

1. INTENT:

- 1.1 To comply with Manitoba eHealth, WRHA Privacy and Provincial legislation that is aligned with the Canadian Medical Protective Association Electronic Medical Records Handbook
- 1.2 To ensure electronic signatures in the Community EMR (Accuro EMR) have the required controls in place to mitigate risk associated with the opportunity for misuse of the Electronic Medical Record
- 1.3 To support optimal workflow practices to affix Electronic Signatures in the Community EMR within a safe process and at a minimum a random audit to be conducted annually to ensure compliance is met with the signature methods outlined

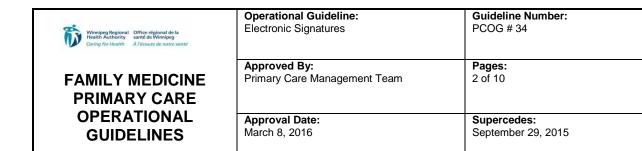
2. BACKGROUND:

As per the <u>Canadian Medical Protective Association Electronic Medical Records Handbook</u>, "a critical function of an electronic signature is to associate the signatory with the contents of the document. Can an electronic signature effectively serve the same purpose in an eRecord? Legally, it can. An electronic signature, although not tangible in nature, can still be evidence of the association of the signatory with the document and its contents. Electronic signature is a generic term that refers to a wide variety of non-manual signature options, including digital signatures. It is commonly defined as electronic data created or adopted by a person to sign a document. The data is then attached to or associated with the document. A digital signature is a technology-specific type of electronic signature. It is one of the many techniques that satisfy the functions sought to be performed by electronic signatures. A common misconception is that electronic signatures are merely a digital version of a handwritten signature. While a signature entered on a touchpad is one example of an electronic signature, a more common example are those consisting of one or more letters, characters, numbers or symbols that are attached to or associated with an electronic document. Although electronic signatures are generally recognized as being as valid as manual signatures, they cannot yet be used in all circumstances.

When they are permissible, electronic signature devices must meet certain reliability requirements. In the event of a potential future legal proceeding, Prescribers using this type of device will want to be able to explain how it works and attest to its reliability. Without this assurance of reliability, a court or tribunal may not allow the electronically signed document to be admitted as evidence or it may be given reduced weight. It is therefore important to be able to demonstrate the electronic signature was properly associated with the document in question (e.g. report, consent form, etc.). Without this assurance of reliability, the other side in a dispute could argue that the patient did not know what document to which he or she was affixing a digital signature when signing with a stylus on a digital signature pad. Alternatively, it could be argued the physician's signature was not associated with the correct report and the physician did not, in fact, review the relevant document.

To effectively respond to such arguments, Prescribers should consider a system with the following characteristics identified:

2.1 The person signing the document electronically is able to verify the electronic signature on the screen.



- 2.2 An audit function that permits the Prescriber to ascertain the date and time the signature was made, and to what document it was associated at that time.
- 2.3 Individuals are only able to enter their own electronic signature." (CMPA, 2014)

The Electronic Medical Record (referred to Accuro EMR or C-EMR) used in Family Medicine Primary Care Clinics and services, has the capacity to affix signatures electronically (electronic signatures) to certain documents.

Background Issues

Manitoba eHealth, Application Administrators, Solution Group Manager for the EMR, WRHA Legal and Security and Privacy & Risk programs at Manitoba eHealth conducted a review on the potential use of electronic signatures to identify potential risks. The concerns included who the EMR actually permitted to use the electronic signatures, what opportunities there might be for inappropriate or possibly fraudulent use of the electronic signatures, what information regarding the use of signatures the EMR records in its logs and whether those logs are capable of being manipulated to mask inappropriate use. The logs are important not only to comply with the requirements in the PHIA Regulation for Records of User Activity but also to allow for tracking of whether an electronic signature was used, which signature was used, which document it was affixed to and who made use of that signature.

The review determined that access to the EMR requires authorization as a user, and that some users may be assigned higher privileges by being designated as a "Prescriber". Prescribers have the following:

- · A pre-determined list of authorizations/privileges and
- Additional authorizations that can be added.

The Family Medicine Primary Care program and clinic sites using the EMR determine who is authorized as a Prescriber and a Delegate that is aligned with all applicable regulatory and professional requirements, who is designated as a Prescriber and a Delegate, and the specific privileges extended to the Delegate. Currently, electronic signature practices within the Family Medicine Primary Care sites vary as Prescribers have created workarounds to address the fact the electronic signature was not yet in place.

For Family Medicine Primary Care, the actual implementation in the EMR of all users including Prescribers and Delegates and their privileges is performed by System Administrators and Data Analysts located at Manitoba eHealth (300 Carlton) and WRHA Program Community Services Information Systems (CSIS - Integrated Support) located on 1st floor - 496 Hargrave.

Therefore, the review recommendations and the controls that are being put in place <u>shall not</u> vary between sites.

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FAMILY MEDICINE PRIMARY CARE	Approved By: Primary Care Management Team	Pages: 3 of 10	
OPERATIONAL GUIDELINES	Approval Date: March 8, 2016	Supercedes: September 29, 2015	

3. DEFINITIONS:

<u>Prescriber:</u> includes Physicians, Nurse Practitioners, Midwives, Physician Assistants and Pharmacists see specifics within each role as indicated in <u>College of Pharmacists of Manitoba - Prescribing Authority Table</u>.

<u>Principles</u> as well as the <u>Joint Guideline # 132 The College of Physicians and Surgeons of Manitoba</u> & The College of Registered Nurses of Manitoba: Shared Competencies and Delegated Physician Services "provide the principles and guidelines that are required to be met for delegation of function and shared competencies for Primary Care Nurses or for any individual (Dieticians, Shared Care Counsellors or by a Medical Resident)".^{2,3} Therefore, Delegates must meet their College and regulatory requirements in order to generate / create either a prescription or form. However, in the EMR for both prescription and forms Delegates cannot affix a Prescriber's electronic signature. The reason is based on the EMR set up of the permission templates as they are assigned to the Prescriber account. The designation of Delegates for a Prescriber is done by the Prescriber designating a role (note all staff having the role of 'Provider' in the EMR are deemed Delegates).

<u>Clinical Support Staff:</u> unregulated health care workers, for example, Primary Care Assistants, Unit Assistants, Nursing Assistants or Medical Office Assistants, or equivalent role.

EDUCATIONAL REQUIREMENTS:

 Ensure all Clinic Team members understand the rules and regulations of the Privacy Policy <u>Security and Storage of</u> <u>Personal Health Information 10.40.120</u> specific to section 4.1 of the policy CSIS to provide education to Prescriber, Delegates and Clinical Support Staff prior to witnessing the Prescriber capture their electronic signature. Education includes the following:

- User Passwords are not to be shared with anyone
- C-EMR automatic shut off of 30 minutes
- Default Fuzzy Lock Screen CSIS http://home.wrha.mb.ca/prog/csis/provider.php

4. **OPERATING GUIDELINE:**

The EMR allows electronic signatures to be affixed to 4 types of documents generated within the EMR:

- Prescriptions
- Forms
- Signature footers in letters generated in the EMR (excluded from this guideline)
- Importing a signature image file into a "Clinical Note"



Operational Guideline:	Guideline Number:
Electronic Signatures	PCOG # 34
Approved By: Primary Care Management Team	Pages: 4 of 10
Approval Date:	Supercedes:
March 8, 2016	September 29, 2015

4.1 Prescriptions

Prescribers are authorized to create prescriptions within the EMR which can be printed, but require a handwritten signature if being provided directly to a patient. The 2014 joint statement on Electronic Transmission of Prescriptions states, "Requirements for prescriber issuing an electronic prescription. The prescriber must also ensure that:

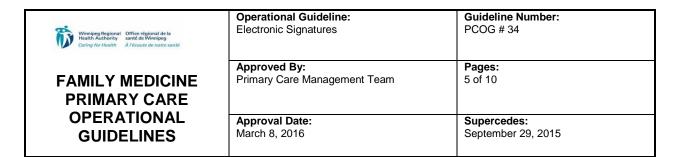
- the prescription is sent directly from the prescriber's office to a single licensed pharmacy of the patient's choice;
- the prescription must be sent only to a pharmacist practicing in a Manitoba licensed pharmacy;
- the prescription is transmitted to the pharmacy in a clear, unambiguous manner; and
- the mode of transmission is secure and maintains confidentiality.

NOTE: The joint statement applies to all medications but cannot include M3P Drugs: The Manitoba Prescribing Practices Program (M3P, formerly known as the "triplicate" program) will supersede this process when the drug being prescribed is covered by the M3P, and a written M3P form is required. Additionally, all other record keeping requirements will prevail. Electronic transmissions of prescriptions shall not be accepted from non-Manitoba licensed prescribers."¹

For the complete joint statements related to electronic transmissions and facsimile transmissions of prescriptions refer to the following:

Facsimile Transmission of Prescriptions
Electronic Transmission of Prescriptions
Q and A: Electronic and Facsimile Transmission of Prescriptions
Facsimile Transmission of Prescription Template

- 4.1.1 **EMR Format** A signature may be added in two different manners:
 - 4.1.1.1 A signature by a Prescriber or Delegate using either a pen or a mouse each time the prescription is being completed. This signature image is stored in the EMR's database as binary data, but is not encrypted and it can't be by guaranteed the signature wasn't altered or removed by any user.
 - 4.1.1.2 A Prescriber's electronic signature will only be affixed to the prescription when that prescriber has logged into the EMR, regardless of whether the prescription was originally generated by that Prescriber or by a delegate. A Prescriber's signature cannot be copied and pasted onto other documents or prescriptions. The prescription is saved into the patient's medication area of the EMR without the signature affixed. As a result, it is possible for any user with access to that patient's file to print out the prescription, but it will print without the signature.
 - Access Set up all Prescribers have the ability to store their signature. Refer to Community EMR eSignature instructions. At the time of entering the signature, the Prescriber indicates



whether the signature is to be made available for prescriptions and /or for forms within the EMR (see below).

- 4.1.1.3 Access Use The ability in the EMR to create a prescription is granted to:
 - Prescribers who are granted this privilege; and
 - their designated Delegates
- 4.1.2 Audit / Fax logs The EMR logs activity related to the creation of a prescription, including copy of the prescription. However the log does not record whether a signature was affixed or retain a copy of that signature. Where a prescription has been faxed directly from the EMR, a copy of that faxed prescription including the signature will be maintained in the fax log. Access to a patient's file and viewing of a prescription in that file will be logged, but viewing of the prescription in the fax log will not itself be logged.
- 4.1.3 Based on the protection for electronic signatures currently contained in the EMR, the prescription arrangements permitted by the EMR comply with all applicable regulatory and professional requirements as outlined by each of the respective Colleges and the College of Pharmacists of Manitoba Prescribing Authority Table.

4.2 EMR Forms

The EMR allows for the creation of standard form templates, which can then be completed online and affixed with a Prescriber's signature electronically.

- 4.2.1 **Format –** A signature may be entered in the following different manners:
 - 4.2.1.1 Using the signature component in the forms editor (managed by Systems Administrator) below are the following options:
 - 4.2.1.1.1 Signature is added to a form from a drop down list allowing for a delegate to affix a Prescriber's signature on their behalf. This is the recommended format.
 - 4.2.1.1.2 Signature to manually add by pen or mouse each time the form is completed. This is <u>not the recommended format</u> as it is not encrypted and it can't be by guaranteed the signature wasn't altered or removed by any user. (A User functionality, not managed by System Administrators)
 - 4.2.1.1.3 A manual signature is scanned and that scanned image is stored in each individual form. This is <u>not the recommended format</u> or is it applied in the shared multi-site C- EMR instance.
- 4.2.2 Access Set up For the Prescriber form set up is identical to Prescriptions 4.2.2.1. System administrator must configure the signature component in the forms editor accordingly.



Operational Guideline: Electronic Signatures	Guideline Number: PCOG # 34
Approved By:	Pages:
Primary Care Management Team	6 of 10
Approval Date:	Supercedes:
March 8, 2016	September 29, 2015

- 4.2.3 **Access Use –** A Prescriber and Delegate has the option of deciding if the completion of forms and affixing of the Prescriber's signature is available under the following conditions:
 - 4.2.3.1 Only to that Prescriber when logged in, or
 - 4.2.3.2 To the Prescriber's Delegates so they can generate / create / complete and print forms on the Provider's behalf.
- 4.2.4 Whether a Prescriber's signature will be affixed to a form automatically is determined when creating the form. Once a completed form is saved to the patient's chart, all users with access to that chart may print out the form with the Prescriber's signature affixed.
- 4.2.5 **Audit logs** The EMR logs activity relating to the completion of forms, specifically when a form is completed, who completes it, and a copy of the form as completed including the signature. However it is possible to print a form and not save it in which event the form's content might not be logged.

4.3 EMR Letters / "Clinical Notes"

Users with access to write in the "Clinical Notes" section of the EMR are able to document on the patient's chart. This functionality can be used, for example, to generate letters. The headers and footers can be configured for these letters so that they are specific to a site and the Prescribers, Delegates and Clinical Support Staff (Primary Care Assistants and Unit Assistants) that work in it.

- 4.3.1 **Format** An end User can import a scanned image of a manual signature into a *"Clinical Note"*. System Administrators can apply a signature to the footers of Letters. This is <u>not the recommended practice</u> and poses a significant risk that any end user has the ability to use a Prescriber's signature that could create mischief.
- 4.3.2 **Access Set Up –** Any user can upload an image to a clinical note. System Administrators manage the headers and footers.
- 4.3.3 **Access Use –** Any user with access to the clinical part of the EMR is able to generate or edit documents, such as letters. Once the document is put onto the patient's file, all users with access to the file may print out the document with the signature. However an image cannot be copied and pasted from one document / letter to another.
- 4.3.4 **Audit Logs** The EMR audit log records the creation of a document, however it does not retain a copy of the document or record whether a signature was affixed.

4.4 EMR System Administrators

4.4.1 System administrators play an important role in the upkeep, configuration, and reliable operation of the EMR. Their role necessarily provides them with heightened privileges, including the authorization of users, the designation of users as Prescribers and the assignment of authorizations/privileges to specific Prescribers and Delegates. Thus they have the opportunity to mimic the activity of any Prescriber including the creation of



Operational Guideline: Electronic Signatures	Guideline Number: PCOG # 34
Approved By:	Pages:
Primary Care Management Team	7 of 10
Approval Date:	Supercedes:
March 8, 2016	September 29, 2015

prescriptions with signatures. All of these activities (but not necessarily all of the details of those activities) will be recorded in the EMR's logs. However System Administrators are not able to modify the logs which contain information on their activities within the EMR, as described above.

4.5 EMR Implementation Controls

4.5.1 Ensure all Clinic Team members understand the rules and regulations of the Privacy Policy Security and Storage of Personal Health Information 10.40.120 as per 4.1.3 which states, "Individuals who sign on to a computer must not leave the computer on in accessible areas when they leave their workstation. User password protocols must be in place and utilized. Where possible, automatic shut offs after a prescribed period of disuse should be programmed for all workstations." within the context of the C-EMR.

CSIS to provide education to Prescriber, Delegates and Clinical Support Staff prior to witnessing the Prescriber capture their electronic signature. Education includes the following:

- User Passwords are not to be shared with anyone
- C-EMR automatic shut off of 30 minutes
- Default Fuzzy Lock Screen CSIS http://home.wrha.mb.ca/prog/csis/provider.php
- 4.5.2 To limit the possibility of mistake or inappropriate designation, the recommendation for all sites is to adopt a formal requirement that the designation of all Clinical Support Staff and Delegates on behalf of a Prescriber must in all cases have the Prescriber's <u>prior</u> written approval. The Prescriber, Delegates and Clinical Support Staff are to fully understand what they <u>shall</u> and <u>shall not</u> adopt as signature methods of the Prescriber.
 - 4.5.2.1 Prescribers and their Delegates <u>shall</u> adopt and comply with the e-signature methods which are as follows:
 - Utilizing e-signatures on prescriptions as outlined in 4.1.1.2 A Prescriber's electronic signature will only be affixed to the prescription when that prescriber has logged into the EMR, regardless of whether the prescription was originally generated by that Prescriber or by a delegate. A Prescriber's signature cannot be copied and pasted onto other documents or prescriptions. The prescription is saved into the patient's medication area of the EMR without the signature affixed. As a result, it is possible for any user with access to that patient's file to print out the prescription, but it will print without the signature.
 - Utilizing e-signatures on forms as outlined in 4.2.1.1.1 Signature is added to a form from a drop down list allowing for a delegate to affix a Prescriber's signature on their behalf

<u>ADDENDUM:</u> As of March 8, 2016: At this time electronic signatures are now added to the form with the use of the forms editor for all Prescribers. However, it currently doesn't allow for a delegate to affix a Prescriber's signature on their behalf. Exceptions to this will be Systems Administrators who provide the appropriate permissions to specific forms for the drop down list allowing for a



Operational Guideline: Electronic Signatures	Guideline Number: PCOG # 34
Approved By: Primary Care Management Team	Pages: 8 of 10
Approval Date:	Supercedes:
March 8, 2016	September 29, 2015

delegate to affix a Prescribers signature on their behalf. Approval for this method to be implemented for Prescribers who have approved delegates to use their signature as well as written approval from their respective College that these forms can be signed by a delegate and submitted to Primary Health Care Program who will advise System Administrators to implement.

- 4.5.2.2 Prescribers and their Delegates <u>shall not</u> adopt the signature methods within the EMR or with other applications (MS Word) which are as follows:
- Signature to manually add by pen or mouse each time the form is completed. This is not the recommended format as it is not encrypted and it can't be by guaranteed the signature wasn't altered or removed by any user (A User functionality, not managed by System Administrators) as outlined in 4.2.1.1.2
- A manual signature is scanned and that scanned image is stored in each individual form. This is not the recommended format or is it applied in the shared multi-site C- EMR instance as outlined in 4.2.1.1.3
- 4.5.3 Team Managers and Site Medical Leads to assist the CSIS Data Analyst to ensure the Appendix A Medical Directive Electronic Signature is completed to ensure prior approval by the Prescriber for requesting electronic signature functionality as well as prior approval for Delegate(s) and Clinical Support Staff. See Appendix A Medical Directive Electronic Signature.
- 4.5.4 CSIS to provide education as described and witness the Medical Directive has been read and understood. CSIS and the Prescriber to ensure the Prescriber's signature is captured on the Medical Directive and that it is representative of the electronic signature capture. Original: Prescriber's Contract File CC: Clinical Support Staff and Delegate Files, CSIS for their records
- 4.5.5 Clinical Team Managers should follow the <u>Community EMR Add Change Move Terminate Flow Chart</u> when submitting a <u>Manitoba eHealth Account Form</u> indicating the Prescriber and Delegate role has written approval with a copy of the Medical Directive on eSignature attached.
- 4.5.6 Clinical Team Managers are responsible to ensure that when changes in employment occur (leave of absence, transfer to another clinic, resigns, etc.) the Prescriber and Delegate access is removed or changed by updating the Medical Directive Electronic signatures
- 4.5.7 No signatures to footers will be applied until further testing is completed due to risks of storing and sharing signatures. Given the wide possibility of documents that can be created by a user, and the relative ease by which a signature may be affixed, this provides ample opportunity for mischief. As it was recommended that the Family Medicine Primary Care Program and CSIS set and enforce rules for who may create documents and of the circumstances in which a signature may be affixed to a document. The most common form of document is letters, and the ability to generate a letter with the signature of a Provider without the Provider's authorization or knowledge could lead to problems.



Operational Guideline:	Guideline Number:
Electronic Signatures	PCOG # 34
Approved By: Primary Care Management Team	Pages: 9 of 10
Approval Date:	Supercedes:
March 8, 2016	September 29, 2015

- System Administrators are the only users within the Community EMR instance that can modify provider configurations which include the footers. Other users will not be granted access to this area of the application. As indicated in 4.5.1.3 users are not to import scanned images of a signature into a clinical note to represent their signature
- 4.5.8 Given it is possible for any user to scan a Prescribers and Delegates manual signature outside of the C-EMR application (i.e., Microsoft Word) all Family Medicine Primary Care clinic teams shall refrain from applying that scanned image to a completed form, as there is opportunity for mischief.
- 4.5.9 System administrators for the Family Medicine Primary Care sites are located at Manitoba eHealth. Data Analysts are located at 496 Hargrave and not located with an EMR site. However, Data Analysts are involved in the ongoing operations and activities at all Family Medicine Primary Care sites, enhances the chances of improper use of their access and privileges. The process of capturing and destroying electronic signatures will always be completed by two Community Information Systems (CSIS) team members.
- 4.5.10 Failure to comply will result in disciplinary action including e-signature being suspended or revoked.
- **4.6 Suspected or Confirmed Forgeries** If a suspected or confirmed forgery of a handwritten or electronic signature by a clinic team member, other staff or patient occurs, the following is the recommended process:

Suspected Forgery

- Complete RL6 and report to Team Manager, Site Medical Lead and Director responsible for Primary Care services immediately
- Verify Prescriber's electronic / handwritten signature
- Check Patient's DPIN profile if suspect a patient forgery
- Request photo identification to verify patient's identity against the prescription
- · Confirm prescription with ordering Prescriber

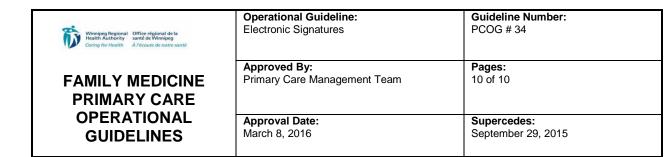
Confirmed Forgery

Once a Forgery is confirmed:

- Contact police. Provide a copy of original prescription to police if requested.
- Prescriber to report forgery to their respective College
- Fill out the <u>Health Canada Forgery Report for Controlled Substances</u> (if applicable) and send copies to Health Canada, respective College, Team Manager, Site Medical Lead and Director responsible for Primary Care.
- If PHIN fraud contact Manitoba Health Auditor, Risk Analyst (204-788-6774)

5. SOURCE/REFERENCES:

- 1. Electronic Records Handbook Canadian Medical Protective Association (2014) retrieved May 2015 https://www.cmpa-acpm.ca/documents/10179/24937/com_electronic_records_handbook-e.pdf
- 2. The College Of Physicians And Surgeons Of Manitoba, College Of Pharmacists Of Manitoba, The Manitoba Dental Association, The Manitoba Veterinary Medical Association, And The



College Of Registered Nurses Of Manitoba (2014) Joint Statement Electronic Transmission of Prescriptions

http://mpha.in1touch.org/uploaded/web/Legislation/Electronic%20Transmission%20of%20Prescriptions%202014.pdf

- 3. The College of Physician's and Surgeons of Manitoba (Revision L&E/12-00) Statement #130 Delegation of Function Principles http://cpsm.mb.ca/cjj39alckF30a/wp-content/uploads/st130.pdf
- 4. The College Of Physicians And Surgeons Of Manitoba and The College Of Registered Nurses Of Manitoba Joint Guideline # 312 Shared Competencies And Delegated Physician Services Revision CPG/09-02 http://cpsm.mb.ca/cjj39alckF30a/wp-content/uploads/gdl132.pdf
- 5. Pharmacy Prescription Forgeries

http://mpha.in1touch.org/uploaded/web/Guidelines/2013Summer%20NewsletterForgeries.pdf adapted for Prescribers

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8. APPENDICES:

APPENDIX A – Medical Directive - Electronic Signatures

SCOPE: Applicable to all WRHA Family Medicine Teaching Clinics, Primary Care Direct Operations Clinics, Quick Care Clinics, Hospital Home Teams and My Health Teams working in the WRHA C-EMR instance, WRHA Fee for Service Staff (Interprofession Team Development Initiative (ITDI) Staff)