individuals (and update shell records accordingly) to reflect changes to information and eligibility.</p>		<p>A shell record is not a My Health Record. It is the collection of identifying information about an individual. Health information is not associated with the shell record. The collection of this information allows an individual to opt-out of participation and for a My Health Record to be created for the individual upon registration.</p> <p>The shell record is not accessible to individuals or their healthcare providers.</p>
3	System Operator (NIO) finalises the list of eligible individuals (and corresponding shell records).	TBA	
4-5	<i>Opt-out period</i>		
4	Individuals notify the System Operator (DHS) of their decision to opt-out.	This must occur within the opt-out period.	<p>The information will be collected through various channels.</p> <p>Individuals who want to opt-out must do so by the end of the opt-out period.</p> <p>If an individual wants to opt-out after the end of the opt-out period, they will need to cancel</p>

National opt-out model: 12 April 2017

ATTACHMENT 1

Step	Particulars	Timing	Other Information
			their My Health Record.
5	System Operator (DHS) may notify the individual that they have been opted out.		It has not been decided whether or not notification will occur.
6-9	<i>Creation of My Health Records</i>		
6	System Operator (NIO) collects: <ul style="list-style-type: none"> from System Operator (DHS) – the list of individuals who opted out; from HI Service Operator – an update of the list of individuals who have an IHI; from Chief Executive Medicare – an update of the list of all individuals indicating who should not have a record because the individual fits within one of the exceptions described in section 2(a) of Part 1. 	Steps 6-9 will occur after the end of the opt-out period.	
7	System Operator (NIO) uses the My Health Record system to determine which individuals have or had a My Health Record, or previously opted out of the opt-out trials.		
8	System Operator (NIO) uses the information obtained in steps 6 and 7 to determine who should and should not be registered for a My Health Record.		
9	System Operator (NIO) registers the eligible individuals and creates My Health Records for them. The System Operator deletes shell records for ineligible individuals.		
10	The My Health Records created in step 9 become accessible to individuals and registered healthcare provider organisations.		
11-13	<i>Setting access controls</i>		
11	Individual may create and access their myGov account, and link their myGov account to their My Health Record.	Steps 11 to 13 are available as soon as the individual's My	

Step	Particulars	Timing	Other Information
		Health Record has been created	
12	<p>Individual may access their My Health Record through myGov, and set their access and content preferences as follows:</p> <ul style="list-style-type: none"> access preferences – if the individual wishes to limit the access by healthcare provider organisations to their My Health Record, they can set a Record Access Code (RAC) which healthcare provider organisations must input into the My Health Record system in order to view the individual's My Health Record, or a Limited Document Access Code (LDAC) to restrict access to certain documents; and content preferences – the individual's preferences for the inclusion of the individual's Medicare Benefits Schedule (MBS – future and past two years), Department of Veterans' Affairs (DVA – future and past two years), Pharmaceutical Benefits Scheme (PBS – future and past two years), Repatriation Pharmaceutical Benefits Scheme (RPBS – future and past two years), Australian Childhood Immunisation Register (ACIR – all) and Australian Organ Donor Register (AODR – all) records into the individual's My Health Record. 		Medicare information will be made available to the individual's My Health Record upon first access (by the individual or registered healthcare provider organisation) unless the individual chooses not to include it.
13	If the individual does not set access controls the System Operator (NIO) will apply the default access and content control settings for each individual's My Health Record.		An individual can change their access controls and content settings at any time.
14-20	Medicare data flow		
14	When either the individual or a registered healthcare provider organisation accesses the individual's My Health Record for the first time after it has been created (in step 9), this sets off a trigger to upload the two years of retrospective MBS/DVA/PBS/RPBS/AODR/ACIR data (Medicare Repository Data) to the individual's My Health Record (unless the individual opted out of this when setting their access controls – see step 12). (In the case of the healthcare provider, the type of 'access' would	Upon first access (by the individual or registered healthcare provider organisation)	<p>Steps 15 to 20 describe the information flows following the trigger set off in this step.</p> <p>In opt-out registration, the default position is that the Medicare Repository Data will be included in the My Health Record unless the individual opted out of this when setting their access controls.</p>

National opt-out model: 12 April 2017

ATTACHMENT 1

Step	Particulars	Timing	Other Information
	be a user viewing the My Health Record.)		
15	An electronic notification is sent from the System Operator (NIO) to Chief Executive Medicare to request that Medicare Repository Data be made available in the My Health Record system. The request will include the individual's IHI, whether they have a My Health Record, and the Medicare Repository Data to be made available (as set in step 12, if applicable).		
16	Chief Executive Medicare as registered repository operator identifies the Medicare record for the individual in the Medicare/DVA claims database, PBS/RPBS claims database and ACIR and AODR (the live system) using the IHI.		
17	Chief Executive Medicare as registered repository operator copies the individual's MBS/DVA claims records, PBS/RPBS records, ACIR records and AODR records from its live system to its My Health Record repository administration system.		
18	Chief Executive Medicare as registered repository operator attaches the individual's IHI to the individual's Medicare Repository Data in its My Health Record repository administration system.		
19	Chief Executive Medicare as registered repository operator sorts the records in its My Health Record repository administration system to match the automatic (default) uploading of Medicare Repository Data. Chief Executive Medicare as registered repository operator indexes the records for individuals who have not opted out of having their retrospective Medicare data from being uploaded.		
20	Chief Executive Medicare as registered repository operator makes the index available to the System Operator (NIO).		

CONFIDENTIAL DRAFT

National opt-out model: 12 April 2017

ATTACHMENT 2**ONGOING OPT-OUT REGISTRATION**

Step	Particulars	Timing	Other Information
<i>1-2</i>	<i>Individual identified</i>		
1	Individual applies to enrol in Medicare or create an IHI. Individual indicates in the application if they want to opt-out of being registered for a My Health Record.		If an individual wants to opt-out after they make this application, they will need to cancel their My Health Record.
2	Application is processed by relevant entity (Chief Executive Medicare and/or HI Service Operator), then referred to the System Operator (NIO) to decide whether to register the individual.		
<i>3-8</i>	<i>Creation of My Health Records</i>		
3	System Operator (NIO) collects: <ul style="list-style-type: none"> from HI Service Operator – the individual's IHI information; and from Chief Executive Medicare – information about whether the individual fits within one of the exceptions described in section 2(a) of Part 1. 		
4	System Operator (NIO) uses: <ul style="list-style-type: none"> the application in received in step 2 to identify whether the individual opted out; and the My Health Record system to determine whether the individual has or had a My Health Record, or previously opted out of the opt-out trials. 		

CONFIDENTIAL DRAFT

National opt-out model: 12 April 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
5	System Operator (DHS) may notify the individual that they have been opted out.		It has not been decided whether or not notification will occur.
6	System Operator (NIO) uses the information obtained in steps 3 and 4 to determine whether the individual should be registered for a My Health Record.		
7	System Operator (NIO) registers the eligible individual and creates a My Health Record for them.		
8	The My Health Record created in step 7 becomes accessible to the individual and registered healthcare provider organisations.		
9-11	<i>Setting access controls</i>		
9	Individual may create and access their myGov account, and link their myGov account to their My Health Record.	Steps 9 to 11 are available as soon as the individual's My Health Record has been created	
10	Individual may access their My Health Record through myGov, and set their access and content preferences as follows: <ul style="list-style-type: none"> access preferences – if the individual wishes to limit the access by healthcare provider organisations to their My Health Record, they can set a Record Access Code (RAC) which healthcare provider organisations must input into the My Health Record system in order to view the individual's My Health Record, or a Limited Document Access Code (LDAC) to restrict access to certain documents; and content preferences – the individual's 		Medicare information will be made available to the individual's My Health Record upon first access (by the individual or registered healthcare provider organisation) unless the individual chooses not to include it.

CONFIDENTIAL DRAFT

National opt-out model: 12 April 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	preferences for the inclusion of the individual's Medicare Benefits Schedule (MBS – future and past two years), Department of Veterans' Affairs (DVA – future and past two years), Pharmaceutical Benefits Scheme (PBS – future and past two years), Repatriation Pharmaceutical Benefits Scheme (RPBS – future and past two years), Australian Childhood Immunisation Register (ACIR – all) and Australian Organ Donor Register (AODR – all) records into the individual's My Health Record.		
11	If the individual does not set access controls the System Operator (NIO) will apply the default access and content control settings for each individual's My Health Record.		An individual can change their access controls and content settings at any time.
12-18	Medicare data flow		
12	When either the individual or a registered healthcare provider organisation accesses the individual's My Health Record for the first time after it has been created (in step 7), this sets off a trigger to upload the two years of retrospective MBS/DVA/PBS/RPBS/AODR/ACIR data (Medicare Repository Data) to the individual's My Health Record (unless the individual opted out of this when setting their access controls – see step 10). (In the case of the healthcare provider, the type of 'access' would be a user viewing the My Health Record.)	Upon first access (by the individual or registered healthcare provider organisation)	Steps 13 to 18 describe the information flows following the trigger set off in this step. In opt-out registration, the default position is that the Medicare Repository Data will be included in the My Health Record unless the individual opted out of this when setting their access controls.
13	An electronic notification is sent from the System Operator (NIO) to Chief Executive		

CONFIDENTIAL DRAFT

National opt-out model: 12 April 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	Medicare to request that Medicare Repository Data be made available in the My Health Record system. The request will include the individual's IHI, whether they have a My Health Record, and the Medicare Repository Data to be made available (as set in step 10, if applicable).		
14	Chief Executive Medicare as registered repository operator identifies the Medicare record for the individual in the Medicare/DVA claims database, PBS/RPBS claims database and ACIR and AODR (the live system) using the IHI.		
15	Chief Executive Medicare as registered repository operator copies the individual's MBS/DVA claims records, PBS/RPBS records, ACIR records and AODR records from its live system to its My Health Record repository administration system.		
16	Chief Executive Medicare as registered repository operator attaches the individual's IHI to the individual's Medicare Repository Data in its My Health Record repository administration system.		
17	Chief Executive Medicare as registered repository operator sorts the records in its My Health Record repository administration system to match the automatic (default) uploading of Medicare Repository Data. Chief Executive Medicare as registered repository operator indexes the records of the individual if they have not opted out of having		

CONFIDENTIAL DRAFT

National opt-out model: 12 April 2017

ATTACHMENT 2

Step	Particulars	Timing	Other Information
	their retrospective Medicare data uploaded.		
18	Chief Executive Medicare as registered repository operator makes the index available to the System Operator (NIO).		

s22

From: s22 @health.gov.au>
Sent: Monday, 10 April 2017 1:00 PM
To: s22
Cc: s22
Subject: RE: LEX 30098 RE: My Health Records Rules - drafting instructions [DLM=Sensitive:Legal]
Attachments: s22

Hi s22

Please find attached the draft drafting instructions, including my comments and suggested changes.

s42

I would be happy to discuss the above.

Please note that I will be commencing leave on Thursday afternoon (13.04.17) and will return on 1 May 2017. s22 will be available while I am on leave.

Regards,

s22

Lawyer
 Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
 Australian Government Department of Health
 T: s22 | E: s22 @health.gov.au
 Location: s22

PO Box 9848, Canberra ACT 2601, Australia

My days at work are Monday & Tuesday (until 4.30pm) and Thursday & Friday (until 2.30pm).

Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Thursday, 30 March 2017 10:50 AM
To: s22
Subject: RE: LEX 30098 RE: My Health Records Rules - drafting instructions [DLM=Sensitive:Legal]

Hi s22

Here is the draft description of the opt-out model for attachment to the DIs. This is a functional document for our own branch purposes rather than for drafting purposes so I'm not seeking LSB comments, however questions or issues with the document are always welcome. Do you think we'll be in a position to send Dis to OPC next week?

s22
Legislation

Digital Health Legislation and Policy Branch | Digital Health Division
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: s22

From: s22
Sent: Thursday, 30 March 2017 10:31 AM
To: s22
Subject: LEX 30098 RE: My Health Records Rules - drafting instructions [DLM=Sensitive:Legal]

Hi s22

I have gotten through most of it, however s22 also needs to see it. s42

Is this correct?

s22
Lawyer
Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: s22

PO Box 9848, Canberra ACT 2601, Australia

My days at work are Monday & Tuesday (until 4.30pm) and Thursday & Friday (until 2.30pm).

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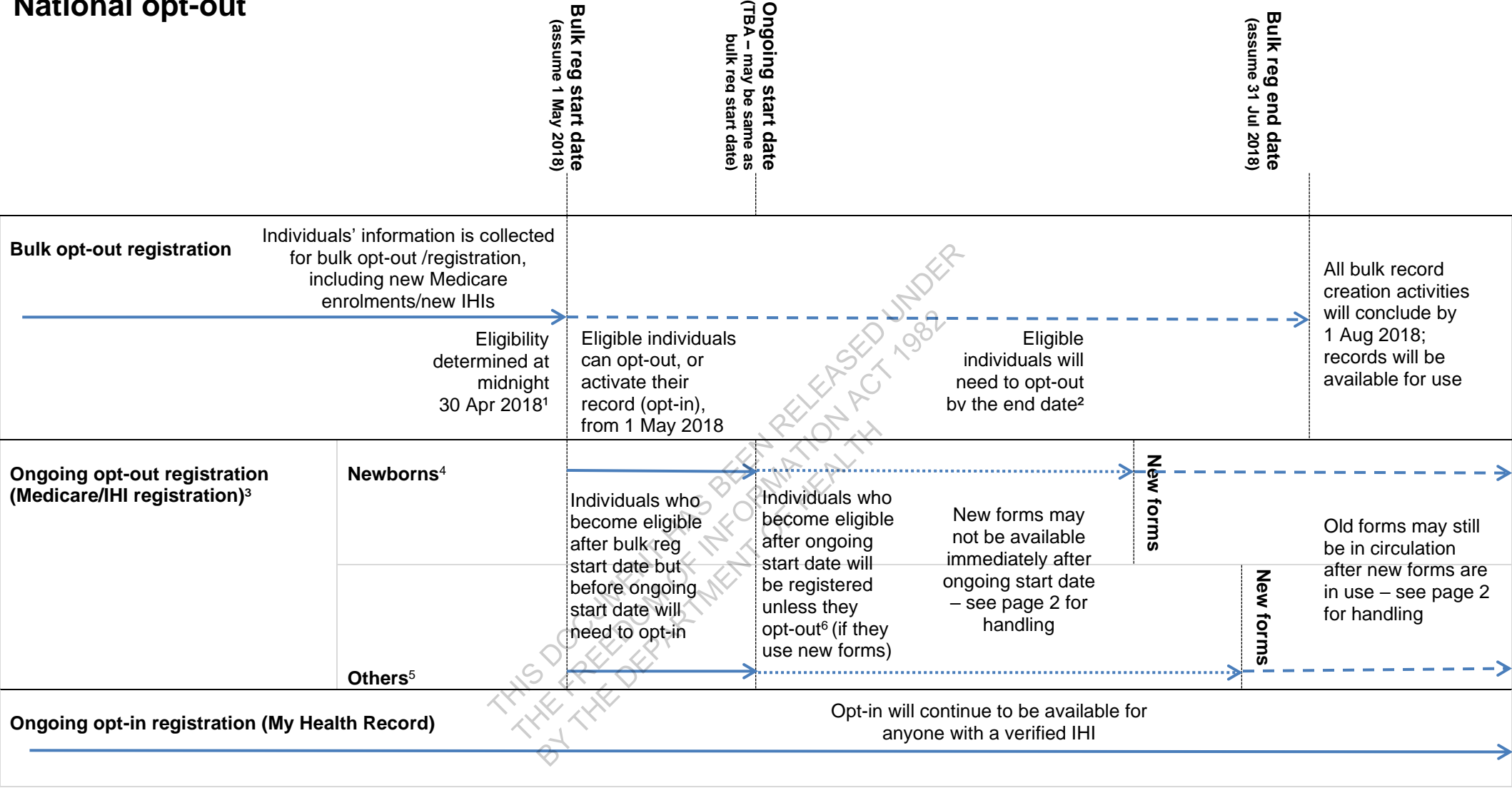
From: s22
Sent: Thursday, 30 March 2017 10:05 AM
To: s22
Subject: My Health Records Rules - drafting instructions [SEC=UNCLASSIFIED]

Hi s22
Can you please let me know how you're progressing with our drafting instructions. Do you have an ETA?

s22
Legislation

Digital Health Legislation and Policy Branch | Digital Health Division
Australian Government Department of Health
T: s22 9 | E: s22 @health.gov.au
Location: s22

National opt-out



¹ If an individual has a verified IHI but is not eligible at this time, they will not have a My Health Record created for them; if they want one they will need to opt-in through regular channels

² An individual's eligibility will be reconsidered at end of opt-out and they may not be registered for other reasons, for example, because they died – exclusion rules need to be agreed; if excluded people want a My Health Record they will need to opt-in through regular channels

³ Currently, individuals can only opt-in through My Health Record registration and newborn Medicare enrolment forms; Medicare enrolment and IHI creation forms do not include My Health Record registration – all forms need to be changed to enable opt-out

⁴ Approximately 26,000 babies are born each month – two thirds of newborns are currently opted in

⁵ Approximately 24,000 individuals become eligible to enrol in Medicare each month (other than newborns)

⁶ There are exceptions – eligible individuals will not be registered if they have not been given an opportunity to opt-out

1

Page 1 of 2

National opt-out: ongoing

			Ongoing reg start date	New form released
Newborn Medicare enrolment form	Old form (opt-in)	<input checked="" type="checkbox"/> Opt-in	Register ⁸	Register ⁸
		<input type="checkbox"/> Opt-in	Don't register ⁹	Don't register ⁹
	New form ⁷ (opt-out)	<input checked="" type="checkbox"/> Opt-out	N/A	Don't register
		<input type="checkbox"/> Opt-out	N/A	Register ¹⁰
Medicare enrolment & IHI creation forms	Old form		Don't register ¹¹	Don't register ¹¹
	New form ⁷ (opt-out)	<input checked="" type="checkbox"/> Opt-out	N/A	Don't register
		<input type="checkbox"/> Opt-out	N/A	Register ¹⁰
My Health Record registration form	(opt-in)		Register	Register

⁷ All opt-out forms must provide sufficient privacy and other information about opt-out to ensure an individual's choice is informed – the forms will need to be self-contained and be sufficient to be used in isolation of broader opt-out communications being undertaken because these will continue to be used

⁸ From ongoing start date, if the opt-in box is selected, decide whether Medicare correspondence should include My Health Record registration confirmation

⁹ From ongoing start date, if the opt-in box is not selected, consider including My Health Record registration information in the Medicare correspondence

¹⁰ Decide whether correspondence should include My Health Record registration confirmation

¹¹ Consider including My Health Record registration information in the correspondence

s22

From: eHPOLICY <eHPOLICY@health.gov.au>
Sent: Wednesday, 12 April 2017 4:55 PM
To: instrument.instructions@opc.gov.au
Cc: s22
Subject: s22 [DLM=For-Official-Use-Only]
Attachments: s42

Good afternoon

I seek your assistance in preparing a s42 pursuant to the *My Health Records Act 2012*. I attach drafting instructions and Attachment 1 to the instructions – the National Opt-out Model.

Please don't hesitate to contact me if you have any questions (noting I am away on 14 April).

Kind regards

s22

s22
Legislation

Digital Health Legislation and Policy Branch | Digital Health Division
Australian Government Department of Health
T s22 | E: s22@health.gov.au
Location: s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

My Health Records Act 2012

My Health Records (National Application) Rules 2017

The *My Health Records Act 2012* (the Act) enabled the establishment of the My Health Record system (formerly referred to as the personally controlled electronic health record or PCEHR system). The My Health Record system allows people and their healthcare providers to access their key health information online where and when they need it. A My Health Record is an electronic summary of a person's health records.

The My Health Record system currently operates on an opt-in basis which means that a person needs to register in order to get a My Health Record.

The *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) provide that an opt-out model will be implemented so that people no longer need to register; instead a My Health Record will be created for every eligible person unless they choose not to have one (i.e. opt-out).

Background

Due to the low numbers of people choosing to register for a My Health Record, the Act was amended in 2015 to allow for an opt-out model of participation to be implemented. Specifically, Schedule 1 to the Act allows the Minister to make rules to undertake trials of an opt-out model, and to implement opt-out nationally.

Participation trials (including opt-out arrangements) were undertaken in 2016 to inform future strategies for increasing uptake and meaningful use of the My Health Record system. An evaluation of the trials showed a high level of support by healthcare providers and individuals for the automatic creation of My Health Records, and found that individuals felt the benefits far outweighed risks to privacy, confidentiality and security.

In May 2017 the Government announced that the My Health Record will transition to national opt-out participation arrangements during 2018.

National Opt-out Rules

The National Opt-out Rules are made under subclause 2(1), and subparagraphs 5(2)(c)(i) and 13(2)(c)(i), of Schedule 1 to the Act.

The purpose of the National Opt-out Rules is to apply the opt-out model, as set out in Part 2 of Schedule 1 to the Act, nationally. The National Opt-out Rules specify:

- the class of people who will have a My Health Record created unless they opt-out;
- when a person will need to elect if they want to opt-out (i.e. do not want a My Health Record created); and
- when a person who has not opted out can elect not to have health information which is held by the Chief Executive Medicare disclosed to the System Operator (i.e. included in their My Health Record).

The National Opt-out Rules do not change the participation arrangements of other entities such as healthcare provider organisations. These entities must still register if they want to participate in the My Health Record system.

Detail of the National Opt-out Rules is set out in the Attachment.

Subsection 109(2) of the Act, together with regulation 5.1.1 of the *My Health Records Regulation 2012*, provides that before making My Health Records Rules, the Minister must consult with Australian Health Ministers' Advisory Council (AHMAC) and the System Operator (i.e. the Australian Digital Health Agency). Consultation occurred in July and August 2017 and the System Operator and AHMAC supported the making of the proposed National Opt-out Rules.

Subclause 2(3) of Schedule 1 to the Act further provides that before making the National Opt-out Rules, the Minister must consult the Council of Australian Governments Health Council (CHC). CHC noted the making of the National Opt-out Rules in December 2017.

Public consultation on the concept of an opt-out My Health Record system has been undertaken:

- during July to September 2014 following the Personally Controlled Electronic Health Record Review, as reported in the *Report to the Commonwealth Department of Health on the public consultation into the implementation of the recommendations of the Review of the Personally Controlled Electronic Health Record*; and
- in May and June 2015 upon the release of the *Electronic Health Records and Healthcare Identifiers: Legislation Discussion Paper*.

Consumers support the concept of an opt-out model for the My Health Record system.

The National Opt-out Rules, with the exception of Part 3, commence on the day after registration on the Federal Register of Legislation. Part 3 will commence on a day to be specified by the Minister.

Regulation Impact Statements were prepared for the *Health Legislation Amendment (eHealth) Bill 2015*, which established the ability to implement opt-out nationally (published at ris.pmc.gov.au/2015/07/21/proposed-changes-personally-controlled-electronic-health-record-system), and as part of the Government decision to transition the My Health Record system to an opt-out system (published at ris.pmc.gov.au/2017/06/01/changes-my-health-record-system).

The National Opt-out Rules are a legislative instrument and are subject to the *Legislation Act 2003*.

ATTACHMENT**Details of the *My Health Records (National Application) Rules 2017*****PART 1—PRELIMINARY****1 Name of Rules**

Rule 1 provides that the title of the Rules is the *My Health Records (National Application) Rules 2017*. For the purposes of this document, the Rules are referred to as the National Opt-out Rules.

2 Commencement

Rule 2 provides for the commencement of the National Opt-out Rules.

With the exception of Part 3, which provides for the period in which people can choose to opt-out, the National Opt-out Rules take effect on the day after the Rules are registered on the Federal Register of Legislation. Of particular importance is the commencement of Part 2 which provides authority for the System Operator to collect information about people who are not registered in the My Health Record system as part of preparation for the implementation of opt-out.

Part 3 will take effect on a day that specified by the Minister in a notifiable instrument or if a day is not specified, 9 months after the Rules are registered on the Federal Register of Legislation. This approach provides the flexibility necessary as the exact timing for implementing opt-out is dependent on technological, communication and operational activities that need to be developed, planned and undertaken in parallel. It also provides certainty that Part 3 will take effect within a 9 month window. It is likely that the day specified for Part 3 to take effect will be in the first half of 2018. The opt-out period referred to in Rule 6 will begin upon the commencement of Part 3 and ends three months later.

3 Authority

Rule 3 identifies that the legal authority for making the National Opt-out Rules is provided by the *My Health Records Act 2012*.

4 Definitions

Rule 4 provides definitions of several terms used in the National Opt-out Rules. Of particular importance is the term ***opt-out model*** which is defined by Part 2 of the Rules. Other terms used in the Rules, such as ***healthcare recipient***, are defined by the Act.

PART 2—APPLYING OPT-OUT MODEL TO ALL HEALTHCARE RECIPIENTS**5 Opt-out model applies to all healthcare recipients in Australia**

Rule 5 applies the opt-out model to all individuals in Australia. This means that Part 2 of Schedule 1 to the Act will begin operating and, in some cases replace existing provisions of the Act, on the day after the Rules are registered on the Federal Register of Legislation. A person cannot be registered unless they have been given an opportunity to opt out or have applied directly to register.

The Rules do not apply the opt-out model ‘afresh’ to individuals who have already been subject to opt-out arrangements. This means it does not apply to:

- people who were in the opt-out trial areas and did not opt-out, and who have since cancelled their My Health Record; or
- people who were in the opt-out trial areas and chose to opt-out.

The Rules do apply to people who previously applied for a My Health Record and have since cancelled their My Health Record. However, when deciding to register individuals as part of these opt-out arrangements, the System Operator will take cancelled My Health Records into account and decide not to register these people.

Rule 5 triggers the authority for the System Operator to collect information about people who are not registered in the My Health Record system as part of preparation for the implementation of opt-out (item 1 of subclause 8(1) of Schedule 1 to the Act provides this authority).

PART 3—REGISTERING HEALTHCARE RECIPIENTS

6 When healthcare recipients may elect not to be registered

People are entitled to choose to opt-out if they do not want a My Health Record (clause 5 of Schedule 1 to the Act refers), and the System Operator cannot register a person unless they have been given the opportunity to opt-out (clause 3 of Schedule 1 of the Act refers). In order to opt-out, a person must give notice to the System Operator in a particular manner. In practice, a person will be able to give this notice in a number of ways and at a time or period specified by the Minister, depending on their circumstances.

Rule 6 provides the arrangements by which a person can opt-out. Rule 6 will commence on a date to be specified by the Minister (this date will not be before March 2018). If the Minister does not specify a date, Rule 6 will commence 9 months after the National Opt-out Rules are registered on the Federal Register of Legislation.

If a person already has an Individual Healthcare Identifier (IHI)¹ they will be provided the opportunity to opt-out during the opt-out period. People who do not have an IHI at the commencement of the opt-out period will be provided the opportunity to opt-out prior to being assigned an IHI.

A person who is enrolled in Medicare² or has a Department of Veterans' Affairs (DVA) file number is automatically assigned an IHI. People who are not enrolled in Medicare or DVA but receive healthcare in Australia, such as international tourists, or people who want a pseudonymous IHI, can apply directly to the Healthcare Identifiers Service for an IHI.

National roll-out (subrules 6(2) and (3) refer)

Everyone who already has an IHI will be given the opportunity to opt-out during an opt-out period, and anyone who does not opt-out will have a My Health Record created for them.³

¹ Healthcare identifiers have been used since June 2010 and were established by the *Healthcare Identifiers Act 2010*. Healthcare identifiers are used for consistently identifying individuals and healthcare providers to, among other things, ensure patients are properly matched with their health records, and support the communication of health information between healthcare providers. The Chief Executive Medicare is currently responsible for operating the Healthcare Identifiers Service.

² In general, any person who resides in Australia is eligible to enrol in Medicare if they hold an Australian or New Zealand citizenship, have been issued with a permanent visa or have applied for a permanent visa. For detailed Medicare eligibility criteria, go to the [Department of Human Services website](#).

³ There are some exceptions. Despite having an IHI, not everyone will be included in this process – that is, they will not be given the opportunity to opt-out and will not be registered. For example, the System Operator will

Subrule 6(2) provides that the class of people specified in paragraph 6(3)(a) – those who have an IHI immediately before this Part commences (i.e. the date to be specified by the Minister) – must give their opt-out notice during the period specified in paragraph 6(3)(b) – the period commencing on the day this Part commences (i.e. the date to be specified by the Minister) and ending three months later (referred to as the opt-out period).

People who are part of the national roll-out will have three months in which to opt-out. This is considered a reasonable amount of time for people to receive information about the creation of My Health Records and take any action necessary.

If a person has been given the opportunity to opt-out, and they don't want to wait until the end of the opt-out period to get a My Health Record, they may choose to register. A My Health Record will be created for them immediately.

Ongoing (subrules 6(4) and (5) refer)

Anyone who gets an IHI after the beginning of the national roll-out will be given the opportunity to opt-out when they apply to enrol in Medicare or get an IHI, and anyone who does not opt-out will have a My Health Record created for them.⁴

Subrule 6(4) provides that the class of people specified in paragraph 6(5)(a) – those who do not have an IHI immediately before this Part commences (i.e. the date to be specified by the Minister) – must give their opt-out notice upon the event specified in paragraph 6(5)(b) – when they apply for something that results in them being assigned an IHI. In practice, a person is assigned an IHI when they apply to enrol in Medicare⁵ or create an IHI⁶.

Unlike national roll-out, the ongoing process does not provide individuals three months in which to opt-out; instead it provides a single point in time. This is because the ongoing process involves an individual taking an action to interact with a relevant Government service (i.e. enrolling in Medicare to requesting an IHI), and this interaction can be leveraged to ensure the person is directly informed about the My Health Record system and the need to opt-out during that interaction if they don't want a My Health Record created.

If an individual has parental or legal authority for another person (such as if they are a parent or guardian), or is found otherwise appropriate to act on behalf of another person, the individual may opt-out that other person. This capability will be available as part of the national roll-out and the ongoing process. Individuals aged 14 years and older will be able to opt themselves out. Individuals younger than 14 years will only be able to opt themselves out if they are able to provide evidence of their capacity to manage their My Health Record.

If a person does not opt-out at the time or during the period specified, the person can still cancel or suspend their registration at any time after their My Health Record is created (under subsection 51(1) of the Act). Conversely, if a person opts out, they may subsequently register for a My Health Record at any time (under clause 6 of Schedule 1 to the Act).

not register any person who previously had a My Health Record and cancelled it, who were part of the opt-out trials and opted out, who has a pseudonymous IHI, or whose registration may compromise the security or integrity of the system.

⁴ The System Operator will not register any person whose registration may compromise the security or integrity of the system.

⁵ The *Medicare enrolment application* form is available on the [Department of Human Services website](#). The form must be completed and either submitted in person at a Medicare service centre or posted to the Department of Human Services.

⁶ The *Healthcare Identifiers Service Application to create or update an Individual Healthcare identifier* form is available on the [Department of Human Services website](#). The form must be completed and either submitted in person at a Medicare service centre or posted to the Department of Human Services.

PART 4—HANDLING HEALTH INFORMATION FOR THE PURPOSES OF A HEALTHCARE RECIPIENT’S MY HEALTH RECORD

7 When healthcare recipients may elect not to have certain health information disclosed to System Operator

The Chief Executive Medicare holds the following health information (referred to as Medicare information) about individuals which may, at his or her discretion, be provided to the My Health Record System Operator to include in an individual’s My Health Record (clause 12 of Schedule 1 to the Act):

- Medicare Benefits Schedule claims information;
- Pharmaceutical Benefits Scheme claims information;
- information about organ and/or tissue donation decisions recorded by the Australian Organ Donor Register; and
- information about immunisations recorded by the Australian Immunisation Register.

People are entitled to choose not to include Medicare information in their My Health Record (clause 13 of Schedule 1 to the Act refers).

In order to choose not to include Medicare information in their My Health Record, a person must give notice to the System Operator at a particular time and in a particular manner.

Rule 7 provides the arrangements by which a person can choose not to include their Medicare information in their My Health Record, whether they are registered because they did not opt-out, or because they applied to register. Rule 7 will commence on the day after the National Opt-out Rules are registered on the Federal Register of Legislation.

The manner for choosing not to include Medicare information will be offered in one of two ways, depending on how a person has been registered for a My Health Record.

People who apply to register (subrules 7(2) and (3) refer)

Under an opt-out model, people can still choose to register at any time (clause 6 of Schedule 1 to the Act). This ensures that people who previously had a My Health Record and cancelled it, or who have opted out, can subsequently change their mind and get a My Health Record.

When a person applies to register⁷, they will be given the opportunity to choose not to include their Medicare information in their My Health Record.

Subrule 7(2) provides that the class of people specified in paragraph 7(3)(a) – people who, from the day after the National Opt-out Rules have been registered on the Federal Register of Legislation, have been registered – must give notice not to include their Medicare information upon the event specified in paragraph 7(3)(b) – when they apply to register for a My Health Record.

⁷ A person can apply to register online at the [My Health Record website](#), in person at a Medicare service centre, by phone on 1800 723 471, or in writing by completing the *Application to register for a My Health Record* form and sending it to the My Health Record System Operator.

People who are registered because they didn't opt-out (subrules 7(4) and (5) refer)

When a person does not opt-out and a My Health Record is created for them, they will be able to choose whether to include Medicare information in their My Health Record.

Subrule 7(4) provides that the class of people specified in paragraph 7(5)(a) – people who, from when Part 3 commences (i.e. the date to be specified by the Minister), have been registered because they didn't opt-out – must give notice not to include their Medicare information within the period specified in paragraph 7(3)(b) – from when they are registered until their My Health Record is first accessed.

It is important to understand that a person's Medicare information will, by default, automatically be included in the person's My Health Record unless the person has given notice not to include it. The transfer process by which Medicare information will be included in a My Health Record is triggered the first time someone accesses a My Health Record – either the person or their healthcare provider.

- If the person is the first to access their My Health Record they will, before the inclusion of any Medicare information, be guided through the various settings associated with the privacy of their My Health Record. This will be the opportunity to notify if they do not want their Medicare information included.
- If the person's healthcare provider organisation is the first to access a person's My Health Record, the Medicare information will be included in the My Health Record. This is because the transfer process has been triggered and no notice has been provided by the person not to include their Medicare information.

A person can change their mind at any time about whether or not to include Medicare information in their My Health Record. It is important to understand that if a person did not initially give notice not to include their Medicare information, and it has been included in their My Health Record, a subsequent decision not to include this information will only affect new information and will not affect the information already in their My Health Record. The person may choose to remove any Medicare information from their My Health Record.

Regardless of how people are registered for a My Health Record, if an individual has parental or legal authority for another person (such as if they are a parent or guardian), the individual may choose not to include that other person's Medicare information in that other person's My Health Record.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

My Health Records (National Application) Rules 2017

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The Legislative Instrument is made under subclause 2(1), and subparagraphs 5(2)(c)(i) and 13(2)(c)(i), of Schedule 1 to the *My Health Records Act 2012* (the Act).

The purpose of the *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) is to apply the opt-out model, as set out in Part 2 of Schedule 1 to the Act, to individuals nationally. This means that the My Health Record System Operator will create a My Health Record for all individuals unless they choose not to have one.

The National Opt-out Rules specify:

- the class of people who will have a My Health Record created unless they opt-out – in this case, everyone who has a healthcare identifier;
- when a person will need to elect if they want to opt-out (i.e. do not want a My Health Record created); and
- when a person who has not opted out can elect not to have health information which is held by the Chief Executive Medicare disclosed to the System Operator (i.e. included in their My Health Record).

The National Opt-out Rules do not change the participation arrangements of other entities such as healthcare provider organisations. These entities must still register if they want to participate in the My Health Record system.

Human rights implications

The Legislative Instrument engages the following human rights and freedoms:

Right to health

Article 12(1) of the *International Covenant on Economic, Social and Cultural Rights* provides for the right to the enjoyment of the highest attainable standard of physical and mental health.

The My Health Record system promotes the right to health by facilitating and improving the sharing of health information between treating healthcare providers, leading to quicker and safer treatment decisions and reducing repetition of information for patients and duplication of tests. Individuals are provided ready access to their own information, empowering them to make informed decisions about their healthcare.

The current opt-in participation arrangements have not effectively encouraged use of My Health Records by individuals and their healthcare providers, and are creating a barrier to achieving the full benefits of the system for individuals.

Participation trials (including opt-out arrangements) were undertaken in 2016 to inform future strategies for increasing uptake and meaningful use of the My Health Record system. An evaluation of the trials showed a high level of support by healthcare providers and individuals for the automatic creation of My Health Records, and found that individuals felt the benefits far outweighed the possibility of risks to privacy, confidentiality and security. As a result, the Government decided to implement the My Health Record system as an opt-out system for individuals.

The Legislative Instrument enables opt-out participation arrangements for every eligible person across Australia. Increased registration, with the accompanying ability for treating healthcare providers to appropriately share health information for treatment purposes, will help improve the physical and mental health of registered individuals. This will increase uptake and meaningful use of the My Health Record system with the aim of achieving a greater standard of physical and mental health for all Australians.

Protection of privacy and reputation

Article 17 of the *International Covenant on Civil and Political Rights* prohibits unlawful or arbitrary interference with a person's privacy and unlawful attacks on a person's reputation. This right is also reflected in Article 22 of the *Convention on the Rights of Persons with Disabilities* and Article 16 of the *Convention on the Rights of the Child*.

The right to privacy encompasses respect for informational privacy, including the right to respect the storing, use and sharing of private information and the right to control the dissemination of private information. The Legislative Instrument engages the right to privacy by prescribing the class of people to participate in an opt-out model of the My Health Record system, unless they opt-out.

The Legislative Instrument and the Act together counterbalance any limitation of the right to privacy by providing an opportunity for every individual (or their representative) across Australia to opt-out of registration and to ensure that a My Health Record is not created for them. Individuals who opt-out may later apply for registration, should they change their mind. Alternatively, individuals who do not opt-out and are registered are able to take advantage of a wide range of privacy protections as outlined below.

As part of the roll-out of opt-out participation arrangements, the Legislative Instrument allows a reasonable period of time (three months) for individuals to consider the benefits of the My Health Record system and their own preferences regarding their privacy and healthcare before making an informed decision as to whether they would like to opt-out of registration and having a My Health Record created. In future, as new individuals become eligible, the opportunity to opt-out will be made available as part of the process for enrolling in Medicare, and individuals would be able to learn about the My Health Record system and decide whether they would like to opt-out in advance of enrolling in Medicare.

Under the Act, individuals who are registered may limit and restrict access to their My Health Record with control settings and may cancel or suspend their registration, should they so wish, as described below.

Individuals need to be able to make informed decisions about the My Health Record system. Individuals will be made aware of the national opt-out arrangements, how their personal information will be handled, and how to opt-out or adjust privacy control settings, so they can make an informed decision. Comprehensive information and communication activities are being planned to ensure all affected individuals, including parents, guardians and carers, are

aware of the opt-out arrangements, what they need to do to participate, how to adjust privacy controls associated with their My Health Record, or opt-out if they choose.

The Legislative Instrument also ensures that individuals who do not opt-out of registration have the opportunity to elect not to have any of their health information held by the Chief Executive Medicare made available to the System Operator for inclusion in their My Health Record. Individuals who initially elect not to have their Medicare health information included in their My Health Record may later have such information included, should they change their mind.

Strong privacy safeguards are in place. People who are registered under opt-out arrangements will retain the same privacy protections as those previously registered under opt-in arrangements. These protections include the ability to do the following, including for children and persons with disabilities:

- set access controls restricting access to their My Health Record entirely or restricting access to certain information in their My Health Record;
- request that their healthcare provider not upload certain information or documents to their My Health Record, in which case the healthcare provider will be required not to upload that information or those documents;
- request that their Medicare data not be included in their My Health Record, in which case the Chief Executive Medicare will be required to not make the data available to the System Operator;
- monitor activity in relation to their My Health Record using the audit log or via electronic messages alerting them that someone has accessed their My Health Record;
- effectively remove documents from their My Health Record;
- make a complaint if they consider there has been a breach of privacy; and
- cancel their registration (that is, cancel their My Health Record).

Increased use of the system under opt-out arrangements is a privacy-positive outcome as it will help reduce the use of paper records, which pose significant privacy risks. For example, where a patient is receiving treatment in a hospital's emergency department for a chronic illness, the hospital may request from the patient's regular doctor information about the patient's clinical history which is likely to be faxed to the hospital. The fax might remain unattended on the fax machine for an extended period of time before being placed into the patient's file, or the information may be sent to the wrong fax number. Either of these things could lead to an interference with the patient's privacy should a third party read the unattended fax or incorrectly receive the fax. In contrast, under the My Health Record system, the patient's Shared Health Summary would be securely available only to those people authorised to see it.

There are other similar scenarios where an increase in the level of use of the My Health Record system, as will occur under opt-out arrangements, is likely to lead to a reduction in privacy breaches associated with paper-based records.

Conclusion

The Legislative Instrument is compatible with human rights because it advances the right to health. Any limitation of the right to privacy is proportionate, necessary and reasonable to

achieving improved healthcare for Australians. Increased use of the My Health Record system, which will occur as a result of opt-out arrangements, will result in a number of privacy positives compared to use of paper-based records.

The Hon Greg Hunt MP

Minister for Health

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH



Briefing Paper

My Health Record Return to Government Programme Management Meeting

Date prepared: 23 May 2017

Prepared by: s22

Prepared for: Programme Board

Briefing point

To agree the timing and handling approaches for ongoing opt-out arrangements

Relevant background information

- Ongoing opt-out registration arrangements need to be in place for individuals who become eligible after roll-out of national opt-out.
- The System Operator has to be satisfied that the individual has been given the opportunity to make an election not to register (opt-out), among other things, before they register an individual.
- The current Medicare registration process for newborns includes an opportunity for parents to opt their baby in to the My Health record. In 2015, there were about 26,000 newborns each month, of which about 15,000 were registered.
- The other Medicare and the individual healthcare identifier registration processes do not include the opportunity for people to opt-in to the My Health Record. This affects about 24,000 people a month.

Discussion Point (revised heading to meet paper requirement)

Handling approach for ongoing opt-out arrangements

In the ongoing registration arrangements, individuals who apply to enrol with Medicare (including newborns), or apply to create an individual healthcare identifier¹, will be given both the opportunity and the information necessary to opt-out, otherwise they will be registered and a My Health Record will be created for them (almost immediately).

The Medicare enrolment processes and individual healthcare identifier creation² process will need to be revised to provide an opportunity for the applicant to opt-out of being registered for a My Health Record. The new processes will need to include the provision of privacy information in accordance with Australian Privacy Principle 5 (notifying an individual about how their information will be used), and information about the benefits and risks of having a My Health Record.

¹ Individuals who enrol with Medicare are automatically assigned an individual healthcare identifier. Visitors and residents who cannot enrol in Medicare but receive healthcare in Australia, may choose to obtain a healthcare identifier.

² Creating a pseudonymous healthcare identifier will not trigger the creation of a My Health Record – any person with a pseudonymous healthcare identifier will need to apply directly to the System Operator to register for a My Health Record.

Timing of ongoing opt-out arrangements

If ongoing opt-out commences later than bulk registration, people who become eligible to be registered during this period will need to opt-in in order to be registered for a My Health Record as they will not have been given the opportunity to opt-out.

It is therefore proposed that the ongoing opt-out arrangements commence at the same time as the opt-out period for bulk registration commences to minimise the number of people who have to opt-in or miss the opportunity to have a record created for them.

Transition

It is unlikely the revised registration processes will immediately replace the existing processes upon the commencement of the ongoing opt-out arrangements, and it is expected that some old forms may continue in circulation for some time (either to exhaust existing stocks or because individuals have taken home forms to complete).

It is proposed that registration only occur if an individual has expressly opted in (using an old form), or has been given the opportunity to opt-out (using a revised form or electronic alternative) and has not elected to do so.

The diagram attached sets out the key events associated with bulk registration and ongoing opt-out, and the handling strategy for dealing with old forms after ongoing opt-out commences.

Risks or Issues to be aware of

If an individual is registered without being given an opportunity to opt-out, it could be considered to be a privacy breach. It is therefore critical that privacy information be included as part of all revised processes, to ensure a decision whether or not to register for a My Health Record is informed.

If the ongoing opt-out arrangements do not commence immediately following bulk registration, there will be approximately 24,000 people each month who will not be registered for a My Health Record and will need to opt-in later if they want one.

Timeframes for both ongoing and bulk opt-out registration arrangements must be established by the Rule to be made under the *My Health Records Act 2012*.

s22

From: s22 @opc.gov.au>
Sent: Friday, 12 May 2017 2:12 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v04.doc

Follow Up Flag: Follow Up
Flag Status: Flagged

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22,

Thank you for your s42. I attach the draft *My Health Records (National Application) Rules 2017*.

Please do not hesitate to contact me if you wish to discuss this draft. We look forward to your comments.

Kind regards,

s22

s22

Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
 | Locked Bag 30 Kingston ACT 2604

T s22 | **M** s22 | **F** s22

W www.opc.gov.au | **E** s22 @opc.gov.au

 Please consider the environmental impact before you print this email

<<I17KH158.v04.doc 12/05/2017 2:10:46 PM My Health Records (National Application) Rules 2017>>

[OPCTRM:PC:BE17/547]

s22

From: s22@opc.gov.au>
Sent: Friday, 26 May 2017 3:03 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v09.doc; I17KH158.V09.V04.doc

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22,

We attach a s42 of the *My Health Records (National Application) Rules 2017*, and a s42.

We look forward to your comments on this draft.

Kind regards,

s22

s22
Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
 | Locked Bag 30 Kingston ACT 2604

T s22 | **M** s22 | **F** s22
W www.opc.gov.au | **E** s22@opc.gov.au

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<<I17KH158.v09.doc 26/05/2017 3:02:08 PM My Health Records (National Application) Rules 2017>>

<<I17KH158.V09.V04.doc 26/05/2017 3:02:08 PM My Health Records (National Application) Rules 2017>>

[OPCTRM:PC:BE17/547]

s22

From: s22 @health.gov.au>
Sent: Monday, 22 May 2017 9:51 AM
To: s22
Cc: s22
Subject: FW: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v04 - Health comments 16may2017.doc

Good morning s22

I do apologise that I sent you the version of the Rules without comments, and that I haven't been able to correct this until now. Please find them attached. The matters that require exec agreement are still under discussion and I will let you know the outcomes as soon as possible.

Kind regards

s22

s22
 Legislation

Digital Health Legislation and Policy Branch | Digital Health Division
 Australian Government Department of Health

s22 @health.gov.au

Location: s22

From: s22
Sent: Wednesday, 17 May 2017 12:39 PM
To: s22
Cc: s22
Subject: FW: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

Good afternoon s22

I apologise for the delay in responding. I'm been out of the office for a couple of days.

I have attached my comments on the draft Rule. I have sought executive agreement to some of my comments, as you'll see below. In the meantime, I thought it would be useful for you to see the direction of our thinking.

We will follow up with you this week with agreed positions.

Kind regards

s22

Sent with Good (www.good.com)

From: s22
Sent: Monday, 15 May 2017 5:29:34 PM
To: s22
Cc: s22
Subject: FW: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

s22
 Some advice for your consideration and discussion.

s22

From: s22
Sent: Monday, 15 May 2017 5:23 PM
To: s22
Subject: FW: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

s22
 I've compiled comments on, and responses to, the draft Opt-out Rule (see attachment). We should respond to OPC no later than tomorrow, subject to agreement to the following positions and assumptions.

1. s42

s22

From: s22 s22
Sent: Friday, 12 May 2017 2:12 PM
To: s22
Cc: s22
Subject: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

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s22
 Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
 | Locked Bag 30 Kingston ACT 2604

T s22 | **M** s22 | **F** s22
W www.opc.gov.au | **E** s22@opc.gov.au

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[OPCTRIM:PC:BE17/547]

s22

From: s22 @health.gov.au>
Sent: Monday, 22 May 2017 3:52 PM
To: s22
Cc: s22
Subject: FW: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v04 - Health comments 22may2017.doc

Good afternoon s22

I can now advise the following decisions which inform the Rule.

s42

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Kind regards

s22

s22
 Legislation

Digital Health Legislation and Policy Branch | Digital Health Division
 Australian Government Department of Health
 s22

From: s22
Sent: Monday, 22 May 2017 9:51 AM
To: s22
Cc: s22
Subject: FW: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

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Digital Health Legislation and Policy Branch | Digital Health Division
 Australian Government Department of Health
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Cc: s22
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I have attached my comments on the draft Rule. I have sought executive agreement to some of my comments, as you'll see below. In the meantime, I thought it would be useful for you to see the direction of our thinking.

We will follow up with you this week with agreed positions.

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Sent: Monday, 15 May 2017 5:29:34 PM
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Cc: s22
Subject: FW: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

s22

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s22

From: s22
Sent: Monday, 15 May 2017 5:23 PM
To: s22
Subject: FW: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

s42

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

s22

From: s22 [@opc.gov.au](mailto:s22@opc.gov.au)
Sent: Friday, 12 May 2017 2:12 PM
To: s22
Cc: s22
Subject: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22,

Thank you for your instructions in this matter. I attach s47C *My Health Records (National Application) Rules 2017*.

Please do not hesitate to contact me if you wish to discuss this draft. We look forward to your comments.

Kind regards,

s22

s22

Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
| Locked Bag 30 Kingston ACT 2604

T s22 | **M** s22 | **F** s22

W www.opc.gov.au | **E** s22 [@opc.gov.au](mailto:s22@opc.gov.au)

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<<I17KH158.v04.doc 12/05/2017 2:10:46 PM My Health Records (National Application) Rules 2017>>

[OPCTRM:PC:BE17/547]

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

s22

From: s22 @health.gov.au>
Sent: Tuesday, 30 May 2017 3:19 PM
To: s22
Cc: s22
Subject: RE: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: 117KH158.v09 - Health comments 30May2017.doc

Good afternoon s22

Here are our comments on the latest draft, including the matters we discussed this morning.

As I mentioned, I will be on leave next week. I will be returning 14 June. I will do my best to get the answers to the outstanding questions before I go.

Kind regards

s22

s22
 Legislation

Digital Health Legislation and Policy Branch | Digital Health Division
 Australian Government Department of Health
 s22

From: s22 @opc.gov.au]
Sent: Friday, 26 May 2017 3:03 PM
To: s22
Cc: s22
Subject: TRIM: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22,

We attach a s42 of the *My Health Records (National Application) Rules 2017*, and s42

We look forward to your comments on this draft.

Kind regards,

s22

s22
 Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
 | Locked Bag 30 Kingston ACT 2604

s22

W www.opc.gov.au | E s22

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<<I17KH158.V09.V04.doc 26/05/2017 3:02:08 PM My Health Records (National Application) Rules 2017>>

[OPCTRIM:PC:BE17/547]

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THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

s22

From: s22 @health.gov.au>
Sent: Tuesday, 6 June 2017 10:27 AM
To: s22
Cc: s22
Subject: RE: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

s22

s42 It is expected this week.

s42

s22

Digital Health Branch
 Health Systems Policy Division
 Department of Health

s22
 s22 @health.gov.au

From: s22 @opc.gov.au]
Sent: Friday, 26 May 2017 3:03 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22,

We attach a s42 of the *My Health Records (National Application) Rules 2017*, and s42

We look forward to your comments on this draft.

Kind regards,

s22

s22

Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
| Locked Bag 30 Kingston ACT 2604

s22

W www.opc.gov.au | **E** s22 [@opc.gov.au](mailto:s22@opc.gov.au)

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<<I17KH158.v09.doc 26/05/2017 3:02:08 PM My Health Records (National Application) Rules 2017>>

<<I17KH158.V09.V04.doc 26/05/2017 3:02:08 PM My Health Records (National Application) Rules 2017>>

[OPCTRIM:PC:BE17/547]

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THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

s22

From: s22 @opc.gov.au>
Sent: Thursday, 22 June 2017 3:25 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22

s42

Please let us know if you wish to discuss this option further.

Kind regards,
s22

s22
Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
| Locked Bag 30 Kingston ACT 2604

s22

W www.opc.gov.au | **E** s22

 Please consider the environmental impact before you print this email

[OPCTIM:PC:BE17/547]



Australian Government
Department of Health

To:	Janet Quigley	Deadline:	4 July 2017
Through:	s22	Contact officer:	s22
From:	s22	Phone:	s22
Date:	July 2017	EA Corro Ref:	

MY HEALTH RECORD: IMPLEMENTING NATIONAL OPT-OUT

Purpose

To request that you approve the Department consulting with the Australian Digital Health Agency on the current draft of the My Health Records (National Application) Rules (the Opt-out Rules).

Timing

s42

The next steps will be to:

- seek the Australian Health Ministers' Advisory Council agreement, out of session, to the proposed Opt-out Rule (by 18 August 2017);
- have the Minister make the Rule and have health ministers note the Rule (by 14 September 2017); and
- table the Rule in Parliament (by 19 October 2017) so that the disallowance period will be completed by 7 December 2017 in advance of national communications on opt-out.

Background

The *My Health Records Act 2012* provides that the Minister may make My Health Records Rules applying the opt-out model nationally if trials of the opt-out model resulted in valuable levels of participation. Participation trials, including the opt-out model, were undertaken in 2016. An evaluation of these trials showed a "high level of support for automatic creation of My Health Records" by healthcare providers and individuals, and found that individuals felt the benefits far outweighed the possibility of risks to privacy, confidentiality and security.

The My Health Record System Operator (i.e. the Australian Digital Health Agency) and the COAG Health Council must be consulted before any My Health Records Rules can be made.

In August 2015 the then Minister for Health gave a commitment to the COAG Health Council that Australian Health Ministers' Advisory Council agreement would be obtained before any legislative instruments relating to the My Health Record system were made.

Issues

The draft Opt-out Rule has been developed to reflect the current design of the opt-out model (Attachment A).

s47C

s42

Consultation

The Australian Digital Health Agency has been consulted regarding the proposed opt-out model.

s42

Recommendation

s47C

Approved / Not Approved / Please Discuss

Janet Quigley
A/g First Assistant Secretary
Health Systems Policy Division
/ 07 / 17

Australian Health Ministers' Advisory Council

Date of issue: (set by Secretariat) **Out-of-Session item no.: (allocated by Secretariat)**
Due date: (set by Secretariat) **Originator: Commonwealth**
() Where a jurisdiction is presenting for a principal committee, this should be shown as
 (Jurisdiction/s for principal committee)*

My Health Records Rule: Implementing National Opt-out

Recommendation

- 1. AGREE to the proposed *My Health Records (National Application) Rules 2017* to implement national opt-out of the My Health Record system.**

Purpose of the paper

To seek agreement to the proposed *My Health Records (National Application) Rules 2017* (the Opt-out Rule).

Summary of issues for discussion

The *My Health Records Act 2012* (the Act) provides that the Minister may make My Health Records Rules applying the opt-out model nationally if trials of the opt-out model resulted in valuable levels of participation.

Participation trials, including the opt-out model, were undertaken in 2016. An evaluation of these trials showed a “high level of support for automatic creation of My Health Records” by healthcare providers and individuals, and found that individuals felt the benefits far outweighed the possibility of risks to privacy, confidentiality and security.

In 2017 the Government decided to transition the My Health Record system to an opt-out system for consumers. In order to implement this decision, the Minister needs to make the proposed Opt-out Rule (**Attachment 1**).

A plain English description of the proposed Opt-out Rule is provided at **Attachment 2**.

Subsection 109(2) of the Act requires that the Minister consult with the System Operator and the Australian Health Ministers' Advisory Council before making My Health Records Rules. The System Operator (i.e. the Australian Digital Health Agency) has been consulted on the Opt-out Rule and supports the making of the Rule.

Subclause 2(3) of Schedule 1 to the Act requires the Minister to consult the Ministerial Council before making a My Health Records Rule to implement national opt-out. In August 2015 the then Minister for Health gave a commitment to the COAG Health Council that Australian Health Ministers' Advisory Council agreement would be obtained before any legislative instruments relating to the My Health Record system were made.

If members agree to the proposed Opt-out Rule, it will be provided to the COAG Health Council for noting.

Background

The Act was amended in 2015 to enable the Minister to undertake opt-out trials, and to apply the opt-out model nationally.

Results of consultations with jurisdictions / implications for other ministerial councils

Jurisdictions have not yet been consulted on the proposed Opt-out Rule.

Regulation impact assessment

A regulation impact statement (RIS) was undertaken in 2015 as part of the amendments to the Act to enable the Minister to make rules to implement opt-out (OBPR ID 16442 and published at ris.pmc.gov.au/2015/07/21/proposed-changes-personally-controlled-electronic-health-record-system), and as part of the Cabinet decision in 2017 to implement national opt-out (OBPR ID 21564 and published at ris.pmc.gov.au/2017/06/01/changes-my-health-record-system). As such, a RIS is not required for the Opt-out Rule.

Cost-shared budget implications

Nil

Attachments

Attachment 1: My Health Records (National Application) Rules 2017
Attachment 2: Plain English description of Rule

Jurisdiction:	Commonwealth
Contact person:	s22
Phone:	s22
Email:	s22 @health.gov.au

s22

From: s22
Sent: Friday, 30 June 2017 10:05 AM
To: s22
Cc: s22
Subject: FW: LEX 30933: s22
 [AGSDMS-DMS.FID3228935] [DLM=Sensitive:Legal]
Attachments: s22 Rules.DOCX

Good morning s22

s42

Let me know if we need to discuss or whether you need anything further from me to progress the drafting.

Kind regards

s22
 A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
 Australian Government Department of Health

s22
 Location: s22

From: s22
Sent: Friday, 30 June 2017 9:45 AM
To: s22
Cc: s22
Subject: FW: s42 [AGSDMS-DMS.FID3228935] [DLM=Sensitive:Legal]

Hi s22

Please find attached the s42

s42

s42

Please contact me if you wish to discuss the options.

Regards,

s22
 Lawyer
 Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
 Australian Government Department of Health
 s22

PO Box 9848, Canberra ACT 2601, Australia

Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 [redacted] @ags.gov.au]

Sent: Friday, 30 June 2017 9:12 AM

To: s22 [redacted]

Cc: s22 [redacted]

Subject: RE: s42 [redacted]

[DLM=Sensitive:Legal] [AGSDMS-DMS.FID3228935]

Good morning s22 [redacted]

s42 [redacted]
[redacted]

Please let me know if you have any questions in relation to this or any other matter. Once you have had the opportunity to review the advice, let me know if you would like for us to finalise it.

Kind regards

s22 [redacted]

s22 [redacted]

Counsel

Australian Government Solicitor

T s22 [redacted]
[redacted]

Find out more about AGS at <http://www.ags.gov.au>

Important: This message may contain confidential or legally privileged information. If you think it was sent to you by mistake, please delete all copies and advise the sender. For the purposes of the *Spam Act 2003*, this email is authorised by AGS.

From: s22 [redacted] @health.gov.au]

Sent: Monday, June 26, 2017 9:22 AM

To: s22 [redacted]

Cc: s22 [redacted]

Subject: RE: s42 [redacted] [AGSDMS-DMS.FID3228935] [SEC=UNCLASSIFIED]

Hi s22 [redacted]

s42 [redacted]
[redacted]

- [redacted]
[redacted]
[redacted]
[redacted]
- [redacted]
[redacted]

s42

A copy of the most recent draft Rule is attached for your reference.

Our client requires advice by the end of this week (i.e. 30 June 2017) so that the draft Rule may be ready for consultation, which is planned to occur in July 2017. You indicated that you think you might be able to provide advice by the end of the week but would need to confirm this with s22 today (26.6.17).

Could you please provide your estimated fees for providing advice on the above options, so that we may increase the purchase order if required?

Regards,

s22

Lawyer

Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
Australian Government Department of Health

s22

PO Box 9848, Canberra ACT 2601, Australia

My days at work are Monday, Tuesday, Thursday & Friday (until 4.30pm)

Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 [REDACTED] [@ags.gov.au](mailto:s22@ags.gov.au)

Sent: Thursday, 8 June 2017 4:00 PM

To: s22 [REDACTED]

Cc: s22 [REDACTED]

Subject: RE: s42 [REDACTED]

[SEC=UNCLASSIFIED] [AGSDMS-DMS.FID3228935]

Good afternoon s22 [REDACTED]

We attach our draft advice associated with the below request. Please let me know if you have any questions, or are happy for us to finalise.

Kind regards

s22

s22

Counsel

Australian Government Solicitor

T s22

s22 [REDACTED] [@ags.gov.au](mailto:s22@ags.gov.au)

Find out more about AGS at <http://www.ags.gov.au>

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From: s22 [REDACTED] [@health.gov.au](mailto:s22@health.gov.au)

Sent: Friday, June 02, 2017 3:55 PM

To: s22 [REDACTED]

Cc: s22 [REDACTED]

Subject: RE: s42 [REDACTED]

[SEC=UNCLASSIFIED]

Legal-in-confidence

Hi s22 [REDACTED]

As just discussed by telephone, please find attached the s42 [REDACTED] *My Health Records (National Application) Rules 2017*.

s42 [REDACTED]

[REDACTED] to Wednesday (7.6.17) or Thursday (8.6.17) next week. I note that you will discuss this time frame with s22 [REDACTED] on Monday and thereafter confirm with me whether you think it is achievable.

I look forward to hearing from you.

Regards,

s22 [REDACTED]

Lawyer

Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
Australian Government Department of Health

s22 [REDACTED]

PO Box 9848, Canberra ACT 2601, Australia

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From: s22 [REDACTED] [@ags.gov.au](mailto:s22@ags.gov.au)

Sent: Tuesday, 30 May 2017 4:18 PM

To: s22 [REDACTED]

Cc: s22 [REDACTED]

Subject: RE: s42 [REDACTED]

[SEC=UNCLASSIFIED]

Good afternoon s22 [REDACTED]

I just tried to call you to follow up with this request in light of the Thursday deadline. Are happy for us to begin work on the basis of the below quote?

Let me know if you have any questions or if I can assist in any other way.

Kind regards

s22

s22

Counsel

Australian Government Solicitor

s22

Find out more about AGS at <http://www.ags.gov.au>

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From: s22

Sent: Monday, May 29, 2017 10:25 AM

To: s22 @health.gov.au'

Cc: s22

Subject: RE: s42

[SEC=UNCLASSIFIED]

Good morning s22

s42

Please let us know if you have any questions or are happy for us to proceed on this basis.

Kind regards

s22

s22

Australian Government Solicitor

T s22

s22 @ags.gov.au

Find out more about AGS at <http://www.ags.gov.au>

Important: This message may contain confidential or legally privileged information. If you think it was sent to you by mistake, please delete all copies and advise the sender. For the purposes of the *Spam Act 2003*, this email is authorised by AGS.

From: s22 @health.gov.au]

Sent: Friday, May 26, 2017 2:10 PM

To: s22
 Cc: s22
 Subject: FW: s42
 [SEC=UNCLASSIFIED]

Hi s22

I have attached the s42 (i.e. the draft *My Health Records (National Application) Rules 2017*). I just realised I did not attach it to my previous email.

Regards,

s22
 Lawyer
 Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
 Australian Government Department of Health
 s22

PO Box 9848, Canberra ACT 2601, Australia

My days at work are Monday & Tuesday (until 4.30pm) and Thursday & Friday (until 2.30pm).

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From: s22
Sent: Friday, 26 May 2017 1:57 PM
To: s22 @ags.gov.au'
Cc: s22
Subject: s42
 [SEC=UNCLASSIFIED]

Hi s22

s42

s22

s22

Page 7 of 8

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BY THE DEPARTMENT OF HEALTH

s22

From: s22
Sent: Tuesday, 20 June 2017 1:04 PM
To: s22
Cc: s22
Subject: s42
 [DLM=Sensitive:Legal]
Attachments: s42.DOCX

Good afternoon s22

s42

By the end of the day I should be back up to speed and I will let you know where things are at and what our plans are for moving forward, including timeframes.

For your information, s22 is on leave for the next few weeks and, upon his return, will take up a temporary position with the Australian Digital Health Agency. I'll be acting for s22 for the next few months.

On another matter, I will contact you by Thursday s42

Kind regards

s22

s22
 A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
 Australian Government Department of Health
 s22

From: s22
Sent: Friday, 9 June 2017 10:56 AM
To: s42
Cc: s22
Subject: s42
 [DLM=Sensitive:Legal]

Hi s22

Please find attached a s42

I would be happy to discuss the draft advice with you after you have considered it. s42

please confirm whether you would like me to arrange such a teleconference or if you have any other questions.

Regards,

s22
 Lawyer
 Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
 Australian Government Department of Health

s22

PO Box 9848, Canberra ACT 2601, Australia

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From: s22 @ags.gov.au]
Sent: Thursday, 8 June 2017 4:00 PM**To:** s22**Cc:** s22**Subject:** s42

Good afternoon s22

We attach our draft advice associated with the below request. Please let me know if you have any questions, or are happy for us to finalise.

Kind regards

s22

s22

Counsel

Australian Government Solicitor

s22

@ags.gov.au

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From: s22 @health.gov.au]
Sent: Friday, June 02, 2017 3:55 PM**To:** s22**Cc:** s22**Subject:** s42

Legal-in-confidence

Hi s22

As just discussed by telephone, please find attached the s42 *My Health Records (National Application) Rules 2017*.

I s42

s42

Wednesday (7.6.17) or Thursday (8.6.17) next week. I note that you will discuss this time frame with s22 e to on Monday and thereafter confirm with me whether you think it is achievable.

I look forward to hearing from you.

Regards,

s22

Lawyer
Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
Australian Government Department of Health
s22

PO Box 9848, Canberra ACT 2601, Australia

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s22

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s22

From: s22 [redacted] [@health.gov.au](mailto:s22@health.gov.au)
 Sent: Friday, May 26, 2017 2:10 PM
 To: s22 [redacted]
 Cc: s22 [redacted]
 Subject: s42 [redacted]

Hi s22 [redacted]

I have attached the s42 [redacted] ail (i.e. the draft *My Health Records (National Application) Rules 2017*). I just realised I did not attach it to my previous email.

Regards,

s22 [redacted]
 Lawyer
 Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
 Australian Government Department of Health
 s22 [redacted] [@health.gov.au](mailto:s22@health.gov.au)
 Location s22 [redacted]

PO Box 9848, Canberra ACT 2601, Australia

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s22

Sent: Friday, 26 May 2017 1:57 PM

To: s22 ags.gov.au'

Cc: s22

Subject: s42

Hi s22

s42

THIS DOCUMENT HAS BEEN RELEASED UNDER
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BY THE DEPARTMENT OF HEALTH

s42

s42
[REDACTED]**Contacts**s22
[REDACTED]

I look forward to hearing from you.

Regards,

s22
[REDACTED]

Lawyer

Corporate Governance and Data Analytics Section

Legal Services Branch | Legal Division
Australian Government Department of Healths22
[REDACTED]

PO Box 9848, Canberra ACT 2601, Australia

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Briefing Paper

My Health Record Expansion Programme

Action Item:

Date prepared: 28 June 2017

Prepared by: s22

Prepared for: Programme Board

Recommendations

That the Members:

1. **AGREE** that the ongoing opt-out arrangements will commence at the same time the opt-out period for bulk registration commences;
2. **AGREE** that the Medicare enrolment process and individual healthcare identifier creation process must be revised to provide an opportunity for an applicant to opt-out of being registered for a My Health Record;
3. **NOTE** that the ongoing opt-out arrangements must include the provision of privacy information in accordance with the Australian Privacy Principles; and
4. **NOTE** that old processes/forms may endure to some extent during the transition into an opt-out system, and the attached handling strategy will be implemented to ensure individuals are not unintentionally registered for a My Health Record.

Purpose

The purpose of the paper is to seek agreement to the proposed ongoing opt-out arrangements.

Relevant background information

- The *My Health Records Act 2012* provides that, in an opt-out model, an individual cannot be registered unless they have been given the opportunity to opt-out. The System Operator must be satisfied that, among other things, such an opportunity has been provided before they can create a My Health Record for the individual.
- The only circumstance in which a My Health Record can be created without an opportunity to opt-out is if the individual applies to register (i.e. they previously cancelled or opted out, but have changed their mind).
- As such, ongoing opt-out registration arrangements need to be in place for individuals who become eligible after roll-out of national opt-out (e.g. newborns and immigrants).
- The current Medicare registration process for newborns includes an opportunity for parents to opt their baby in to the My Health record. In 2015, there were about 26,000 newborns each month, of which about 15,000 were registered.

- The other Medicare and the individual healthcare identifier registration processes do not include the opportunity for people to opt-in to the My Health Record. This affects about 24,000 people a month.

Discussion Point (revised heading to meet paper requirement)

Handling approach for ongoing opt-out arrangements

In the ongoing registration arrangements, individuals who apply to enrol with Medicare (including newborns), or apply to create an individual healthcare identifier¹, will be given both the opportunity and the information necessary to opt-out, otherwise they will be registered and a My Health Record will be created for them (almost immediately).

The Medicare enrolment processes and individual healthcare identifier creation² process will need to be revised to provide an opportunity for the applicant to opt-out of being registered for a My Health Record. The new processes will need to include the provision of privacy information in accordance with Australian Privacy Principle 5 (notifying an individual about how their information will be used), and information about the benefits and risks of having a My Health Record.

Timing of ongoing opt-out arrangements

If ongoing opt-out commences later than bulk registration, people who become eligible to be registered during this period will need to opt-in in order to be registered for a My Health Record as they will not have been given the opportunity to opt-out.

It is therefore proposed that the ongoing opt-out arrangements commence at the same time as the opt-out period for bulk registration commences to minimise the number of people who have to opt-in or miss the opportunity to have a record created for them.

Transition

It is unlikely the revised registration processes will immediately replace the existing processes upon the commencement of the ongoing opt-out arrangements, and it is expected that some old forms may continue in circulation for some time (either to exhaust existing stocks or because individuals have taken home forms to complete).

It is proposed that registration only occur if an individual has expressly opted in (using an old form), or has been given the opportunity to opt-out (using a revised form or electronic alternative) and has not elected to do so.

The diagram at **Attachment 1** sets out the key events associated with bulk registration and ongoing opt-out, and the handling strategy for dealing with old forms after ongoing opt-out commences.

Risks or Issues to be aware of

Eligibility to be registered in an opt-out setting will be triggered when an individual makes an application that results in a healthcare identifier being created. This should mitigate the risk that My Health Records will be created for duplicate healthcare identifiers.

Further, there may be circumstances in which an individual is eligible to be registered in an opt-out setting, but should not be. The My Health Records Act provides the System Operator with some discretion in deciding whether to register an individual. The Agency will need to determine the types of circumstances in which an eligible individual should not be registered.

If an individual is registered without being given an opportunity to opt-out, it could be considered to be a privacy breach. It is therefore critical that privacy information be included

¹ Individuals who enrol with Medicare are automatically assigned an individual healthcare identifier. Visitors and residents who cannot enrol in Medicare but receive healthcare in Australia, may choose to obtain a healthcare identifier.

² Creating a pseudonymous healthcare identifier will not trigger the creation of a My Health Record – any person with a pseudonymous healthcare identifier will need to apply directly to the System Operator to register for a My Health Record.

as part of all revised processes, to ensure a decision whether or not to register for a My Health Record is informed.

If the ongoing opt-out arrangements do not commence immediately following bulk registration, there will be approximately 24,000 people each month who will not be registered for a My Health Record and will need to opt-in later if they want one.

Timeframes for both ongoing and bulk opt-out registration arrangements must be established by the Rule to be made under the My Health Records Act ~~2012~~.

Attachments

Attachment 1 Diagram: opt-out timing and handling

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s22

From: s22 @opc.gov.au>
Sent: Tuesday, 4 July 2017 9:38 AM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v17.doc; I17KH158.V17.V09.doc

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22,

Please find attached the revised draft s42

We look forward to your comments on this draft.

s42

As discussed, I will be on leave from tomorrow, returning next Wednesday. I will be in the office next Wednesday to Friday, and then on secondment for the next 6 months. s22 will continue to be the contact for the matter, and will let you know if another drafter is assigned to work on the matter.

Kind regards,

s22

Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603 | Locked Bag 30 Kingston ACT 2604

s22

W www.opc.gov.au | E s22 @opc.gov.au

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◇

◇

[OPCTRM:PC:BE17/547]

Hi s22

s42

Kind regards

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health

s22

Page 1 of 2

s42

As discussed, I will be on leave from tomorrow, returning next Wednesday. I will be in the office next Wednesday to Friday, and then on secondment for the next 6 months. s22 will continue to be the contact for the matter, and will let you know if another drafter is assigned to work on the matter.

Kind regards,

s22

Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
| Locked Bag 30 Kingston ACT 2604

s22

W www.opc.gov.au | **E** s22@opc.gov.au

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<<I17KH158.v17.doc 4/07/2017 9:32:29 AM My Health Records (National Application) Rules 2017>>

<<I17KH158.V17.V09.doc 4/07/2017 9:32:29 AM My Health Records (National Application) Rules 2017>>

[OPCTRIM:PC:BE17/547]

s22

From: s22@opc.gov.au>
Sent: Tuesday, 4 July 2017 7:29 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v21.doc; I17KH158.V21.V17.doc

Follow Up Flag: Follow Up
Flag Status: Flagged

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal
 Dear s22,

s42

Please let me have your comments on the draft.

s22 is now on leave until 12 July. I am in the office tomorrow (5 July) and will then be on leave until 26 July.

Regards

s22

s22

Senior Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603 | Locked Bag 30 Kingston ACT 2604

s22

W www.opc.gov.au | **E** s22@opc.gov.au

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[OPCTRIM:PC:BE17/547]

Good morning s22

s42

s42

42

Kind regards

s22
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health
s22

From: s22 [redacted]@opc.gov.au]
Sent: Tuesday, 4 July 2017 7:29 PM
To: s22 [redacted]
Cc: s22 [redacted]
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Dear s22,

s42 [redacted]

Please let me have your comments on the draft.

s22 [redacted] is now on leave until 12 July. I am in the office tomorrow (5 July) and will then be on leave until 26 July.

Regards

s22 [redacted]

[redacted]
Senior Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603
| Locked Bag 30 Kingston ACT 2604

s22 [redacted]

W www.opc.gov.au | **E** s22 [redacted]@opc.gov.au

 Please consider the environmental impact before you print this email

<<I17KH158.v21.doc 4/07/2017 7:25:50 PM My Health Records (National Application) Rules 2017>>

<<I17KH158.V21.V17.doc 4/07/2017 7:25:50 PM My Health Records (National Application) Rules 2017>>

[OPCTRIM:PC:BE17/547]

s22

From: s22
Sent: Wednesday, 5 July 2017 11:46 AM
To: s22
Cc: s22
Subject: RE: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

Thanks so much s22 That looks good and I'm happy for it to be made an s42 . Can we please use block 3 for presenting the draft.

s22

s22
 A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
 Australian Government Department of Health

s22

From: s22 @opc.gov.au]
Sent: Wednesday, 5 July 2017 11:25 AM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22,

Thank you for your s42 If you are happy with this draft, s42 .

(s42 . Is that ok?)

There are a number of different standard “blocks” that are used for presenting an exposure drafts. I have set these out below. Please let me know which of these you would like to use, or if you would like something different.

Regards

s22

s22
 Senior Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrester ACT 2603 | Locked Bag 30 Kingston ACT 2604

s22

W www.opc.gov.au | **E** s22 @opc.gov.au

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s42

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s22

From: s22@opc.gov.au>
Sent: Wednesday, 5 July 2017 5:21 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v25.doc

Follow Up Flag: Follow up
Flag Status: Flagged

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal
 Dear s22,

s42

As requested, I attach an s42 .

Contact details for this matter from 6 July until 26 July

I am going to be on leave from tomorrow until 26 July.

s22 will be back in the office, and will be the contact for this matter, from 12-14 July. She will then be going on a secondment for 6 months.

In my and s22's absence, the contact details for this matter from 6-11 July and 17-25 July are:

6-11 July: First Parliamentary Counsel, s22, email s22@opc.gov.au.

17-25 July: s22, email s22@opc.gov.au.

Regards

s22

s22

Senior Assistant Parliamentary Counsel

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603 | Locked Bag 30 Kingston ACT 2604

s22

W www.opc.gov.au | **Es22** @opc.gov.au

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◇

[OPCTRIM:PC:BE17/547]

s22

From: s22 @digitalhealth.gov.au>
Sent: Thursday, 6 July 2017 4:52 PM
To: s22
 [REDACTED]
 [REDACTED]
 [REDACTED]
Cc: s22
Subject: RE: For Review - s42 [SEC=No Protective Marking]

Hi All

Please note that the material can be shared with DHS.

This will be distributed to DHS via a separate email

Regards

s22 – Program Manager, My Health Record Expansion Program – Core Services Systems Operations
 Phone s22 ; Email: s22 @digitalhealth.gov.au Web: www.digitalhealth.gov.au

From: s22
Sent: Thursday, 6 July 2017 4:09 PM
To: s22
 [REDACTED]
 [REDACTED]

Cc: s22
Subject: For Review - s42

Hi Folks

Please find attached for your review the s42

These are provided by the Department of Health (Legislation, Policy and Hard to Service work stream) for consideration by the Agency, in accordance with the My Health Records Act. We are seeking feedback from the Agency Program Implementation Working Group members.

Please note that these documents are confidential and must not be shared outside the Agency (for example DHS).

Please provide feedback to s22 by the **21st July 2017**. Feel free to call s22 should you have any queries. If required, an out of session Working Group can be scheduled to facilitate discussion and address issues.

Regards

s22
 Program Manager, My Health Record Expansion Program
 Core Services Systems Operations Division

Australian Digital Health Agency
Level 25, 56 Pitt Street, Sydney NSW 2000
Phone s22
s22
Web www.digitalhealth.gov.au

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s22

From: s22 @digitalhealth.gov.au>
Sent: Thursday, 6 July 2017 4:09 PM
To: s22
Subject: For Review - Exposure Draft: My Health Record Rule [SEC=No Protective Marking]
Attachments: My Health Records (National Application) Rules 2017 -s42.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Folks

Please find attached for your review the s42

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Regards

s22
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 Core Services Systems Operations Division

Australian Digital Health Agency
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 Phone s22
 Email s22 @digitalhealth.gov.au
 Web www.digitalhealth.gov.au

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BY THE DEPARTMENT OF HEALTH

s42

A plain English explanation of the Rules is provided at **Attachment 2**.

The Act provides that before making My Health Records Rules, the Minister must consult with Australian Health Ministers' Advisory Council and the System Operator (i.e. the Australian Digital Health Agency). The System Operator was given the opportunity to review and provide feedback on an earlier draft of the Rules. Changes were subsequently made to the Rules, in consultation with the Agency.

The Act further provides that before making rules to implement opt-out nationally, the Minister must consult the Ministerial Council. If members agree to the proposed Rules, they will be provided to the COAG Health Council for noting.

Background

Due to the low numbers of people choosing to register for a My Health Record system, the Act was amended in 2015 to allow for an opt-out model of participation to be implemented. Specifically, Schedule 1 to the Act allows the Minister to make rules to undertake trials of an opt-out model, and to implement opt-out nationally.

Results of consultations with jurisdictions / implications for other ministerial councils

Jurisdictions have not yet been consulted on the proposed amendment, though were consulted on the move to opt-out participation arrangements.

Regulation impact assessment

A Regulation Impact Statement (RIS) was prepared for the *Health Legislation Amendment (eHealth) Bill 2015*, which established the ability to implement opt-out nationally: ris.pmc.gov.au/2015/07/21/proposed-changes-personally-controlled-electronic-health-record-system), and a RIS was prepared as part of the Government decision to transition the My Health Record system to an opt-out system: ris.pmc.gov.au/2017/06/01/changes-my-health-record-system. As such, a RIS is not required for the making of these Rules.

Cost-shared budget implications

Nil

Attachments

Attachment 1: Draft *My Health Records (National Application) Rules 2017*
Attachment 2: Plain English explanation of the Rules

Jurisdiction: Commonwealth
Contact person: Nicole Jarvis
Phone: (02) 6289 8001
Email: nicole.jarvis@health.gov.au



Australian Government
Department of Health

FOR OFFICIAL USE ONLY
Ministerial Submission – Standard
<PDR No> Version (1)
MPEG to complete Date sent to MO:<dd/mm/yy>

To: Minister Hunt

cc: Martin Bowles

Subject: MY HEALTH RECORDS RULES: IMPLEMENTING NATIONAL OPT-OUT

Critical date: 4 October 2017, to ensure the Rules can be tabled in Parliament in time for the disallowance period to run its course in 2017

Recommendation/s:			
1.	s47C	1.	Agreed/ Not agreed
2.	s47C	2.	Approved/ Not approved
3.	Sign and date the Rules (Attachment B)	3.	Signed/Not signed
4.	Note the explanatory statement, including the human rights compatibility statement, to the regulations (Attachment C)	4.	Noted
Signature		Date: / /	
Comments:			
Contact Officer:	Nicole Jarvis	Assistant Secretary, Digital Health Branch, Health Systems Policy Division	Ph: (02) 6289 8001 Mobile: s22
Clearance Officer:	Mark Cormack	Deputy Secretary, Health Systems Policy Division	Ph: (02) 6289 3348 Mobile: s22

Issues:

- The *My Health Records Act 2012* allows you to make rules to implement opt-out nationally if you are satisfied that the opt-out model results in participation in the My Health Record system at a level that provides value for those using the system.
- Based on the evaluation of the trials and the subsequent Government decision as part of Budget 2017, it is proposed that you now make such a rule.
- s47C
It is important to note that health ministers agreed to national implementation of opt-out in March 2017, as part of the return to Government.
- The draft *My Health Records (National Application) Rules 2017* are provided for your approval (**Attachment B**).
- s47C

FOR OFFICIAL USE ONLY

6.

s47C
[REDACTED]
[REDACTED]
[REDACTED]

Background: The My Health Records Act was amended in 2015 to enable to make rules to implement the opt-out model through trials and nationally.

Attachments:

A: COAG Health Council out of session agenda paper

B: My Health Records (National Application) Rules

C: Explanatory statement, including human rights compatibility statement

Consultations: The Australian Digital Health Agency and Australian Health Ministers' Advisory Council have been consulted on, and have agreed to, the Rules.

The Act requires that the Minister consult the COAG Health Council before rules implementing opt-out national.

Regulatory Burden Implications and/or Deregulation Opportunities: The regulatory impacts of the proposed Rules were assessed as part of the *Health Legislation Amendment (eHealth) Bill 2015*, which established the ability to implement opt-out nationally, and the Government decision to transition the My Health Record system to an opt-out system. Implementing an opt-out system has a deregulatory impact. The regulation impact statements are available at ris.pmc.gov.au/2015/07/21/proposed-changes-personally-controlled-electronic-health-record-system and ris.pmc.gov.au/2017/06/01/changes-my-health-record-system, respectively.

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BY THE DEPARTMENT OF HEALTH



Australian Government

Department of Health

MINUTE TO THE SECRETARY

To: Martin Bowles PSM **Deadline:** 16 August 2017
Through Dep Sec: Mark Cormack **Contact officer:** s22
Through FAS: Maria Jolly **Phone:** s22
From AS: Nicole Jarvis **EA Corro Ref:**
Date: 1 August 2017

MY HEALTH RECORDS RULES: IMPLEMENTING NATIONAL OPT-OUT

Purpose

To seek your:

- s47C [redacted]; and
- s47C [redacted].

Timing

s47C [redacted]
[redacted]
[redacted]
[redacted]
[redacted]

To meet this timeframe, it is proposed that AHMAC be given 15 business days to consider this matter. The agenda paper will need to be circulated to AHMAC no later than 16 August 2017.

The Rules then need to be finalised and submitted to the Minister by 19 September 2017 and provided to the COAG Health Council for noting out of session, concurrently with making the Rules.

Background

In 2015 substantial amendments were made to the *My Health Records Act 2012* (the Act) as part of implementing the recommendations of various reviews. Among other things, these changes included enabling the Minister to implement an opt-out model of individual participation in the My Health Record system. The former Minister implemented the opt-out model as part of participation trials in 2016. These Rules allow the Minister to implement the opt-out model nationally.

Issues

s47C [redacted]
[redacted]
[redacted]

- The opt-out model also provides that opt-in arrangements will continue to be available. This is to enable any person who has previously opted out, or has cancelled their My Health Record, to apply for a My Health Record.

Subsection 109(2) of the Act requires the Minister to consult with the System Operator and AHMAC before making My Health Records Rules. Further, subclause 2(3) of the Act requires the Minister to consult with the COAG Health Council before making Rules to implement opt-out nationally. However, the Rules are not invalidated if AHMAC and CHC are not consulted, or are consulted and do not agree.

Consultation

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UNCLASSIFIED

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For Official Use Only (FOUO)

Recommendation

That you:

- AGREE to provide the proposed Rules for out of session AHMAC consideration

Agreed / Not Agreed / Please Discuss

- APPROVE the out of session agenda paper.

Approved / Not Approved / Please Discuss

Martin Bowles PSM
/ 08 / 17

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UNCLASSIFIED

s22

From: s22
Sent: Tuesday, 11 July 2017 2:29 PM
To: s22
Cc: s22
Subject: s42
Attachments: s42

Hi s22

s42

Please call me if you wish to discuss. Otherwise I will be in contact with you regarding your second question in your email below of 6 July 2017.

Regards,

s22
 Lawyer
 Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
 Australian Government Department of Health
 s22

PO Box 9848, Canberra ACT 2601, Australia

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The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Thursday, 6 July 2017 2:12 PM
To: s22
Cc: s22
Subject: s42 DLM=Sensitive:Legal]

Good afternoon s22

s42

I would usually be working with s22 to get the Rules sorted so I'm working without a safety net this time and just want to be certain that the Rules are doing (legally) what I think they're doing.

Kind regards

s22

s22
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health

s22

From: s22
Sent: Thursday, 6 July 2017 9:27 AM
To: s22
Cc: s22
Subject: s42 [DLM=Sensitive:Legal]

Thanks s22

s42

s22

s22
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health

s22

From: s22
Sent: Thursday, 6 July 2017 9:23 AM
To: s22
Cc: s22
Subject: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Hi s22

s22 and I have some capacity issues today and tomorrow, but I should be able to get back to you on Monday morning (10 July 2017).

Please let me know if this would be problematic.

s22
Lawyer
Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
Australian Government Department of Health

s22

PO Box 9848, Canberra ACT 2601, Australia

My days at work are Monday & Tuesday (until 4.30pm) and Thursday & Friday (until 2.30pm).

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From: s22
Sent: Tuesday, 4 July 2017 3:53 PM

To: s22
Cc: s22
Subject: s42

Good afternoon s22

s42

. If there are big mistakes in my explanation I'll need to delay consultation.

Kind regards

s22

s22
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health

s22
s22

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BY THE DEPARTMENT OF HEALTH

s22

From: s22
Sent: Tuesday, 25 July 2017 2:23 PM
To: s22
Cc: s22
Subject: RE: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Hi s22

I refer to your instructions of s42.

s42

I also make the following comments:

s42

Please contact me if you wish to discuss.

Regards,

s22

Lawyer
 Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
 Australian Government Department of Health
 T s22 | E: s22@health.gov.au
 s22

PO Box 9848, Canberra ACT 2601, Australia

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From: s22
Sent: Tuesday, 11 July 2017 2:33 PM
To: s22
Cc: s22
Subject: RE: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Thanks Leanne
 I really appreciate your quick advice.

s22

s22
 A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
 Australian Government Department of Health
 T: s22 | E: s22 @health.gov.au
 s22

From: s22
Sent: Tuesday, 11 July 2017 2:29 PM
To: s22
Cc: s22
Subject: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Hi s22

Please find attached my s42
 Rules.

Please call me if you wish to discuss. Otherwise I will be in contact with you regarding your second question in your email below of 6 July 2017.

Regards,

s22
 Lawyer
 Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
 Australian Government Department of Health
 T: s22 | E: s22 @health.gov.au
 s22

PO Box 9848, Canberra ACT 2601, Australia

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The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Thursday, 6 July 2017 2:12 PM
To: s22
Cc: s22
Subject: FW: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Good afternoon s22

I attach the latest version of the ps42

1. As previously requested, s42 [REDACTED]
2. Further, s42 [REDACTED]. I am happy to meet with you at your convenience to discuss this further.

I would usually be working with Geoff Adams to get the Rules sorted so I'm working without a safety net this time and just want to be certain that the s42 [REDACTED].

Kind regards

s22 [REDACTED]

s22 [REDACTED]
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health
T: s22 [REDACTED] | E: s22 [REDACTED] @health.gov.au
s22 [REDACTED]

From: s22 [REDACTED]
Sent: Thursday, 6 July 2017 9:27 AM
To: s22 [REDACTED]
Cc: s22 [REDACTED]
Subject: RE: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Thanks s22 [REDACTED]
In that case I'll send you an updated version of the plain English explanation today to reflect the latest changes to Part 4 (in the Exposure draft sent at 5:27pm on 5 July).

s22 [REDACTED]

s22 [REDACTED]
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health
T: s22 [REDACTED] | E: s22 [REDACTED] @health.gov.au
s22 [REDACTED]

From: s22 [REDACTED]
Sent: Thursday, 6 July 2017 9:23 AM
To: s22 [REDACTED]
Cc: s22 [REDACTED]
Subject: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Hi s22 [REDACTED]

s22 [REDACTED] and I have some capacity issues today and tomorrow, but I should be able to get back to you on Monday morning (10 July 2017).

Please let me know if this would be problematic.

s22 [REDACTED]
Lawyer
Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
Australian Government Department of Health
T: s22 [REDACTED] | E: s22 [REDACTED] @health.gov.au
s22 [REDACTED]

PO Box 9848, Canberra ACT 2601, Australia

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From: s22
Sent: Tuesday, 4 July 2017 3:53 PM
To: s22
Cc: s22
Subject: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Good afternoon s22

s42

Kind regards

s22

s22
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health

T: s22 | E: s22 [@health.gov.au](mailto:s22@health.gov.au)

s22

s22

From: s22 @opc.gov.au>
Sent: Friday, 21 July 2017 2:57 PM
To: s22
Cc: s22
Subject: s42
Attachments: I17KH158.v26.doc; I17KH158.V26.V25.doc

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal
Hi s22

I refer to your email earlier today requesting s42 *My Health Records (National Application) Rules 2017*.

s42, along the lines we discussed a little earlier, is attached.

Let me know if this gives effect to your policy requirements.

Regards

s22

s22

◇

◇

[OPCTRM:PC:BE17/547]

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s22

From: s22
Sent: Friday, 21 July 2017 12:02 PM
To: s22
Cc: s22
Subject: s42

Good afternoon s22

I'm contacting you in Fiona's absence in relation to the My Health Records (National Application) Rules.

I have spent the last two weeks consulting with the Australian Digital Health Agency on s42

I'm seeking a revised draft by Tuesday (25/7) so that I can consult further with the Australian Digital Health Agency, but I understand Fiona isn't back until Wednesday. I'm hoping you're able to arrange for a new draft to be provided.

s42

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

s42

[Redacted]

I'm happy to discuss this or answer any questions you may have.

Kind regards

s22

s22

A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health

s22

s22

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s22

From: s22
Sent: Wednesday, 26 July 2017 9:14 AM
To: s22
Cc: s22
Subject: FW: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

Good morning s22 and welcome back

s47C

s42

Please let me know if there is anything further you require.

Kind regards

s22

s22
 A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
 Australian Government Department of Health

s22

s22

From: s22 [mailto:s22@opc.gov.au]
Sent: Friday, 21 July 2017 2:57 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22

I refer to your email earlier today requesting s42 t *My Health Records (National Application) Rules 2017*.

A revised draft, along the lines we discussed a little earlier, is attached.

Let me know if this gives s42 .

Regards

s22

s22

<>

<>

[OPCTRIM:PC:BE17/547]

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s22

From: s22 @digitalhealth.gov.au>
Sent: Monday, 17 July 2017 4:04 PM
To: s22
Cc: s22
Subject: FW: s22 : My Health Record Rule [SEC=No Protective Marking]
Attachments: My Health Records (National Application) Rules 2017 s42 docx
Importance: High

Hi Folks

Just a reminder that feedback on the Rule is required by COB Friday 21st July.

Thanks

s22 – Program Manager, My Health Record Expansion Program – Core Services Systems Operations
 Phone: s22 ; Email: s22 @digitalhealth.gov.au Web: www.digitalhealth.gov.au

From: s22
Sent: Thursday, 6 July 2017 4:54 PM
To: s22
Subject: For Review - Exposure Draft: My Health Record Rule

Hi Folks

Please find attached for your review the s42

These are provided by the Department of Health (Legislation, Policy and Hard to Service work stream) for consideration by the Agency and DHS, in accordance with the My Health Records Act. We are seeking feedback from the Program Implementation Working Group members.

Please provide feedback to s22 by the **21st July 2017**. Feel free to call s22 should you have any queries. If required, an out of session Working Group can be scheduled to facilitate discussion and address issues.

Regards

s22
 Program Manager, My Health Record Expansion Program
 Core Services Systems Operations Division

Australian Digital Health Agency
 Level 25, 56 Pitt Street, Sydney NSW 2000
 Phone s22
 Email s22 @digitalhealth.gov.au
 Web www.digitalhealth.gov.au

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s22

From: s22 @digitalhealth.gov.au>
Sent: Monday, 17 July 2017 4:03 PM
To: s22
 s22
 s22
Cc: s22
Subject: FW: For Review - Exposure Draft: My Health Record Rule [SEC=No Protective Marking]
Attachments: My Health Records (National Application) Rules 2017 - Exposure Draft.doc; For consultation Draft Opt-out Rule with plain English explanations.docx
Importance: High

Hi Folks

Just a reminder to provide feedback on the My Health Record rule by COB this Friday

Thanks

s22 Program Manager, My Health Record Expansion Program – Core Services Systems Operations
 Phone: s22 ; Email: s22 @digitalhealth.gov.au Web: www.digitalhealth.gov.au

From: s22
Sent: Thursday, 6 July 2017 4:09 PM
To: s22

Subject: For Review - Exposure Draft: My Health Record Rule

Hi Folks

Please find attached for your review the s42

These are provided by the Department of Health (Legislation, Policy and Hard to Service work stream) for consideration by the Agency, in accordance with the My Health Records Act. We are seeking feedback from the Agency Program Implementation Working Group members.

Please note that these documents are confidential and must not be shared outside the Agency (for example DHS).

Please provide feedback to s22 by the **21st July 2017**. Feel free to call s22 should you have any queries. If required, an out of session Working Group can be scheduled to facilitate discussion and address issues.

Regards

s22
 Program Manager, My Health Record Expansion Program
 Core Services Systems Operations Division



Australian Digital Health Agency
Level 25, 56 Pitt Street, Sydney NSW 2000
Phone s22
Email s22@digitalhealth.gov.au
Web www.digitalhealth.gov.au

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s22

From: s22@opc.gov.au>
Sent: Thursday, 27 July 2017 4:49 PM
To: s22
Cc: s22@health.gov.au'; s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v27.doc; I17KH158.V27.V26.doc

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

Hi s22,

When I was looking at the s42 I thought that a slightly different approach to the change to s42.

I attach a s42 and my reasons for this.

I am sorry to do this at this late stage but thought it was worth raising for your consideration.

Happy to discuss of course.

Regards

s22

s22
s22

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603 | Locked Bag 30 Kingston ACT 2604

T s22 | **F** s22

W www.opc.gov.au | **E** s22@opc.gov.au

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◇

◇

[OPCTRIM:PC:BE17/547]

s22

From: s22@opc.gov.au>
Sent: Friday, 28 July 2017 2:14 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.v31.doc; I17KH158.V31.V26.doc; I17KH158.V31.V27.doc

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal
 Hi s22,

I refer to our discussions earlier today. I attach an s42

As discussed, the changes to the draft are:

s42

I have attached comparisons of s42.

Regards

s22

s22

s22

Office of Parliamentary Counsel | 28 Sydney Ave Forrest ACT 2603 | Locked Bag 30 Kingston ACT 2604

T s22 | **F** s22

W www.opc.gov.au | **E** s22@opc.gov.au

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[OPCTRIM:PC:BE17/547]

The Act provides that before making My Health Records Rules, the Minister must consult with Australian Health Ministers' Advisory Council (AHMAC) and the System Operator (i.e. the Australian Digital Health Agency). The System Operator was given the opportunity to review and provide feedback on an earlier draft of the Rules. Changes were subsequently made to the Rules, in consultation with the System Operator, and agreed by AHMAC.

Next steps

Background

Results of consultations with jurisdictions / Implications for other ministerial councils

Regulation Impact Assessment

Attachments

-
- CHC Out-of-Session item xx*

EFFECTS OF OPT-OUT COMMENCEMENT

Part 2 of the proposed *My Health Records (National Application) Rules 2017* will implement the opt-out model¹ from the day after the Rules are registered on the Federal Register of Legislation. This is proposed to occur mid-October 2017. This means that technically the My Health Record system will begin operating as an opt-out system during October 2017. Practically however, since opt-out arrangements will not be specified to commence until 2018, the only way to get a My Health Record from October 2017 is to opt-in.

Another effect of the opt-out model applying from October 2017 is that certain provisions of the *My Health Records Act 2012* will, from that date, no longer apply, and the provisions of Part 2 of Schedule 1 of the Act will apply. The affected provisions are described below with differences in red. This may affect the making and recording of registration decisions. Most notably, consumer consent to the uploading of information by healthcare providers is no longer required.

Provisions that will not apply from October 2017		Equivalent and new provisions that will apply from October 2017	
s.38	<ul style="list-style-type: none"> Chief Executive Medicare (CEM) will apply to become a registered repository operator As a registered repository operator, the CEM may include Medicare information about registered consumers in its repository As a registered repository operator, the CEM may, with the consumer's consent, disclose it to the System Operator 	cl.10-12	<ul style="list-style-type: none"> CEM will apply to become a registered repository operator As a registered repository operator, the CEM may include Medicare information about registered consumers in its repository As a registered repository operator, the CEM may disclose it to the System Operator unless the consumer has elected not to include Medicare information
s.39-41	<ul style="list-style-type: none"> Consumer can apply to be registered Consumer is eligible if they have an IHI and provide specified information System Operator must register if proper application made and identity verified System Operator does not need to register if doing so poses a security/integrity risk System Operator does not need to register if consumer does not consent to registered HPOs uploading information* Registered HPOs can upload information that includes third party information <p>*Consumer can still instruct provider not to upload, and provider cannot upload if it contravenes a preserved privacy law</p>	cl.4, 6 & 9	<ul style="list-style-type: none"> Consumer can apply to be registered Consumer is eligible if they have an IHI and the System Operator has collected the specified information System Operator must register if proper application made and identity verified System Operator does not need to register if doing so poses a security/integrity risk or for other reasons specified in Rules Registered HPOs can upload information (consent not required)* Registered HPOs can upload information that includes third party information <p>*Consumer can still instruct provider not to upload, and provider cannot upload if it contravenes a preserved privacy law</p>

¹ The opt-out model is described in Part 2 of Schedule 1 to the *My Health Records Act 2012*.

Provisions that will not apply from October 2017		Equivalent and new provisions that will apply from October 2017	
	N/A	cl.3-5	<ul style="list-style-type: none"> System Operator can register an consumer eligible, identity verified, and given opportunity to opt-out System Operator does not need to register if doing so poses a security/integrity risk or for other reasons specified in Rules Consumer is eligible if they have an IHI and the System Operator has collected the specified information
s.46	<ul style="list-style-type: none"> Registered HPOs cannot refuse to provide care to a person who is not registered under section 41 	s.46	<ul style="list-style-type: none"> Registered HPOs cannot refuse to provide care to a person who is not registered under clause 6 of Schedule 1
s.50D	<ul style="list-style-type: none"> Registered repository operators (other than CEM) can provide information about registered consumers to the System Operator 	cl.16	<ul style="list-style-type: none"> Registered repository operators (other than CEM) can provide information about registered consumers to the System Operator
p.51(2)(d) & (e)	<ul style="list-style-type: none"> System Operator may cancel consumer's registration if the consumer withdraws consent or the consent is invalid 		
s.57	<ul style="list-style-type: none"> System Operator must record in the Register decisions to register (under section 41), vary or cancel a consumer's registration 	s.57	<ul style="list-style-type: none"> System Operator must record in the Register decisions to register (under clause 6 of Schedule 1), vary or cancel a consumer's registration
s.58 & 58A	<ul style="list-style-type: none"> General authorisations for verifying identities, including information in a consumer's My Health Record, and for My health Record system purposes 	cl.7-8	<ul style="list-style-type: none"> General authorisations for verifying identities, including information in a consumer's My Health Record (unless it is Medicare information and the consumer has elected not to include it), and for My health Record system purposes
p.97(1)(b)	<ul style="list-style-type: none"> System Operator must give written notice of a decision not to refuse to register a consumer under section 41 	p.97(1)(b)	<ul style="list-style-type: none"> System Operator must give written notice of a decision not to refuse to register a consumer under clause 6 of Schedule 1

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BY THE DEPARTMENT OF HEALTH

s22

From: s22
Sent: Wednesday, 6 September 2017 3:31 PM
To: s22
Cc: s22
Subject: FW: AHMAC OOS 817 - My Health Records Rules: National Opt-out - responses [SEC=UNCLASSIFIED]
Attachments: OOS817_ACT_230817.pdf; OOS817_NSW_040917.pdf; OOS817_NT_280817.pdf; OOS817_QLD_280817.pdf; OOS817_TAS_280817.pdf; OOS817_VIC_240817.pdf

FYI and for file pls. Just waiting on WA and SA (assuming we are not expecting a CW response?).

s22
Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
s22

From: HMCU
Sent: Wednesday, 6 September 2017 3:21 PM
To: s22
Cc: HMCU
Subject: AHMAC OOS 817 - My Health Records Rules: National Opt-out - responses [SEC=UNCLASSIFIED]

Hi s22 ,

To date, responses have been received from ACT, NSW, NT, QLD, TAS and VIC.

Happy to discuss.

Thanks
s22

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BY THE DEPARTMENT OF HEALTH

s22

From: s22
Sent: Tuesday, 12 September 2017 1:52 PM
To: s22
Cc: s22 HMCU
Subject: RE: Draft AHMAC and AHMAC CEOs decisions - Digital Health Opt-Out decision [SEC=UNCLASSIFIED]
Attachments: OOS817_SA_120917.pdf; OOS817_WA_120917.pdf

Hi s22 ,

Responses have been received from WA and SA (see attached).

As all responses have now been received, are you able to please advise whether this item can now be considered finalised?

Thanks

s22

s22

A/g Director

Health Ministers' Coordination Unit

Portfolio Strategies, Engagement and Coordination Branch

Department of Health

Ph: s22

Email: s22 @health.gov.au

From: s22
Sent: Tuesday, 12 September 2017 9:59 AM**To:** s22**Cc:** s22**Subject:** RE: Draft AHMAC and AHMAC CEOs decisions - Digital Health Opt-Out decision [SEC=UNCLASSIFIED]

Hi s22 – how are you? Have we had anything come through from WA? Could you pls request for the AHMAC Secretariat to follow-up with them? We are expecting SA tomorrow.

Cheers

s22

s22

Director, Legislation

 Digital Health Branch | Health Systems Policy Division

Australian Government Department of Health

T: s22 | E: s22 @health.gov.au

Location: s22

From: s22
Sent: Thursday, 8 June 2017 11:35 AM**To:** s22**Subject:** Draft AHMAC and AHMAC CEOs decisions [SEC=UNCLASSIFIED]

Here they are ☺

s22

A/g Director

Health Ministers' Coordination Unit

Portfolio Strategies, Engagement and Coordination Branch

Department of Health

Ph: s22

Email: s22 [@health.gov.au](mailto:s22@health.gov.au)

THIS DOCUMENT HAS BEEN RELEASED UNDER
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s22

From: s22 @opc.gov.au>
Sent: Wednesday, 13 September 2017 2:25 PM
To: s22
Cc: s22
Subject: My Health Records (National Application) Rules 2017 [DLM=Sensitive:Legal]
Attachments: I17KH158.PDF

This e-mail and/or its attachments have been classified by OPC as Sensitive:Legal

s22
s22
Department of Health
s22 @health.gov.au

Dear s22

My Health Records (National Application) Rules 2017

s42

5 Please note that there is a fee for express or peak period registration of an instrument on the Register. General registration services are covered by an annual fee. Further information on the process and fees for registration is available on the secure lodgement site for the Register at <https://lodge.legislation.gov.au/>. If you do not have a login for the lodgement site, please contact OPC Publications ((02) 6120 1350 or lodge@legislation.gov.au.

6 The OPC number for this matter appears at the top of this letter and in the footer of the instrument and will need to be entered in the lodgement site for the Register.

7 Thank you for your instructions on this matter. We welcome any comments you may have on the quality of the service received. You may direct any feedback to the s22, s22 s22 or s22 @opc.gov.au) or email feedback@opc.gov.au.

Yours sincerely

s22
s22
1s22

[OPCTRIM:PC:BE17/547]

MINUTE TO DEPUTY SECRETARY CORMACK

To: Mark Cormack

MAKING RULES TO IMPLEMENT NATIONAL OPT-OUT FOR THE MY HEALTH RECORD SYSTEM

Purpose

s47C

[REDACTED]

Timing

s47C

[REDACTED]

The Minister had requested that the Rules be submitted following the conclusion of public consultations on secondary use of My Health Record Data. The consultations are nearing completion and have been positive overall. The Department sees no reason to hold off on submitting the Opt-out Rules.

Issues/Sensitivities

The *My Health Records Act 2012* enables the Minister to make rules to implement opt-out participation arrangements nationally, provided he is satisfied that the opt-out model will result in valuable participation and usage.

s47C

[REDACTED]

s47C

[REDACTED]

s47C

[REDACTED]:

- s47C [REDACTED]; and
- s47C [REDACTED].

s47C

[REDACTED]

s47C

Consultation

The Department consulted the My Health Record System Operator (i.e. the Australian Digital Health Agency) in developing the Opt-out Rules, as required by the My Health Records Act.

The Department provided briefings on the proposed Opt-out Rules to the Office of the Australian Information Commissioner, Consumers Health Forum and the Australian Medical Association.

Recommendation

That you:

s47C

Approved / Not approved

- NOTE the conditional agreement to the Opt-out Rules by the Australian Health Ministers' Advisory Council.

Noted

Mark Cormack
/ 11 / 17

Attachments:

Refer to MS17-002661

Contact officer:

s22

Phone:

s22

s42

EA Corro Ref:

463332

TRIM ref:

D17-2645029

s22

From: HMCU
Sent: Friday, 11 August 2017 11:10 AM
To: s22
Cc: HMCU
Subject: AHMAC OOS item 817 - My Health Records Rules: National Opt-out
 [SEC=UNCLASSIFIED]
Attachments: OOS817 - Attachment 2.pdf; OOS817 - My Health Records Rules - National Opt-out.docx; OOS817 - Attachment 1.pdf

Good morning s22

For your information, please find attached the circulated version of AHMAC OOS item 817 - My Health Records Rules: National Opt-out.

Jurisdictional responses are due 1 September 2017.

Kind regards

s22

Health Ministers' Coordination Unit

Portfolio Strategies, Engagement and Coordination Branch
 Health Systems Policy Division

s22

HMCU@health.gov.au

Please note all CHC/AHMAC documents are to be considered as confidential with circulation limited to AHMAC Members and their Departments unless otherwise directed by CHC/AHMAC.

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 BY THE DEPARTMENT OF HEALTH

MINUTE TO DEPUTY SECRETARY CORMACK

To: Mark Cormack

MAKING RULES TO IMPLEMENT NATIONAL OPT-OUT FOR THE MY HEALTH RECORD SYSTEM

Purpose.

To request that you:

- s47C [REDACTED]

Timing

To ensure tabling by 7 December 2017, the Opt-out Rules should be approved by 30 November 2017. This will ensure the disallowance period for the Opt-out Rules ends before national opt-out of the My Health Record system begins, currently expected to occur on 1 May 2018.

The Minister had requested that the Rules be submitted following the conclusion of public consultations on secondary use of My Health Record Data. The consultations are nearing completion and have been positive overall. The Department sees no reason to hold off on submitting the Opt-out Rules.

Issues/Sensitivities

The *My Health Records Act 2012* enables the Minister to make rules to implement opt-out participation arrangements nationally, provided he is satisfied that the opt-out model will result in valuable participation and usage.

Based on the evaluation of the participation trials and the Government decision as part of Budget 2017-18, it is now proposed that the Minister determine such rules.

The My Health Records Act requires the Minister consult with AHMAC and the COAG Health Council before making rules to implement national opt-out participation arrangements. Further, as agreed by health ministers on 7 August 2015, all subordinate digital health legislation must be agreed by AHMAC before it is made.

s47C [REDACTED]

s47C [REDACTED]

Consultation

The Department consulted the My Health Record System Operator (i.e. the Australian Digital Health Agency) in developing the Opt-out Rules, as required by the My Health Records Act.

The Department provided briefings on the proposed Opt-out Rules to the Office of the Australian Information Commissioner, Consumers Health Forum and the Australian Medical Association.

Recommendation

That you:

1. APPROVE the submission MS17-002661 seeking the Minister's approval of the *My Health Records (National Application) Rules 2017* (Opt-out Rules) which implement the opt-out model nationally for the My Health Record system.

Approved / Not approved

2. NOTE the conditional agreement to the Opt-out Rules by the Australian Health Ministers' Advisory Council.

Noted

Mark Cormack

17 / 11 / 17

Attachments:

Refer to MS17-002661

Contact officer: Nicole Jarvis
Phone: (02) 6289 8001
0407 495 847
EA Corro Ref: 463332
TRIM ref: D17-2645029

* CHC papers will
require Sec clearing



Australian Government
Department of Health

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Ministerial Submission – Standard

MS17-002661 Version (1)

Date sent to MO: 24/11/2017

To: Minister Hunt

Subject: MY HEALTH RECORDS RULES: IMPLEMENTING NATIONAL OPT-OUT

Critical date: 30 November 2017, if you would like the disallowance period on the Rules to conclude before opt-out begins in May 2018.

Recommendations:			
1.	Agree to implement the opt-out model nationally, if you are satisfied that the opt-out model results in participation in the My Health Record at a level that provides value for those using the system	1.	Agreed/Not agreed
2.	Sign and date the My Health Records Rules (Attachment A)	3.	Signed/Not signed
3.	Approve the COAG Health Council out of session agenda paper providing the My Health Records Rules for noting (Attachment B)	2.	Approved/Not approved
4.	Note the explanatory statement, including the human rights compatibility statement, to the Rules (Attachment C)	4.	Noted
Signature		Date: 30/11/17	
Comments:			

Contact Officer:	Nicole Jarvis	Assistant Secretary, Digital Health Branch, Health Systems Policy Division	Ph: (02) 6289 8001 Mobile: s22
Clearance Officer:	Glenys Beauchamp	Secretary	Ph: (02) 6289 8400 Mobile: s22

Issues:

1. The *My Health Records Act 2012* empowers you to make My Health Records Rules. In 2015, the My Health Records Act was amended to allow for national opt-out. My Health Record Rules are critical to enact these provisions to implement opt-out nationally, provided you are satisfied the opt-out model results in participation in the My Health Record system at a level that provides value for those using the system.
2. In light of the evaluation of the opt-out trials and the subsequent Government decision to implement opt-out nationally as part of the 2017-18 Budget, it is proposed that you make the My Health Records (National Application) Rules (the Rules).
- 3.

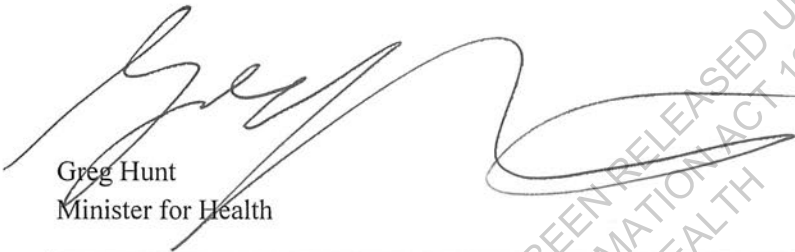
s22



My Health Records (National Application) Rules 2017

I, Greg Hunt, Minister for Health, make the following rules.

Dated *30 NOV* 2017


Greg Hunt
Minister for Health

s22

From: s22
Sent: Friday, 1 December 2017 5:16 PM
To: HMCU
Cc: s22
Subject: For action: CHC out of session - My Health Records Rules: National Opt-out [DLM=For-Official-Use-Only]
Attachments: My Health Records Rules National opt-out - COAG out of session agenda paper.docx; Signed MS17-002661 coverpage.pdf

Hi HMCU,

Please find attached a COAG Health Council (CHC) out of session agenda paper providing the My Health Records Rules for Noting. Minister Hunt signed the Rules and approved this paper yesterday, 30 November 2017 (see attached signed minsub).

Background:

CHC agreed in principle to national opt-out, at the 24 March 2017 meeting. "Ministers agreed to a national opt out model for long term participation arrangements in the My Health Record system." (CHC Communique 24 March 2017)

The Rules have been agreed by AHMAC in accordance with a CHC decision in August 2015 that requires all digital health subordinate legislation to be agreed by AHMAC and noted by CHC.

Action requested:

Can HMCU send this paper to the CHC Secretariat to circulate to CHC members for noting out of session?

Thank you, and please let me know if you need further information.

Kind Regards,

s22

s22

Legislation Section | Digital Innovation & AHMAC Branch | Portfolio Strategies Division
 Australian Government Department of Health
 T: s22 | E s22 @health.gov.au

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[PDR REFERENCE]

BRIEF**February Additional Estimates 2017-18****MY HEALTH RECORDS RULES: IMPLEMENTING NATIONAL OPT-OUT****KEY ISSUE:**

On 30 November 2017 the Minister for Health, made the *My Health Records (National Application) Rules 2017* ("National Opt-out Rules").

KEY POINTS

- The National Opt-Out Rules apply the opt-out model, as set out in the *My Health Records Act 2012*, nationally.
- This has no practical effect until the opportunity to opt-out begins, which will occur on a day to be prescribed by the Minister.
- The Minister will, through an instrument that will be published online, specify a date that Part 3 of the National Opt-out Rules will commence.
- The opt-out period will begin on this date and will end three months later.
- It is anticipated that this date will be around mid-2018 and will be clearly identified to the public.
- If a date is not prescribed by the Minister by 1 September 2018, the National Opt-Out Rules provide that the three month opt-out period will automatically begin on 2 September 2018.
- The National Opt-Out Rules do not change the participation arrangements of other entities such as healthcare provider organisations. These entities must still register if they want to participate in the My Health Record system.
- The National Opt-Out Rules are currently subject to Parliamentary scrutiny, with the disallowance period ending after 26 March 2018.

BUDGET ALLOCATION

N/A

SENSITIVITIES: NIL

Subject Matter Lead:	Nicole Jarvis Assistant Secretary Digital Innovation and AHMAC Branch Portfolio Strategies Division	(02) 6289 8001	s22
Cleared by:	Caroline Edwards Deputy Secretary Health Systems Policy and Primary Care Group	(02) 6289 1235	s22
Date Brief Created: 24 January 2018		Last Updated:	

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[PDR REFERENCE]

BRIEF**February Additional Estimates 2017-18****BACKGROUND**

- The participation trials of the My Health Record system (including opt-out arrangements) were undertaken in 2016 to inform future strategies for increasing uptake and meaningful use of the My Health Record system.
- The evaluation of the trials showed a high level of support by healthcare providers and individuals for the automatic creation of My Health Records, and found that individuals felt the benefits far outweighed the possibility of risks to privacy, confidentiality and security.
- CHC agreed in principle to national opt-out on 24 March 2017.
- In May 2017 the Commonwealth Government announced that the My Health Record will transition to national opt-out arrangements in 2018.
- The National Opt-Out Rules were agreed by AHMAC in accordance with a CHC decision in August 2015 that requires all digital health subordinate legislation to be agreed by AHMAC and noted by CHC.
- The National Opt-out Rules enable the My Health Record system to operate on an opt-out basis for consumer participation by:
 - applying the opt-out model to all consumers in Australia;
 - specifying when a consumer can opt-out as part of the national roll-out;
 - specifying when a consumer can opt-out after the national roll-out; and
 - specifying when, under the opt-out model, a consumer can choose not to have Medicare information included in their My Health Record.

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BY THE DEPARTMENT OF HEALTH

Subject Matter Lead:	Nicole Jarvis Assistant Secretary Digital Innovation and AHMAC Branch Portfolio Strategies Division	(02) 6289 8001	s22
Cleared by:	Caroline Edwards Deputy Secretary Health Systems Policy and Primary Care Group	(02) 6289 1235	s22
Date Brief Created: 24 January 2018		Last Updated:	

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Department of Health

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Ministerial Submission – Standard
MS18-000376 Version (1)

MPF to complete Date sent to MO:<dd/mm/yy>

To: Minister Hunt

Subject: MY HEALTH RECORD: COMMENCEMENT OF NATIONAL OPT-OUT

Critical date: 11 April 2018, to allow the instrument that specifies the opt-out commencement date to be published in time for communications material to be prepared and disseminated before the opt-out period begins.

Recommendation/s:			
1.	s47C	1.	Agreed/Not agreed
2.	s47C	2.	Signed/Not signed
3.	Agree that key delivery partners be notified of the opt-out date ahead of registration of the instrument	3.	Agreed/Not agreed
Signature		Date: / /	
Comments:			
Contact Officer:	Nicole Jarvis	Assistant Secretary, International, AHMAC and Digital Health Branch, Portfolio Strategies Division	Ph: (02) 6289 8001 Mobile: s22
Clearance Officer:	Caroline Edwards	Deputy Secretary	Ph: (02) 6289 1235 Mobile: s22

Issues:

- The *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) implement opt-out participation for the My Health Record system nationally.
- Part 3 of those Rules provides that a consumer can elect not to be registered for a My Health Record (i.e. they can opt-out). Part 3 and, in effect, the opportunity to opt-out, begins on a date to be specified by you. If you decided not to specify a date the opt-out period would commence automatically on 2 September 2018.
- The draft My Health Records (National Application) Commencement Instrument is provided for your approval (**Attachment A**). This instrument declares to the public that Part 3 of the National Opt-out Rules will commence on 16 July 2018.
- s47C

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5. s47C
6. The instrument is a notifiable instrument which means that it must be registered on the Federal Register of Legislation but will not be tabled in Parliament and is not disallowable.
7. In order to support key delivery partners working with healthcare professionals and those preparing to commence consumer communications, the Agency would like to provide early advice of the opt-out date to Primary Health Networks and peak organisations.

Background:

The *My Health Records Act 2012* enables you to make rules to implement opt-out participation arrangements nationally. You made the National Opt-Out Rules on 30 November 2017.

The National Opt-Out Rules are currently subject to Parliamentary scrutiny, with the disallowance period ending after 26 March 2018.

Readiness

The opt-out period is predicated on establishing an operational readiness that considers:

- providing the means by which all consumers can opt-out;
- establishment of effective consumer communication;
- technology, including cyber security, enablement;
- operational readiness, including establishment of the contact centre services;
- provider awareness to ensure the education of consumers; and
- achievement of minimum levels of high value content within the My Health Record system.

s47C

(s22

Following a review of these criteria and after consultation, the Agency has recommended that the opt-out period commence on 16 July 2018. The Agency is confident that this date provides sufficient time to ensure system readiness is achieved for the commencement of the opt-out period.

The opt-out period will last for three months and end on 15 October 2018. The opt-out window will be followed by a reconciliation period of four weeks for quality and assurance checks. My Health Records will be created on 13 November 2018 for those who have not chosen to opt-out.

In the event that the opt-out date must be changed, you will be required to revoke this instrument and make a new one, which will specify the new date.

If the date is not prescribed by you by 1 September 2018, the National Opt-Out Rules provide that the three month opt-out period will automatically begin on 2 September 2018.

Communications

The Agency has developed a comprehensive communications strategy for the implementation of opt-out, which will see:

- Information in every general practice in Australia
- Communications to consumers through other health and non-health channels
- National and local partnerships with Medicare, Primary Health Networks, corporate, peak and consumer organisations, as well as through direct Australian Digital Health Agency activities.

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- A range of channels utilised including, traditional and social media, public relations, and events.
- Hard-to-reach audiences specifically supported
- Information available in multiple languages
- Thousands of face-to-face briefings at community events around the country
- Distribution of communications material through consumer peak organisations
- Provision of information at the point of care and other community places such as doctors' surgeries, hospitals, libraries and post offices.

This will ensure all Australians are informed about the opt-out period and specifically how to access the opt-out portal.

s47C

Framework for Secondary Use

The framework for the secondary use of My Health Record data will be released publicly prior to the commencement of the opt-out period.

Attachments:

A: My Health Records (National Application) Commencement Instrument 2018

s47C

Relevance to Election Commitments / Budget Measures:

This instrument will implement opt-out as announced in the 2017-18 Budget Measure A *My Health Record for Every Australian*.

Sensitivities:

The setting of this commencement date is likely to attract broad public interest. The Australian Digital Health Agency has prepared public communications in preparation for the registration of the notifiable instrument on the Federal Register of Legislation.

Consultations:

On 13 March 2018 the Agency met with you to discuss My Health Record system readiness for opt-out. The Agency was consulted on the preparation of this Minute.



Australian Government
Department of Health

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Ministerial Submission – Standard
MS17-002661 Version (1)
Date sent to MO: 24/11/2017

To: Minister Hunt

Subject: MY HEALTH RECORDS RULES: IMPLEMENTING NATIONAL OPT-OUT

Critical date: 30 November 2017, if you would like the disallowance period on the Rules to conclude before opt-out begins in May 2018.

Recommendations:			
1.	s47C	1.	Agreed/Not agreed
2.	Sign and date the My Health Records Rules (Attachment A)	3.	Signed/Not signed
3.	s47C	2.	Approved/Not approved
4.	Note the explanatory statement, including the human rights compatibility statement, to the Rules (Attachment C)	4.	Noted
Signature		Date: / /	
Comments:			
Contact Officer:	Nicole Jarvis	Assistant Secretary, Digital Health Branch, Health Systems Policy Division	Ph: (02) 6289 8001 Mobile: s22
Clearance Officer:	Glenys Beauchamp	Secretary	Ph: (02) 6289 8400 Mobile: s22

Issues:

- The *My Health Records Act 2012* empowers you to make My Health Records Rules. In 2015, the My Health Records Act was amended to allow for national opt-out. My Health Record Rules are critical to enact these provisions to implement opt-out nationally, provided you are satisfied the opt-out model results in participation in the My Health Record system at a level that provides value for those using the system.
- In light of the evaluation of the opt-out trials and the subsequent Government decision to implement opt-out nationally as part of the 2017-18 Budget, it is proposed that you make the My Health Records (National Application) Rules (the Rules).
- s47C

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There are three different groups of individuals covered by the Rule – those that are eligible at the time of national roll-out, those that will become eligible after roll-out (such as newborns and immigrants), and those who choose to apply to register (such as if they opted out or cancelled their record and changed their mind). The Rules specify:

- transition to opt-out: the system will operate on an opt-out basis once the Rules have been registered (i.e. published on the Federal Register of Legislation);
- the opt-out period: from a date specified by you, eligible individuals (i.e. those with an Individual Healthcare Identifier at that time) will have three months in which to notify the System Operator if they want to opt-out, otherwise they will be registered;
- ongoing opt-out arrangements: individuals who become eligible once the opt-out period has begun (i.e. those who enrol in Medicare or apply for an Individual Healthcare Identifier) will need to notify the System Operator if they want to opt-out at the time they enrol in Medicare or apply for an Individual Healthcare Identifier; and
- how Medicare information can be excluded: individuals who are registered because they didn't opt-out will have from when they are registered until their My Health Record is first accessed by a health care provider to notify the System Operator if they do not want their Medicare information included, while individuals who apply to register (opt-in) will be able to notify this decision at the time they apply.

4. s47C
5. s47C
6. s47C
7. s47C
8. s47C

Notifiable instrument

9. The national opt-out period will begin on a date to be specified by you in a notifiable instrument.
10. The Department will prepare this instrument for your approval in 2018 once the Department has reasonable certainty that the Australian Digital Health Agency can support the proposed timing for national opt-out.
11. Subject to your future approval of this instrument, it is proposed that the national opt-out period begin from 1 May 2018.

Framework for secondary use of My Health Record system data

12. In developing the secondary use framework, the Department will need to decide whether to enable consumers to opt-out of having their information used for certain types of secondary use, and whether express consent will be required for particular uses. These controls are still to be determined and are not in scope for the purpose of these Rules. If legislative change is required to implement these controls, this can be undertaken during implementation of the secondary use framework.

Background:

The *My Health Records Act 2012* was amended in 2015 to enable you to undertake trials of an opt-out model, and to make My Health Records Rules to implement opt-out arrangements nationally.

Attachments:

- A: My Health Records (National Application) Rules
- B: COAG Health Council out of session agenda paper
- C: Explanatory statement, including human rights compatibility statement
- D: MS17-001437

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Sensitivities:

The Rules have significant privacy implications and are likely to attract public interest. However, the changes to the primary legislation in 2015 to enable opt-out were consulted on and amendments were passed by Parliament. Further, the opt-out trials did not generate negative media attention. The Office of the Australian Information Commissioner was briefed on the Rules and did not raise any concerns.

In response to MS17-001437 (**Attachment D**) you agreed to consider the Rules following the public consultation on the My Health Record secondary use framework. Consultation ended on 17 November 2017. Consistent with the weekly updates to your office, the themes that have consistently arisen include:

- consent – dynamic consent is preferred, with specific consent required for clinical trials. The Department is meeting with the Australian Digital Health Agency to progress system design to meet this community preference;
- purpose – commercialisation and balancing public good. The framework will identify principles to guide the decision making of the governance body;
- defining “health” – preference for broadest possible definition, such as to include wellbeing and social services;
- consumer trust in the governance arrangements – preference to be independent of the system operator with the data custodian residing in an organisation with the skills in management of health data;
- compliance – need for audit and legal penalties for breaches. Existing legal penalties in the My Health Records Act were considered appropriate;
- cost – cost recovery model is needed. The Department will review existing cost recovery mechanisms operating in the health sector, for example the Australian Institute of Health and Welfare; and
- data – quality, security and governance, all of which are being addressed in the move to opt-out.

The consultations were positive and constructive and the suggestions presented by attendees were largely sensible and practical. s47C

A briefing with your office is being arranged for mid December to outline the detailed results of the consultation process. The Consultation Report is due to the Department on 22 December 2017. s47C

Relevance to Election Commitments / Budget Measures:

The Rules are critical to implementing the 2017-18 Budget measure *A My Health Record for Every Australian*.

Consultations:

The Rules were drafted by the Office of Parliamentary Counsel, in consultation with the Department’s Legal Division.

s47C

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The Department has provided briefings on the proposed Rules to the Office of the Australian Information Commissioner, Consumers Health Forum and the Australian Medical Association.

The Department will offer crossbench briefings on the Rules.

Regulatory Burden Implications and/or Deregulation Opportunities:

The regulatory impacts of the proposed Rules were assessed as part of the Health Legislation Amendment (eHealth) Bill 2015 which established the ability to implement opt-out nationally, and of the Government decision to transition to an opt-out My Health Record system. Implementing an opt-out system has a deregulatory impact. The regulation impact statements are available at ris.pmc.gov.au/2015/07/21/proposed-changes-personally-controlled-electronic-health-record-system, and ris.pmc.gov.au/2017/06/01/changes-my-health-record-system, respectively.

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- s42 [REDACTED]
- [REDACTED]
- [REDACTED]

A plain English explanation of the Rules is provided at **Attachment 2**.

The Act provides that before making My Health Records Rules, the Minister must consult with Australian Health Ministers' Advisory Council (AHMAC) and the System Operator (i.e. the Australian Digital Health Agency). The System Operator was given the opportunity to review and provide feedback on an earlier draft of the Rules. Changes were subsequently made to the Rules, in consultation with the System Operator, and agreed by AHMAC.

The Act further provides that before making rules to implement opt-out nationally, the Minister must consult the Ministerial Council.

Next steps

The Rules will be made by the Commonwealth Health Minister and registered on the Federal Register of Legislation, taking legal effect the following day. The Rules will then be tabled in Parliament with 15 sitting days, during which it may be disallowed.

Background

Due to the low numbers of people choosing to register for a My Health Record system, the Act was amended in 2015 to allow for an opt-out model of participation to be implemented. Specifically, Schedule 1 to the Act allows the Minister to make rules to undertake trials of an opt-out model, and to implement opt-out nationally.

Results of consultations with jurisdictions / Implications for other ministerial councils

The Rules have been agreed by AHMAC.

Regulation Impact Assessment

A Regulation Impact Statement (RIS) was prepared for the *Health Legislation Amendment (eHealth) Bill 2015*, which established the ability to implement opt-out nationally: ris.pmc.gov.au/2015/07/21/proposed-changes-personally-controlled-electronic-health-record-system), and a RIS was prepared as part of the Government decision to transition the My Health Record system to an opt-out system: ris.pmc.gov.au/2017/06/01/changes-my-health-record-system. As such, a RIS is not required for the making of these Rules.

Attachments

- Attachment 1: *My Health Records (National Application) Rules 2017*
- Attachment 2: Plain English explanation of the Rules

EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

My Health Records Act 2012

My Health Records (National Application) Rules 2017

The *My Health Records Act 2012* (the Act) enabled the establishment of the My Health Record system (formerly referred to as the personally controlled electronic health record or PCEHR system). The My Health Record system allows people and their healthcare providers to access their key health information online where and when they need it. A My Health Record is an electronic summary of a person's health records.

The My Health Record system currently operates on an opt-in basis which means that a person needs to register in order to get a My Health Record.

The *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) provide that an opt-out model will be implemented so that people no longer need to register; instead a My Health Record will be created for every eligible person unless they choose not to have one (i.e. opt-out).

Background

Due to the low numbers of people choosing to register for a My Health Record, the Act was amended in 2015 to allow for an opt-out model of participation to be implemented. Specifically, Schedule 1 to the Act allows the Minister to make rules to undertake trials of an opt-out model, and to implement opt-out nationally.

Participation trials (including opt-out arrangements) were undertaken in 2016 to inform future strategies for increasing uptake and meaningful use of the My Health Record system. An evaluation of the trials showed a high level of support by healthcare providers and individuals for the automatic creation of My Health Records, and found that individuals felt the benefits far outweighed risks to privacy, confidentiality and security.

In May 2017 the Government announced that the My Health Record will transition to national opt-out participation arrangements during 2018.

National Opt-out Rules

The National Opt-out Rules are made under subclause 2(1), and subparagraphs 5(2)(c)(i) and 13(2)(c)(i), of Schedule 1 to the Act.

The purpose of the National Opt-out Rules is to apply the opt-out model, as set out in Part 2 of Schedule 1 to the Act, nationally. The National Opt-out Rules specify:

- the class of people who will have a My Health Record created unless they opt-out;
- when a person will need to elect if they want to opt-out (i.e. do not want a My Health Record created); and
- when a person who has not opted out can elect not to have health information which is held by the Chief Executive Medicare disclosed to the System Operator (i.e. included in their My Health Record).

The National Opt-out Rules do not change the participation arrangements of other entities such as healthcare provider organisations. These entities must still register if they want to participate in the My Health Record system.

Detail of the National Opt-out Rules is set out in the Attachment.

Subsection 109(2) of the Act, together with regulation 5.1.1 of the *My Health Records Regulation 2012*, provides that before making My Health Records Rules, the Minister must consult with Australian Health Ministers' Advisory Council (AHMAC) and the System Operator (i.e. the Australian Digital Health Agency). Consultation occurred in July and August 2017 and the System Operator and AHMAC supported the making of the proposed National Opt-out Rules.

Subclause 2(3) of Schedule 1 to the Act further provides that before making the National Opt-out Rules, the Minister must consult the Council of Australian Governments Health Council (CHC). CHC noted the making of the National Opt-out Rules in December 2017.

Public consultation on the concept of an opt-out My Health Record system has been undertaken:

- during July to September 2014 following the Personally Controlled Electronic Health Record Review, as reported in the *Report to the Commonwealth Department of Health on the public consultation into the implementation of the recommendations of the Review of the Personally Controlled Electronic Health Record*; and
- in May and June 2015 upon the release of the *Electronic Health Records and Healthcare Identifiers: Legislation Discussion Paper*.

Consumers support the concept of an opt-out model for the My Health Record system.

The National Opt-out Rules, with the exception of Part 3, commence on the day after registration on the Federal Register of Legislation. Part 3 will commence on a day to be specified by the Minister.

Regulation Impact Statements were prepared for the *Health Legislation Amendment (eHealth) Bill 2015*, which established the ability to implement opt-out nationally (published at ris.pmc.gov.au/2015/07/21/proposed-changes-personally-controlled-electronic-health-record-system), and as part of the Government decision to transition the My Health Record system to an opt-out system (published at ris.pmc.gov.au/2017/06/01/changes-my-health-record-system).

The National Opt-out Rules are a legislative instrument and are subject to the *Legislation Act 2003*.

ATTACHMENT**Details of the *My Health Records (National Application) Rules 2017*****PART 1—PRELIMINARY****1 Name of Rules**

Rule 1 provides that the title of the Rules is the *My Health Records (National Application) Rules 2017*. For the purposes of this document, the Rules are referred to as the National Opt-out Rules.

2 Commencement

Rule 2 provides for the commencement of the National Opt-out Rules.

With the exception of Part 3, which provides for the period in which people can choose to opt-out, the National Opt-out Rules take effect on the day after the Rules are registered on the Federal Register of Legislation. Of particular importance is the commencement of Part 2 which provides authority for the System Operator to collect information about people who are not registered in the My Health Record system as part of preparation for the implementation of opt-out.

Part 3 will take effect on a day that specified by the Minister in a notifiable instrument or if a day is not specified, 9 months after the Rules are registered on the Federal Register of Legislation. This approach provides the flexibility necessary as the exact timing for implementing opt-out is dependent on technological, communication and operational activities that need to be developed, planned and undertaken in parallel. It also provides certainty that Part 3 will take effect within a 9 month window. It is likely that the day specified for Part 3 to take effect will be in the first half of 2018. The opt-out period referred to in Rule 6 will begin upon the commencement of Part 3 and ends three months later.

3 Authority

Rule 3 identifies that the legal authority for making the National Opt-out Rules is provided by the *My Health Records Act 2012*.

4 Definitions

Rule 4 provides definitions of several terms used in the National Opt-out Rules. Of particular importance is the term ***opt-out model*** which is defined by Part 2 of the Rules. Other terms used in the Rules, such as ***healthcare recipient***, are defined by the Act.

PART 2—APPLYING OPT-OUT MODEL TO ALL HEALTHCARE RECIPIENTS**5 Opt-out model applies to all healthcare recipients in Australia**

Rule 5 applies the opt-out model to all individuals in Australia. This means that Part 2 of Schedule 1 to the Act will begin operating and, in some cases replace existing provisions of the Act, on the day after the Rules are registered on the Federal Register of Legislation. A person cannot be registered unless they have been given an opportunity to opt out or have applied directly to register.

The Rules do not apply the opt-out model ‘afresh’ to individuals who have already been subject to opt-out arrangements. This means it does not apply to:

- people who were in the opt-out trial areas and did not opt-out, and who have since cancelled their My Health Record; or
- people who were in the opt-out trial areas and chose to opt-out.

The Rules do apply to people who previously applied for a My Health Record and have since cancelled their My Health Record. However, when deciding to register individuals as part of these opt-out arrangements, the System Operator will take cancelled My Health Records into account and decide not to register these people.

Rule 5 triggers the authority for the System Operator to collect information about people who are not registered in the My Health Record system as part of preparation for the implementation of opt-out (item 1 of subclause 8(1) of Schedule 1 to the Act provides this authority).

PART 3—REGISTERING HEALTHCARE RECIPIENTS

6 When healthcare recipients may elect not to be registered

People are entitled to choose to opt-out if they do not want a My Health Record (clause 5 of Schedule 1 to the Act refers), and the System Operator cannot register a person unless they have been given the opportunity to opt-out (clause 3 of Schedule 1 of the Act refers). In order to opt-out, a person must give notice to the System Operator in a particular manner. In practice, a person will be able to give this notice in a number of ways and at a time or period specified by the Minister, depending on their circumstances.

Rule 6 provides the arrangements by which a person can opt-out. Rule 6 will commence on a date to be specified by the Minister (this date will not be before March 2018). If the Minister does not specify a date, Rule 6 will commence 9 months after the National Opt-out Rules are registered on the Federal Register of Legislation.

If a person already has an Individual Healthcare Identifier (IHI)¹ they will be provided the opportunity to opt-out during the opt-out period. People who do not have an IHI at the commencement of the opt-out period will be provided the opportunity to opt-out prior to being assigned an IHI.

A person who is enrolled in Medicare² or has a Department of Veterans' Affairs (DVA) file number is automatically assigned an IHI. People who are not enrolled in Medicare or DVA but receive healthcare in Australia, such as international tourists, or people who want a pseudonymous IHI, can apply directly to the Healthcare Identifiers Service for an IHI.

National roll-out (subrules 6(2) and (3) refer)

Everyone who already has an IHI will be given the opportunity to opt-out during an opt-out period, and anyone who does not opt-out will have a My Health Record created for them.³

¹ Healthcare identifiers have been used since June 2010 and were established by the *Healthcare Identifiers Act 2010*. Healthcare identifiers are used for consistently identifying individuals and healthcare providers to, among other things, ensure patients are properly matched with their health records, and support the communication of health information between healthcare providers. The Chief Executive Medicare is currently responsible for operating the Healthcare Identifiers Service.

² In general, any person who resides in Australia is eligible to enrol in Medicare if they hold an Australian or New Zealand citizenship, have been issued with a permanent visa or have applied for a permanent visa. For detailed Medicare eligibility criteria, go to the [Department of Human Services website](#).

³ There are some exceptions. Despite having an IHI, not everyone will be included in this process – that is, they will not be given the opportunity to opt-out and will not be registered. For example, the System Operator will

Subrule 6(2) provides that the class of people specified in paragraph 6(3)(a) – those who have an IHI immediately before this Part commences (i.e. the date to be specified by the Minister) – must give their opt-out notice during the period specified in paragraph 6(3)(b) – the period commencing on the day this Part commences (i.e. the date to be specified by the Minister) and ending three months later (referred to as the opt-out period).

People who are part of the national roll-out will have three months in which to opt-out. This is considered a reasonable amount of time for people to receive information about the creation of My Health Records and take any action necessary.

If a person has been given the opportunity to opt-out, and they don't want to wait until the end of the opt-out period to get a My Health Record, they may choose to register. A My Health Record will be created for them immediately.

Ongoing (subrules 6(4) and (5) refer)

Anyone who gets an IHI after the beginning of the national roll-out will be given the opportunity to opt-out when they apply to enrol in Medicare or get an IHI, and anyone who does not opt-out will have a My Health Record created for them.⁴

Subrule 6(4) provides that the class of people specified in paragraph 6(5)(a) – those who do not have an IHI immediately before this Part commences (i.e. the date to be specified by the Minister) – must give their opt-out notice upon the event specified in paragraph 6(5)(b) – when they apply for something that results in them being assigned an IHI. In practice, a person is assigned an IHI when they apply to enrol in Medicare⁵ or create an IHI⁶.

Unlike national roll-out, the ongoing process does not provide individuals three months in which to opt-out; instead it provides a single point in time. This is because the ongoing process involves an individual taking an action to interact with a relevant Government service (i.e. enrolling in Medicare to requesting an IHI), and this interaction can be leveraged to ensure the person is directly informed about the My Health Record system and the need to opt-out during that interaction if they don't want a My Health Record created.

If an individual has parental or legal authority for another person (such as if they are a parent or guardian), or is found otherwise appropriate to act on behalf of another person, the individual may opt-out that other person. This capability will be available as part of the national roll-out and the ongoing process. Individuals aged 14 years and older will be able to opt themselves out. Individuals younger than 14 years will only be able to opt themselves out if they are able to provide evidence of their capacity to manage their My Health Record.

If a person does not opt-out at the time or during the period specified, the person can still cancel or suspend their registration at any time after their My Health Record is created (under subsection 51(1) of the Act). Conversely, if a person opts out, they may subsequently register for a My Health Record at any time (under clause 6 of Schedule 1 to the Act).

not register any person who previously had a My Health Record and cancelled it, who were part of the opt-out trials and opted out, who has a pseudonymous IHI, or whose registration may compromise the security or integrity of the system.

⁴ The System Operator will not register any person whose registration may compromise the security or integrity of the system.

⁵ The *Medicare enrolment application* form is available on the [Department of Human Services website](#). The form must be completed and either submitted in person at a Medicare service centre or posted to the Department of Human Services.

⁶ The *Healthcare Identifiers Service Application to create or update an Individual Healthcare identifier* form is available on the [Department of Human Services website](#). The form must be completed and either submitted in person at a Medicare service centre or posted to the Department of Human Services.

PART 4—HANDLING HEALTH INFORMATION FOR THE PURPOSES OF A HEALTHCARE RECIPIENT’S MY HEALTH RECORD

7 When healthcare recipients may elect not to have certain health information disclosed to System Operator

The Chief Executive Medicare holds the following health information (referred to as Medicare information) about individuals which may, at his or her discretion, be provided to the My Health Record System Operator to include in an individual’s My Health Record (clause 12 of Schedule 1 to the Act):

- Medicare Benefits Schedule claims information;
- Pharmaceutical Benefits Scheme claims information;
- information about organ and/or tissue donation decisions recorded by the Australian Organ Donor Register; and
- information about immunisations recorded by the Australian Immunisation Register.

People are entitled to choose not to include Medicare information in their My Health Record (clause 13 of Schedule 1 to the Act refers).

In order to choose not to include Medicare information in their My Health Record, a person must give notice to the System Operator at a particular time and in a particular manner.

Rule 7 provides the arrangements by which a person can choose not to include their Medicare information in their My Health Record, whether they are registered because they did not opt-out, or because they applied to register. Rule 7 will commence on the day after the National Opt-out Rules are registered on the Federal Register of Legislation.

The manner for choosing not to include Medicare information will be offered in one of two ways, depending on how a person has been registered for a My Health Record.

People who apply to register (subrules 7(2) and (3) refer)

Under an opt-out model, people can still choose to register at any time (clause 6 of Schedule 1 to the Act). This ensures that people who previously had a My Health Record and cancelled it, or who have opted out, can subsequently change their mind and get a My Health Record.

When a person applies to register⁷, they will be given the opportunity to choose not to include their Medicare information in their My Health Record.

Subrule 7(2) provides that the class of people specified in paragraph 7(3)(a) – people who, from the day after the National Opt-out Rules have been registered on the Federal Register of Legislation, have been registered – must give notice not to include their Medicare information upon the event specified in paragraph 7(3)(b) – when they apply to register for a My Health Record.

⁷ A person can apply to register online at the [My Health Record website](#), in person at a Medicare service centre, by phone on 1800 723 471, or in writing by completing the *Application to register for a My Health Record* form and sending it to the My Health Record System Operator.

People who are registered because they didn't opt-out (subrules 7(4) and (5) refer)

When a person does not opt-out and a My Health Record is created for them, they will be able to choose whether to include Medicare information in their My Health Record.

Subrule 7(4) provides that the class of people specified in paragraph 7(5)(a) – people who, from when Part 3 commences (i.e. the date to be specified by the Minister), have been registered because they didn't opt-out – must give notice not to include their Medicare information within the period specified in paragraph 7(3)(b) – from when they are registered until their My Health Record is first accessed.

It is important to understand that a person's Medicare information will, by default, automatically be included in the person's My Health Record unless the person has given notice not to include it. The transfer process by which Medicare information will be included in a My Health Record is triggered the first time someone accesses a My Health Record – either the person or their healthcare provider.

- If the person is the first to access their My Health Record they will, before the inclusion of any Medicare information, be guided through the various settings associated with the privacy of their My Health Record. This will be the opportunity to notify if they do not want their Medicare information included.
- If the person's healthcare provider organisation is the first to access a person's My Health Record, the Medicare information will be included in the My Health Record. This is because the transfer process has been triggered and no notice has been provided by the person not to include their Medicare information.

A person can change their mind at any time about whether or not to include Medicare information in their My Health Record. It is important to understand that if a person did not initially give notice not to include their Medicare information, and it has been included in their My Health Record, a subsequent decision not to include this information will only affect new information and will not affect the information already in their My Health Record. The person may choose to remove any Medicare information from their My Health Record.

Regardless of how people are registered for a My Health Record, if an individual has parental or legal authority for another person (such as if they are a parent or guardian), the individual may choose not to include that other person's Medicare information in that other person's My Health Record.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

My Health Records (National Application) Rules 2017

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The Legislative Instrument is made under subclause 2(1), and subparagraphs 5(2)(c)(i) and 13(2)(c)(i), of Schedule 1 to the *My Health Records Act 2012* (the Act).

The purpose of the *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) is to apply the opt-out model, as set out in Part 2 of Schedule 1 to the Act, to individuals nationally. This means that the My Health Record System Operator will create a My Health Record for all individuals unless they choose not to have one.

The National Opt-out Rules specify:

- the class of people who will have a My Health Record created unless they opt-out – in this case, everyone who has a healthcare identifier;
- when a person will need to elect if they want to opt-out (i.e. do not want a My Health Record created); and
- when a person who has not opted out can elect not to have health information which is held by the Chief Executive Medicare disclosed to the System Operator (i.e. included in their My Health Record).

The National Opt-out Rules do not change the participation arrangements of other entities such as healthcare provider organisations. These entities must still register if they want to participate in the My Health Record system.

Human rights implications

The Legislative Instrument engages the following human rights and freedoms:

Right to health

Article 12(1) of the *International Covenant on Economic, Social and Cultural Rights* provides for the right to the enjoyment of the highest attainable standard of physical and mental health.

The My Health Record system promotes the right to health by facilitating and improving the sharing of health information between treating healthcare providers, leading to quicker and safer treatment decisions and reducing repetition of information for patients and duplication of tests. Individuals are provided ready access to their own information, empowering them to make informed decisions about their healthcare.

The current opt-in participation arrangements have not effectively encouraged use of My Health Records by individuals and their healthcare providers, and are creating a barrier to achieving the full benefits of the system for individuals.

Participation trials (including opt-out arrangements) were undertaken in 2016 to inform future strategies for increasing uptake and meaningful use of the My Health Record system. An evaluation of the trials showed a high level of support by healthcare providers and individuals for the automatic creation of My Health Records, and found that individuals felt the benefits far outweighed the possibility of risks to privacy, confidentiality and security. As a result, the Government decided to implement the My Health Record system as an opt-out system for individuals.

The Legislative Instrument enables opt-out participation arrangements for every eligible person across Australia. Increased registration, with the accompanying ability for treating healthcare providers to appropriately share health information for treatment purposes, will help improve the physical and mental health of registered individuals. This will increase uptake and meaningful use of the My Health Record system with the aim of achieving a greater standard of physical and mental health for all Australians.

Protection of privacy and reputation

Article 17 of the *International Covenant on Civil and Political Rights* prohibits unlawful or arbitrary interference with a person's privacy and unlawful attacks on a person's reputation. This right is also reflected in Article 22 of the *Convention on the Rights of Persons with Disabilities* and Article 16 of the *Convention on the Rights of the Child*.

The right to privacy encompasses respect for informational privacy, including the right to respect the storing, use and sharing of private information and the right to control the dissemination of private information. The Legislative Instrument engages the right to privacy by prescribing the class of people to participate in an opt-out model of the My Health Record system, unless they opt-out.

The Legislative Instrument and the Act together counterbalance any limitation of the right to privacy by providing an opportunity for every individual (or their representative) across Australia to opt-out of registration and to ensure that a My Health Record is not created for them. Individuals who opt-out may later apply for registration, should they change their mind. Alternatively, individuals who do not opt-out and are registered are able to take advantage of a wide range of privacy protections as outlined below.

As part of the roll-out of opt-out participation arrangements, the Legislative Instrument allows a reasonable period of time (three months) for individuals to consider the benefits of the My Health Record system and their own preferences regarding their privacy and healthcare before making an informed decision as to whether they would like to opt-out of registration and having a My Health Record created. In future, as new individuals become eligible, the opportunity to opt-out will be made available as part of the process for enrolling in Medicare, and individuals would be able to learn about the My Health Record system and decide whether they would like to opt-out in advance of enrolling in Medicare.

Under the Act, individuals who are registered may limit and restrict access to their My Health Record with control settings and may cancel or suspend their registration, should they so wish, as described below.

Individuals need to be able to make informed decisions about the My Health Record system. Individuals will be made aware of the national opt-out arrangements, how their personal information will be handled, and how to opt-out or adjust privacy control settings, so they can make an informed decision. Comprehensive information and communication activities are being planned to ensure all affected individuals, including parents, guardians and carers, are

aware of the opt-out arrangements, what they need to do to participate, how to adjust privacy controls associated with their My Health Record, or opt-out if they choose.

The Legislative Instrument also ensures that individuals who do not opt-out of registration have the opportunity to elect not to have any of their health information held by the Chief Executive Medicare made available to the System Operator for inclusion in their My Health Record. Individuals who initially elect not to have their Medicare health information included in their My Health Record may later have such information included, should they change their mind.

Strong privacy safeguards are in place. People who are registered under opt-out arrangements will retain the same privacy protections as those previously registered under opt-in arrangements. These protections include the ability to do the following, including for children and persons with disabilities:

- set access controls restricting access to their My Health Record entirely or restricting access to certain information in their My Health Record;
- request that their healthcare provider not upload certain information or documents to their My Health Record, in which case the healthcare provider will be required not to upload that information or those documents;
- request that their Medicare data not be included in their My Health Record, in which case the Chief Executive Medicare will be required to not make the data available to the System Operator;
- monitor activity in relation to their My Health Record using the audit log or via electronic messages alerting them that someone has accessed their My Health Record;
- effectively remove documents from their My Health Record;
- make a complaint if they consider there has been a breach of privacy; and
- cancel their registration (that is, cancel their My Health Record).

Increased use of the system under opt-out arrangements is a privacy-positive outcome as it will help reduce the use of paper records, which pose significant privacy risks. For example, where a patient is receiving treatment in a hospital's emergency department for a chronic illness, the hospital may request from the patient's regular doctor information about the patient's clinical history which is likely to be faxed to the hospital. The fax might remain unattended on the fax machine for an extended period of time before being placed into the patient's file, or the information may be sent to the wrong fax number. Either of these things could lead to an interference with the patient's privacy should a third party read the unattended fax or incorrectly receive the fax. In contrast, under the My Health Record system, the patient's Shared Health Summary would be securely available only to those people authorised to see it.

There are other similar scenarios where an increase in the level of use of the My Health Record system, as will occur under opt-out arrangements, is likely to lead to a reduction in privacy breaches associated with paper-based records.

Conclusion

The Legislative Instrument is compatible with human rights because it advances the right to health. Any limitation of the right to privacy is proportionate, necessary and reasonable to

achieving improved healthcare for Australians. Increased use of the My Health Record system, which will occur as a result of opt-out arrangements, will result in a number of privacy positives compared to use of paper-based records.

The Hon Greg Hunt MP

Minister for Health

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THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH

From: s22
Sent: Tuesday, 25 July 2017 2:23 PM
To: s22
Cc: s22
Subject: RE: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Hi s22

s42

Please contact me if you wish to discuss.

Regards,

s22
Lawyer
Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
s22

PO Box 9848, Canberra ACT 2601, Australia

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The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Tuesday, 11 July 2017 2:33 PM
To: s22
Cc: s22
Subject: RE: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Thanks Leanne
 I really appreciate your quick advice.

s22

s22
 A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
 Australian Government Department of Health
 T: s22 | E: s22 @health.gov.au
 s22

From: s22
Sent: Tuesday, 11 July 2017 2:29 PM
To: s22
Cc: s22
Subject: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Hi s22

s42

Please call me if you wish to discuss. Otherwise I will be in contact with you regarding your second question in your email below of 6 July 2017.

Regards,

s22
 Lawyer
 Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
 Australian Government Department of Health
 T: s22 | E: s22
 s22

PO Box 9848, Canberra ACT 2601, Australia

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The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Thursday, 6 July 2017 2:12 PM
To: s22
Cc: s22
Subject: FW: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Good afternoon s22

s42

1. s42 [REDACTED] I understand you will get back to me on Monday, 10 July.
2. s42 [REDACTED] I am seeking this advice no later than 14 July so that s42 [REDACTED]. I am happy to meet with you at your convenience to discuss this further.

I would usually be working with s22 [REDACTED] to get the Rules sorted so I'm working without a safety net this time and just want to be certain that the Rules are doing (legally) what I think they're doing.

Kind regards

s22 [REDACTED]

s22 [REDACTED]
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health
T: s22 [REDACTED] | E: s22 [REDACTED] @health.gov.au
s22 [REDACTED]

From: s22 [REDACTED]
Sent: Thursday, 6 July 2017 9:27 AM
To: s22 [REDACTED]
Cc: s22 [REDACTED]
Subject: RE: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Thanks s22 [REDACTED]
In that case I'll send you an updated version of the s42 [REDACTED]

s22 [REDACTED]

s22 [REDACTED]
A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
Australian Government Department of Health
T: s22 [REDACTED] | E: s22 [REDACTED] @health.gov.au
s22 [REDACTED]

From: s22 [REDACTED]
Sent: Thursday, 6 July 2017 9:23 AM
To: s22 [REDACTED]
Cc: s22 [REDACTED]
Subject: LEX 30098 RE: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Hi s22 [REDACTED]

s42 [REDACTED] and I have some capacity issues today and tomorrow, but I should be able to get back to you on Monday morning (10 July 2017).

Please let me know if this would be problematic.

s22 [REDACTED]
Lawyer
Corporate Governance and Data Analytics Section

I do not work on Wednesdays

Legal Services Branch | Legal Division
Australian Government Department of Health
T: s22 [REDACTED] | E: s22 [REDACTED] @health.gov.au
s22 [REDACTED]

PO Box 9848, Canberra ACT 2601, Australia

My days at work are Monday & Tuesday (until 4.30pm) and Thursday & Friday (until 2.30pm).

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The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Tuesday, 4 July 2017 3:53 PM
To: s22
Cc: s22
Subject: My Health Records: National Opt-out Rule [DLM=Sensitive:Legal]

Good afternoon s22

s42

s42

s42

Are you able to let me know by Friday if there are any vast misinterpretations? We're supposed to be consulting with the Agency before next week in order to meet our timeframe for consulting s42. If there are big mistakes in my explanation I'll need to delay consultation.

Kind regards

s22

s22
 A/g Director, Legislation

Digital Health Branch | Health Systems Policy Division
 Australian Government Department of Health
 T: s22 | E: s22 [@health.gov.au](mailto:s22@health.gov.au)
 s22

s22

From: HMCU
Sent: Monday, 12 February 2018 3:14 PM
To: s22
Cc: HMCU
Subject: CHC OOS item 331 - My Health Records Rules National Opt Out [SEC=UNCLASSIFIED]
Attachments: CHC Out of Session Item 331 [DLM=For-Official-Use-Only]; OOS331_NT_020118.pdf; OOS331_VIC_201217.pdf; OOS331_WA_120118.tif

Hi s22

Please find attached the responses received in relation to CHC OOS item 331.

As this item was for noting only, the Secretariat now considers this item finalised.

Kind regards

s22

Health Ministers' Coordination Unit
Digital Innovation & AHMAC Branch
Portfolio Strategies Division

s22

Please note all CHC/AHMAC documents are to be considered as confidential with circulation limited to AHMAC Members and their Departments unless otherwise directed by CHC/AHMAC.



Hon Jill Hennessy MP

Minister for Health
Minister for Ambulance Services

GPO Box 4057
Melbourne Victoria 3001
Telephone: +61 3 9096 8561
www.dhhs.vic.gov.au
DX: 210081

igr4706576

Hon Meegan Fitzharris MLA
Chair
COAG Health Council
PO Box 3410
RUNDLE MALL SA 5000

Dear Minister

meegan

I write regarding the COAG Health Council Out-of-Session item 331 – My Health Records Rules: National Opt-out.

In response to the recommendation of the paper, Victoria notes the *My Health Records (National Application) Rules 2017* that will implement opt-out consumer participation arrangements nationally.

Yours sincerely

[Handwritten signature of Jill Hennessy]

Hon Jill Hennessy MP
Minister for Health
Minister for Ambulance Services

19/12 / 2017



**The Hon Roger Cook MLA
Deputy Premier
Minister for Health; Mental Health**

Our Ref: 4-106551

Ms Barbara Levings
Secretary
COAG Health Council
PO Box 3410
RUNDLE MALL SA 5000

Dear Ms Levings

COUNCIL OF AUSTRALIAN GOVERNMENTS HEALTH COUNCIL OUT-OF-SESSION ITEM 331 – MY HEALTH RECORDS RULES: NATIONAL OPT-OUT

I refer to the out-of-session paper dated 4 December 2017 requesting a response to one recommendation, and am able to advise that Western Australia supports that recommendation.

Yours sincerely

A handwritten signature in black ink, appearing to be 'R. Cook', written over a diagonal watermark.

**HON ROGER COOK MLA
DEPUTY PREMIER
MINISTER FOR HEALTH; MENTAL HEALTH**

9 JAN 2018

From: s22 [REDACTED]@act.gov.au> on behalf of AHMAC-
ACT <AHMAC-ACT@act.gov.au>
Sent: Monday, 8 January 2018 9:39 AM
To: Health:CHC Secretariat
Cc: s22 [REDACTED]@act.gov.au
Subject: CHC Out of Session Item 331 [DLM=For-Official-Use-Only]

Good morning

ACT notes Out of Session Item 331.

Apologies for the delay.

Kind regards

s22 [REDACTED] | AHMAC/COAG Health Council Coordinator and Administrative Officer
Ministerial and Government
ACT Health | ACT Government
Level 5 6 Bowes Street Woden ACT 2606
GPO Box 825 Canberra ACT 2601
Ph: s22 [REDACTED] Email: s22 [REDACTED]@act.gov.au
[health.act.gov.au](mailto:s22@act.gov.au)

This email, and any attachments, may be confidential and also privileged. If you are not the intended recipient, please notify the sender and delete all copies of this transmission along with any attachments immediately. You should not copy or use it for any purpose, nor disclose its contents to any other person.

s22

From: HMCU
Sent: Tuesday, 20 February 2018 3:28 PM
To: s22
Cc: HMCU; s22
Subject: FW: CHC OOS 331: My Health Records Rules National Opt Out
[SEC=UNCLASSIFIED]
Attachments: Signed letter.pdf

Hi s22

Please find attached the NSW response to CHC OOS item 331 - My Health Records Rules National Opt Out.

As the CHC Secretariat finalised this OOS item on 12 February 2018, could you please let me know if there are any issues accepting this response.

Kind regards
Jenni

Health Ministers' Coordination Unit
International, AHMAC and Digital Health Branch
Portfolio Strategies Division

s22

HMCU@health.gov.au

Please note all CHC/AHMAC documents are to be considered as confidential with circulation limited to AHMAC Members and their Departments unless otherwise directed by CHC/AHMAC.

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BY THE DEPARTMENT OF HEALTH



The Hon Brad Hazzard MP
Minister for Health
Minister for Medical Research

A17/746

Ms Barbara Levings
Secretary
COAG Health Council Secretariat
PO Box 3410
RUNDLE MALL SA 5000

Dear Ms Levings

CHC Out of Session Item 331: My Health Records Rules - National opt out

Thank you for your letter seeking comments on the above paper.

I note the proposed My Health Records (National Application) Rules 2017 and confirm NSW support for the Rules to enable the implementation of the national opt-out arrangements for consumer participation.

I further note that a solution for restricting My Health Records for children in out of home care is still to be agreed between the Australian Digital Health Agency and the NSW Department of Family and Community Services.

The Agency has proposed a number of solutions to manage the restriction of Individual Health Identifiers for children in out of home care. I have been advised that the proposed solutions will require changes to work practices and additional resources which have not been supported or funded by the Agency.

I understand that the Secretary of NSW Health will discuss these issues with the NSW Secretary of the Department of Family & Community Services and the Chief Executive Officer of the Australian Digital Health Agency. It would be beneficial to find a solution to this issue prior to the implementation of the opt-out consumer participation arrangements.

Yours sincerely

Brad Hazzard MP

The issue of protecting the address / identity of FACS children is crucial and must be addressed before the opt out system goes live.



My Health Records (National Application) Rules 2017

made under section 109 of the *My Health Records Act 2012*

Compilation No. 2

Compilation date:

15 November 2018

Includes amendments up to:

*My Health Records (National Application)
Amendment (Extension of Opt-Out Period No. 2)
Rules 2018*

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BY THE DEPARTMENT OF HEALTH

Prepared by Department of Health

About this compilation

This compilation

This is a compilation of the *My Health Records (National Application Rules) 2017* that shows the text of the law as amended and in force on 15/11/2018 (the **compilation date**).

The notes at the end of this compilation (the **endnotes**) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary	1
1 Name.....	1
3 Authority.....	1
4 Definitions.....	1
Part 2—Applying opt-out model to all healthcare recipients	2
5 Opt-out model applies to all healthcare recipients in Australia.....	2
Part 3—Registering healthcare recipients.....	3
6 When healthcare recipients may elect not to be registered.....	3
Part 4—Handling health information for the purposes of a healthcare recipient's My Health Record	4
7 When healthcare recipients may elect not to have certain health information disclosed to System Operator.....	4
Endnotes.....	Error! Bookmark not defined.
Endnote 1—About the endnotes	Error! Bookmark not defined.
Endnote 2—Abbreviation key	Error! Bookmark not defined.
Endnote 3—Legislation history	Error! Bookmark not defined.
Endnote 4—Amendment history	Error! Bookmark not defined.

Part 1—Preliminary

1 Name

This instrument is the *My Health Records (National Application) Rules 2017*.

3 Authority

This instrument is made under the *My Health Records Act 2012*.

4 Definitions

Note: A number of expressions used in this instrument are defined in the Act, including the following:

- (a) healthcare recipient;
- (b) My Health Record system;
- (c) registered healthcare recipient.

In this instrument:

Act means the *My Health Records Act 2012*.

healthcare identifier has the same meaning as in the *Healthcare Identifiers Act 2010*.

opt-out model: see section 5.

Part 2—Applying opt-out model to all healthcare recipients

5 Opt-out model applies to all healthcare recipients in Australia

For the purposes of clause 2 of Schedule 1 to the Act, Part 2 of that Schedule (the *opt-out model*) applies to all healthcare recipients in Australia.

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BY THE DEPARTMENT OF HEALTH

Part 3—Registering healthcare recipients

6 When healthcare recipients may elect not to be registered

- (1) This section is made for the purposes of subparagraph 5(2)(c)(i) of Schedule 1 to the Act.

Healthcare recipients who have a healthcare identifier immediately before the day this Part commences

- (2) An election by a member of the class of healthcare recipients mentioned in paragraph (3)(a) not to be registered must be given within the period mentioned in paragraph (3)(b).
- (3) For the purposes of subsection (2):
- (a) the class of healthcare recipients is the class of healthcare recipients, each of whom, immediately before the day on which this Part commences, has a healthcare identifier; and
 - (b) the period is the period beginning on the day on which this Part commences and ending on 31 January 2019.

Healthcare recipients who do not have a healthcare identifier immediately before the day this Part commences

- (4) An election by a member of the class of healthcare recipients mentioned in paragraph (5)(a) not to be registered must be given on the occurrence of the event mentioned in paragraph (5)(b).
- (5) For the purposes of subsection (4):
- (a) the class of healthcare recipients is the class of healthcare recipients, each of whom, immediately before the day on which this Part commences, does not have a healthcare identifier; and
 - (b) the event is when the healthcare recipient makes an application that will result in the healthcare recipient being assigned a healthcare identifier.

Part 4—Handling health information for the purposes of a healthcare recipient's My Health Record

7 When healthcare recipients may elect not to have certain health information disclosed to System Operator

- (1) This section is made for the purposes of subparagraph 13(2)(c)(i) of Schedule 1 to the Act.

Healthcare recipients registered under clause 6 of Schedule 1 to the Act

- (2) An election by a member of the class of healthcare recipients mentioned in paragraph (3)(a) not to have health information about the healthcare recipient held by the Chief Executive Medicare made available to the System Operator must be given on the occurrence of the event mentioned in paragraph (3)(b).
- (3) For the purposes of subsection (2):
- (a) the class of healthcare recipients is the class of healthcare recipients, each of whom is registered under clause 6 of Schedule 1 to the Act on or after the day on which this Part commences; and
 - (b) the event is when the healthcare recipient applies to be registered.

Healthcare recipients registered under clause 3 of Schedule 1 to the Act

- (4) An election by a member of the class of healthcare recipients mentioned in paragraph (5)(a) not to have health information about the healthcare recipient held by the Chief Executive Medicare made available to the System Operator must be given within the period mentioned in paragraph (5)(b).
- (5) For the purposes of subsection (4):
- (a) the class of healthcare recipients is the class of healthcare recipients, each of whom is registered under clause 3 of Schedule 1 to the Act on or after the day on which Part 3 commences; and
 - (b) the period is the period:
 - (i) beginning when the healthcare recipient is registered; and
 - (ii) ending when the healthcare recipient's My Health Record is first accessed.

Endnotes

Endnote 1—About the endnotes

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	
exp = expires/expired or ceases/ceased to have effect	reloc = relocated
F = Federal Register of Legislation	renum = renumbered
gaz = gazette	rep = repealed
LA = <i>Legislation Act 2003</i>	rs = repealed and substituted
LIA = <i>Legislative Instruments Act 2003</i>	s = section(s)/subsection(s)
(md) = misdescribed amendment can be given effect	Sch = Schedule(s)
(md not incorp) = misdescribed amendment cannot be given effect	Sdiv = Subdivision(s)
mod = modified/modification	SLI = Select Legislative Instrument
No. = Number(s)	SR = Statutory Rules
	Sub-Ch = Sub-Chapter(s)
	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

Endnotes

Endnote 3—Legislation history

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
<i>My Health Records (National Application) Rules 2017</i>	F2017L01558	2 December 2017	
<i>My Health Records (National Application) Amendment (Extension of Opt-out Period) Rules 2018</i>	F2018L01099	10 August 2018	
<i>My Health Records (National Application) Amendment (Extension of Opt-out Period No.2) Rules 2018</i>	F2018L01575	15 November 2018	

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

Provision affected	How affected
Par. 6(3)(b)	F2018L01575

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Australian Government
Department of Health

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Ministerial Submission – Standard
MS18-000376 Version (1)

MPF to complete Date sent to MO:<dd/mm/yy>

To: Minister Hunt

Subject: MY HEALTH RECORD: COMMENCEMENT OF NATIONAL OPT-OUT

Critical date: 11 April 2018, to allow the instrument that specifies the opt-out commencement date to be published in time for communications material to be prepared and disseminated before the opt-out period begins.

Recommendation/s:

- | | |
|--|----------------------|
| 1. Agree that national opt-out participation in My Health Record will commence on 16 July 2018 | 1. Agreed/Not agreed |
| 2. Sign and date the instrument (Attachment A) to specify that Part 3 of the <i>My Health Records (National Application) Rules 2017</i> will commence on 16 July 2018 | 2. Signed/Not signed |
| 3. Agree that key delivery partners be notified of the opt-out date ahead of registration of the instrument | 3. Agreed/Not agreed |

Signature

Date: / /

Comments:

Contact Officer:	Nicole Jarvis	Assistant Secretary, International, AHMAC and Digital Health Branch, Portfolio Strategies Division	Ph: (02) 6289 8001 Mobile: s22
Clearance Officer:	Caroline Edwards	Deputy Secretary	Ph: (02) 6289 1235 Mobile: s22

Issues:

- The *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) implement opt-out participation for the My Health Record system nationally.
- Part 3 of the National Opt-out those Rules provides that a consumer can elect not to be registered for a My Health Record (i.e. they can opt-out). Part 3 and, in effect, the opportunity to opt-out, begins on a date to be specified by you. If you decided not to specify a date the opt out period would commence automatically on 2 September 2018.
- The draft My Health Records (National Application) Commencement Instrument is provided for your approval (**Attachment A**). This instrument declares to the public that Part 3 of the National Opt-out Rules will commence on 16 July 2018.

~~3.4.~~ s47C

Formatted: Highlight

- ~~4.5.~~ Subject to your agreement, consumers who are eligible will have three months to opt-out – from 16 July 2018 until 15 October 2018. Ongoing opt-out arrangements for consumers who become eligible (such as newborns and immigrants) will be available from 16 July 2018.

Page 1

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5.6. The instrument is a notifiable instrument which means that it must be registered on the Federal Register of Legislation but will not be tabled in Parliament and is not disallowable.

6.7. In order to support key delivery partners working with healthcare professionals and those preparing to commence consumer communications, the Australian Digital Health Agency would like to provide early advice of the opt-out date to Primary Health Networks and peak organisations.

Background:

The *My Health Records Act 2012* enables you to make rules to implement opt-out participation arrangements nationally. You made the National Opt-Out Rules on 30 November 2017.

The National Opt-Out Rules are currently subject to Parliamentary scrutiny, with the disallowance period ending after 26 March 2018.

Readiness

The opt-out period is predicated on establishing an operational readiness that considers:

- providing the means by which all consumers can opt-out;
- establishment of effective consumer communication;
- technology, including cyber security, enablement;
- operational readiness, including establishment of the contact centre services;
- provider awareness to ensure the education of consumers; and
- achievement of minimum levels of high value content within the My Health Record system.

s47C

s47C

s47C

s42

The opt-out period will last for three months and end on 15 October 2018. The opt-out window will be followed by a reconciliation period of four weeks for quality and assurance checks. My Health Records will be created on 13 November 2018 for those who have not chosen to opt-out.

In the event that the opt-out date must be changed, you will be required to revoke this instrument and make a new one, which will specify the new date.

If the date is not prescribed by you by 1 September 2018, the National Opt-Out Rules provide that the three month opt-out period will automatically begin on 2 September 2018.

Communications

The Agency has developed a comprehensive communications strategy for the implementation of opt-out, which will see:

- Information in every general practice in Australia
- Communications to consumers through other health and non-health channels
- National and local partnerships with Medicare, Primary Health Networks, corporate, peak and consumer organisations, as well as through direct Australian Digital Health Agency activities.
- A range of channels utilised including, traditional and social media, public relations, and events.

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- Hard-to-reach audiences specifically supported
- Information available in multiple languages
- Thousands of face-to-face briefings at community events around the country
- Distribution of communications material through consumer peak organisations
- Provision of information at the point of care and other community places such as doctors' surgeries, hospitals, libraries and post offices.

This will ensure all Australians are informed about the opt-out period and specifically how to access the opt-out portal.

A lead time of 12 weeks for the commencement of the opt-out period is required in order to print and distribute the consumer communications materials, undertake data extracts from the Department of Human Services for bulk registration and ensure provider preparation. This cannot occur until after you have made the My Health Records (National Application) Commencement Instrument.

Framework for Secondary Use

The framework for the secondary use of My Health Record data will be released publicly prior to the commencement of the opt-out period.

Attachments:

A: My Health Records (National Application) Commencement Instrument 2018

B: §47C

Relevance to Election Commitments / Budget Measures:

This instrument will implement opt-out as announced in the 2017-18 Budget Measure *A My Health Record for Every Australian*.

Sensitivities:

The setting of this commencement date is likely to attract broad public interest. The Australian Digital Health Agency has prepared public communications in preparation for the registration of the notifiable instrument on the Federal Register of Legislation.

Consultations:

On 13 March 2018 the Agency met with you to discuss My Health Record system readiness for opt-out. The Agency was consulted on the preparation of this Minute.

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Australian Government
Department of Health

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Ministerial Submission- Standard
MSIS-000376 Version (1)
Date sent to MO: 20/03/18

To: Minister Hunt

Subject: MY HEALTH RECORD: COMMENCEMENT OF NATIONAL OPT-OUT

Critical date: 11 April 2018, to allow the instrument that specifies the opt-out commencement date to be published in time for communications material to be prepared and disseminated before the opt-out period begins.

Recommendation/s:

- | | |
|--|----------------------|
| 1. Agree that national opt-out participation in My Health Record will commence on 16 July 2018 | 1. Agreed/Not agreed |
| 2. Sign and date the instrument (Attachment A) to specify that Part 3 of the <i>My Health Records (National Application) Rules 2017</i> will commence on 16 July 2018 | 2. Signed/Not signed |
| 3. Agree that key delivery partners be notified of the opt-out date ahead of registration of the instrument | 3. Agreed/Not agreed |

Signature

Date:

Comments:

Contact Officer:	Nicole Jarvis	Assistant Secretary, International, AHMAC and Digital Health Branch, Portfolio Strategies Division	Ph: (02) 6289 8001 Mobile: s22
Clearance Officer:	Caroline Edwards	Deputy Secretary, Health Systems Policy & Primary Care Group	Ph: (02) 6289 1235 Mobile: s22

Issues:

- The *My Health Records (National Application) Rules 2017* (the National Opt-out Rules) implement opt-out participation for the My Health Record system nationally.
- Part 3 of those Rules provides that a consumer can elect not to be registered for a My Health Record (i.e. they can opt-out). Part 3 and, in effect, the opportunity to opt-out, begins on a date to be specified by you. If you decided not to specify a date the opt-out period would commence automatically on 2 September 2018.
- The draft *My Health Records (National Application) Commencement Instrument* is provided for your approval (**Attachment A**). This instrument declares to the public that Part 3 of the National Opt-out Rules will commence on 16 July 2018.

4.

s47C

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s47C

5. from 16 July 2018 until 15 October 2018. Ongoing opt-out arrangements for consumers who become eligible (such as newborns and immigrants) will be available from 16 July 2018.
6. The instrument is a notifiable instrument which means that it must be registered on the Federal Register of Legislation but will not be tabled in Parliament and is not disallowable.

7. s47C

Background:

The *My Health Records Act 2012* enables you to make rules to implement opt-out participation arrangements nationally. You made the National Opt-Out Rules on 30 November 2017.

The National Opt-Out Rules are currently subject to Parliamentary scrutiny, with the disallowance period ending after 26 March 2018.

Readiness

s47C

s47C

Following a review of these criteria and after consultation, the Agency has recommended that the opt-out period commence on 16 July 2018.

s47C

be followed by a reconciliation period of four weeks for quality and assurance checks. My Health Records will be created on 13 November 2018 for those who have not chosen to opt-out.

In the event that the opt-out date must be changed, you will be required to revoke this instrument and make a new one, which will specify the new date.

If the date is not prescribed by you by 1 September 2018, the National Opt-Out Rules provide that the three month opt-out period will automatically begin on 2 September 2018.

Communications

The Agency has developed a comprehensive communications strategy for the implementation of opt-out, which will see:

- Information in every general practice in Australia

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- National and local partnerships with Medicare, Primary Health Networks, corporate, peak and consumer organisations, as well as through direct Australian Digital Health Agency activities.
- A range of channels utilised including, traditional and social media, public relations, and events.
- Hard-to-reach audiences specifically supported.
- Information available in multiple languages.
- Thousands of face-to-face briefings at community events around the country.
- Distribution of communications material through consumer peak organisations.
- Provision of information at the point of care and other community places such as doctors' surgeries, hospitals, libraries and post offices.

This will ensure all Australians are informed about the opt-out period and specifically how to access the opt-out portal.

s47C

Framework for Secondary Use

The framework for the secondary use of My Health Record data will be released publicly prior to the commencement of the opt-out period.

Attachments:

- My Health Records (National Application) Commencement Instrument 2018.
- s47C

Relevance to Election Commitments / Budget Measures:

This instrument will implement opt-out as announced in the 2017-18 Budget Measure *A My Health Record for Every Australian*.

Sensitivities:

The setting of this commencement date is likely to attract broad public interest. The Australian Digital Health Agency has prepared public communications in preparation for the registration of the notifiable instrument on the Federal Register of Legislation.

Consultations:

On 13 March 2018 the Agency met with you to discuss My Health Record system readiness for opt-out. The Agency was consulted on the preparation of this Minute.

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My Health Records (National Application) Commencement Instrument 2018

I, Greg Hunt, Minister for Health, acting under item 3 of the table in subsection 2(1) of the *My Health Records (National Application) Rules 2017*, fix 16 July 2018 for the commencement of Part 3 of those Rules.

Dated 25-3 : 2018


GREG HUNT
Health Minister

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Attachment B

Readiness Assessment - Information provided by the Australian Digital Health Agency

s47C


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My Health Records (National Application) Commencement Instrument 2018

I, Greg Hunt, Minister for Health, acting under item 3 of the table in subsection 2(1) of the *My Health Records (National Application) Rules 2017*, fix 16 July 2018 for the commencement of Part 3 of those Rules.

Dated 25.3. 2018


GREG HUNT
Health Minister

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My Health Records (National Application) Commencement Instrument 2018

I, Greg Hunt, Minister for Health, acting under item 3 of the table in subsection 2(1) of the *My Health Records (National Application) Rules 2017*, fix 16 July 2018 for the commencement of Part 3 of those Rules.

Dated 25 March 2018

GREG HUNT
Health Minister

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From: s22
Sent: Tuesday, 24 April 2018 5:00 PM
To: Legislative Instruments
Cc: s22
Subject: My Health Records (National Application) Commencement Instrument 2018 - For Consideration [DLM=For-Official-Use-Only]
Attachments: My Health Records (National Application)~ment 2018 - word version to pro....docx; Signed My Health Records (National Application) Commencement Instrumentpdf; Spreadsheet - Notifiable Instrument details.xlsx

Hi s22 ,

Please find attached the notifiable instrument - *My Health Records (National Application) Commencement Instrument 2018*, which has been signed by the Minister.

s42

s42

. It is expected that this announcement will be made early next week so we may require registration to occur on Monday 30 April 2018. We are waiting on advice from the Ministers Office.

Once we know when the instrument can be registered we will let you know s42

Attached is:

- A soft copy of instrument;
- A copy of the signed instrument; and
- The Legislative instruments spreadsheet

I am away on Thursday and Friday this week so if you require additional information please contact s22 who I have cc'd into this email.

Kind regards

s22

s22

Digital Health Legislation and Policy Section
 International, AHMAC and Digital Health Branch
 Portfolio Strategies Division
 Australian Government Department of Health
 s22 | Level 10.S.410 Sirius Building
 s22 @health.gov.au



My Health Records (National Application) Commencement Instrument 2018

I, Greg Hunt, Minister for Health, acting under item 3 of the table in subsection 2(1) of the *My Health Records (National Application) Rules 2017*, fix 16 July 2018 for the commencement of Part 3 of those Rules.

Dated 25 March 2018

GREG HUNT
Health Minister


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THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH



My Health Records (National Application) Commencement Instrument 2018

I, Greg Hunt, Minister for Health, acting under item 3 of the table in subsection 2(1) of the *My Health Records (National Application) Rules 2017*, fix 16 July 2018 for the commencement of Part 3 of those Rules.

Dated 25.3. 2018


GREG HUNT
Health Minister

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