ENTERPRISE POSITION STATEMENT

TITLE: SHARED EMR LEGAL HEALTH RECORD GUIDANCE

Original Effective Date: August 1, 2006 **Effective Date of Current Revision:** April 1, 2012 **Review/Revision Date(s**): April, 2012 **Scope:** Ministry Health Care and all Wholly Owned Ministry Health Care Organizations, including Ministry Door County Medical Center and Ministry Saint Elizabeth's Medical Center, Except Agape	**Position Statement Number:** PS-HH

Defined terms are **"Capitalized."** Definitions are imbedded in or included at the end of the Position Statement.

Issue: **Understanding and Defining the Organizations' Designated Record Set/Legal Health Record**

Position Statements/Guidance:

1. Ministry Health Care and its wholly owned subsidiaries identified in the "Scope" section above ("**Organizations**") recognize the need to understand and define the Organization's Legal Health Record ("**LHR**"), particularly as it relates to the Shared Electronic Medical Record ("**Shared EMR**") system. While this guidance has been developed primarily for the Shared EMR system, it can also be used to guide management of patient health records in other health record applications (e.g., Meditech, Centricity, CattailsMD, etc.).

2. The Organization shall review components of its the Health Record System and determine how it impacts the definition of its LHR by addressing:
    A.   Who is the owner (individual or department) responsible for the health record component, application or system?
    B.   Who will create, maintain, and retain the health record component, application, or system?
    C.   How and by whom will the health record component, application, or system be accessed, used or disclosed?
    D.   What is the output, if any, of the health record component, application or system to the DRS and/or LHR (paper, electronic, computer screen, transmission, etc.)?
    E.   Does the information generated in reports or files relate to the provision of health services provided to the patient?
    F.   Does the information generated in reports or files support charges for the provision of health services?

3. The LHR serves many purposes and also identifies what information constitutes the official business record of the Organization for evidentiary purposes. The LHR is a subset of the all patient information databases (systems, applications, repositories); it is the documentation of health care services provided to the individual (patient) during any aspect of health care delivery. The Organization's LHR definition must explicitly identify the sources, medium, and location of the individually identifiable data that it includes. The Organization shall define and establish the LHR to:

    A.   Support the decisions made in patient care;

    B.   Support the revenue sought from third-party payers;

    C.   Document the services provided as legal testimony regarding the patient's illness or injury, response to treatment, and caregiver decisions; and

    D.   Serve as the Organization's business and legal record.

4. The LHR must meet the requirements and standards of state and federal laws, CMS (Medicare and Medicaid), accrediting agencies, as well as the Organization's policies.

5. When establishing the LHR, the Organization shall take into consideration the following:

    A.   <u>Authorship</u>: Individuals documenting in the health record have the authority and right to do so as defined by the Organization's policies and procedures. These individuals are trained and competent in the fundamental documentation practices of the organization and understand their responsibility for complete and accurate entries into the health record.

    B.   <u>Authentication of Entries</u>: Entries in the health record are authenticated and traceable to the author of the entry.

    C.   <u>Electronic Signatures</u>: Individuals authenticating entries into the health record understand the responsibilities of doing so in a timely manner as well as protecting the integrity of their electronic signature access.

    D.   <u>Documentation Principles</u>: Regardless of the format or entry mechanism, content of entries should be specific, objective, and complete. Abbreviations are appropriate as approved by the Organization.

    E.   <u>Cut, Copy, and Paste Functionality</u>: The primary issue with this functionality is who the author is and what is the date of origination. It is recommended that the original author and date should be evidenced in the copied information.[1]

    F.   <u>Linking Each Patient to a Record</u>: Every page in a health care record (paper or electronic) must identify the patient by name and health record number. Each data field in an Electronic Health Record document must be linked to the patient's name and number on every page printed, viewed, or otherwise transmitted. The system in use must have a means of authenticating information reported from other systems.

    G.   <u>Timeliness and Chronology of Entries</u>: Entries should be made as soon as possible after an event or observation is made. The health record must reflect the continuous

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[1] The need to identify the original author and date may be unnecessary if the direction to copy into another document comes from the same author (e.g., attending physician requests transcriptionist to copy section from his/her admission H&P to his/her discharge summary). This process will need to be clarified at the local level.

chronology of the patient's health care. Every entry into the health record must include a complete date (including month, day, and year) and a time.

H.   Legibility and Display: All entries to the record should be legible regardless of output (e.g., computer screen, printout, transmission, etc.).

I.   Corrections, Errors, and Amendments: Procedures must be in place to allow for appropriate corrections, errors, or amendments through tracking corrections and changes to the entry once the entry has been entered or authenticated. Changes to the health record must be made in a manner that makes it clear that a change was made, when the change was made and does not undermine the integrity of the health record.

J.   Output Format: Issues that require consideration regarding output format include (e.g., paper, CD, USB, other imaging device, transmission, etc.):

1.   Whether the document/record must be complete before output is generated.
2.   Who has the authority to generate output from the Electronic Health Record ("**EHR**")?
3.   What standardized forms, formats, and order are to be addressed in the output format?
4.   What version of the documents/records will be included in the output format?

K.   Printing Guidelines: The Organization must define the standard form and format of the paper health record output format.

L.   Permanency: All entries in the health record, regardless of form or format, must be permanent. Policies and procedures must be in place to prevent alteration, tampering, or loss.

M.   Retention: Retention of health records (paper or electronic) must be carried out in accordance with the Organization's retention schedule.

N.   Storage: The Organization must store health records in a manner that will prevent loss, destruction, or unauthorized access and use.

O.   Obsolescence of Technology: Stored health records must be accessible for the length of the retention period regardless of the technology used. Organizations must have a plan to access or reproduce EHR information. As technology changes, there must be consideration of the need to access previous systems from the new or upgraded systems.

6.   With regard to patient care records (paper, CD, USB, e-mail, etc.) received from health care providers outside of the Organization, the patient's provider and/or the Organization's health information management department shall evaluate the records to determine the need to incorporate the information into the Organization's patient health record/LHR. Ideally, the patient's provider should abstract only the key data from the external health records used in the care and treatment of the patient and incorporate it into his or her documentation; the external records may then be returned to the source or destroyed in a confidential manner. Any external health records retained by the Organization are to be considered part of the patient's LHR (see

Shared EMR Policy 7: Processing Outside (External) Records in the Shared EMR System and PV-19: Disclosure of Patient Health Information).

7. Health records accessed through the Shared EMR system and/or any other electronic health information exchange **shall not** be considered part of the Organization's LHR unless actual documents are downloaded/printed. If information from these sources is utilized, the provider shall document in the patient's health record the source of the information and the key elements of information gathered and used. Exception: If actual documents/files are downloaded/printed and incorporated into the Organization's patient health record, than these documents/files shall be considered part of the LHR.[2]

8. As identified by American Health Information Management Association ("**AHIMA**"), the following documents/files generally **are** included in the LHR:
    A.   Provider documentation (H&P, operative report, consultation, discharge summary, progress notes, physician orders, etc.).
    B.   Nursing documentation (assessments, progress notes, flow sheets, etc.).
    C.   Ancillary department documentation (PT, RT, OT, social services, dietary services, spiritual services, etc.).
    D.   Consents and parental permission slips that serve as consent for care.
    E.   Medication records.
    F.   Diagnostic studies (laboratory, pathology, diagnostic imaging reports, etc.).
    G.   Patient photographs and images.
    H.   Advance directive documents.

9. As identified by AHIMA, the following documents/files are generally **not** included in the LHR and not released pursuant to a standard authorization or request:
    A.   Alerts, reminders, and pop-ups used as aids on clinical decision-making processes.
    B.   Administrative documents used for administrative, regulatory, health care operation, and financial purposes. This would include:
        1.   Adoption papers to include administrative correspondence or court documents related to adoptions.
        2.   Appointment information and appointment slips.
        3.   Payer pre-authorizations and certifications for tests, diagnostic studies, other care and treatment.
        4.   Authorization forms for release of information and correspondence concerning requests for records.
        5.   Blood donor registration forms.
        6.   Public health reporting forms (e.g., communicable diseases, cancer registry, etc.).
        7.   Clinic correspondence for non appointments.
        8.   Court documents.

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[2] Based on industry best practices (ThedaCare/UW-M). Information available in HIE may not always be utilized and should not be included in the organization's LHR as it is not created or maintained by the organization and may also raise questions regarding liability of knowledge/review of all available patient health information resources.

9.   Durable Medical Equipment forms and purchase agreements (excludes provider orders).
10.   FMLA and disability forms for the purpose of communicating incapacity for third party payer purposes (excluding provider assessments and exams).
11.   Legal correspondence not related to health care.
12.   Patient appointment information.
13.   Patient requests for information, patient consent for release of information, and accounting of disclosures.
14.   Patient satisfaction questionnaires.
15.   Patient financial information (MECCA, charge sheets).
16.   Procedure supporting documents such as appointment schedules
17.   Third party forms required for activities.
18.   Documents identified as "organizational" by the facility.

C.   Working notes used by a provider in completing a final report unless they are made available to others providing care to a patient.

D.   Derived data and documents containing selected data elements to aid in the provision, support, evaluation, or advancement of patient care. This would include dashboard data to include problem lists and medication lists.

E.   Human resource employee health, wellness, and occupational health records of the Organization's employees.

F.   Patient identifiable research data.

G.   Third party forms required for activities/programs, government programs.

H.   Patient education/instructional materials not specific to a patient.

10. The Organization shall determine who internally "owns" or is responsible for maintenance of the health record/Legal Health Record (record custodian). This individual should be involved in all decisions regarding patient health information applications and systems that will contribute to the generation of the health record including:

A.   Investigating and establishing health record components, applications, and systems used to generate the health record/Legal Health Record.

B.   Establishing the ability to bring together health record documents from disparate paper and electronic (applications and systems) components to produce the health record/Legal Health Record upon request.

C.   Establishing who or what departments may disclose health record/Legal Health Record information in response to external requests. Generally, the Health Information Management Department is responsible for disclosure of patient health information.

11. Upon request for disclosure of the patient's health record, the Organization shall disclose only those components of the health record that make up the defined LHR. There may be times when an individual has a legitimate need to access source data that are not considered part of the LHR or Designated Record Set. These requests shall be referred to the privacy officer and/or legal counsel.

Attachments:
- Attachment A: Health Record Matrix Components of DRS/LHR SAMPLE
- Attachment B: Documents Not Considered Part of LHR

Definitions: In order to fully understand the complexity of the various components of the LHR, it is important to be able to understand the following definitions.

Custodian of the Health Record: An established legal designation that assigns responsibility for the management and production of the health record to one individual. Traditionally this has been the leader of the Health Information Management Department; however, in the Electronic Health Record environment it is managed in collaboration with information technology leadership. The health information leader oversees the health record operational functions. Information technology leaders oversee the technical infrastructure components of the Electronic Health Record. Legal requests will often require certification or testimony to the accuracy and completeness of the record by the "custodian of the medical/health record."

Derived Data and Documents: Derived or administrative data are derived from the primary health care record and contain selected data elements to aid in the provision, support, evaluation, or advancement of patient care. Derived data and documents should be provided the same level of confidentiality as the Legal Health Record. However, derived data should not be considered part of the record and would not be produced in response to a subpoena for the medical record.

Derived data consist of information aggregated or summarized from patient records so that there are no means to identify patients. Examples of derived data are:
- Accreditation reports
- Anonymous patient data for research purposes
- Best-practice guidelines created from aggregate patient data
- OASIS reports
- ORYX, Quality Indicator, Quality Measure, or other reports
- Public health reports that do not contain patient-identifiable data
- Statistical reports
- Transmission reports for MDS, OASIS, and IRF PAI

Designated Record Set (DRS): Defined in the HIPAA Privacy Rule as a group of records maintained by or for a health care Organization that includes:
- The medical and billing records about individuals maintained by or for a covered health care provider;
- The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan, or
- Information used in whole or in part by or for the health care Organization to make decisions about the individual.[3]

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[3] May 31, 2011; NPR – Right to electronic access report provides requestor right to request an access report to all records/files maintained in designated record set.

The Designated Record Set is generally broader in scope than the LHR because it addresses all protected health information. Under HIPAA, used to clarify the rights of individuals to inspect and obtain a copy, request amendments, and set restrictions and accountings of medical and billing information.

Health Record System: Encompasses all electronic and paper applications and systems within the health care Organization that receive, collect, disseminate, and store patient protected health information. The Health Record System may include applications and systems, which are not part of the Designated Record Set or Legal Health Record (e.g., scheduling information) and do not result in transfer of information to the actual patient health record.

Electronic Health Record (EHR): An EHR system consists of integrate component information system and technologies; medical information compiled in a data-gathering format for retention and transfer of protected information via a secured, encrypted communication line. The information can be readily stored onto an acceptable storage medium, such as a compact disk. Other common terms used interchangeably for the EHR: electronic medical record (EMR), computerized patient record (CPR), computerized medical record (CMR). Inputs into the EHR may include laboratory information, pharmacy information, picture archiving and communications (PACS), cardiology information, results reporting, computerized provider order entry, nurse care planning, transcription, document imaging, etc.

Legal Health Record (LHR): The LHR is the documentation of the health care services provided to an individual in any aspect of health care delivery by a health care provider organization. The LHR is individually identifiable data, in any medium, collected and directly used in and/or documenting health care or health status. The term includes records of care in any health-related setting used by health care professionals while providing patient care services, for reviewing patient data, or documenting observations, actions, or instructions. Some types of documentation that comprise the Legal Health Record may physically exist in separate and multiple paper-based or electronic/computer-based databases.[4] The Legal Health Record is generated at or for a health care organization as its business record *and is the record that would be released upon request.* It does not affect the discoverability of other information held by the Organization.

Metadata: Data that provides a detailed description about other data. "Information about a particular data set or document that describes how, when, and by whom it was collected, created, accessed, or modified and how it is formatted.

Personal Health Record (PHR): An electronic subset of patient health information that captures, stores, and processes the data and provides sufficient functionality to access and exchange health information, as well as to assist the individual in making health decisions. PHRs are for patient personal use, regardless of who creates, stores or maintains them.

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[4] Limited definition as developed by the American Health Information Management Association, October, 2001.

<u>Shared EMR</u>: For the purposes of this Position Statement the Shared EMR is defined as the patient Electronic Health Record (EHR) application which has been developed by the Marshfield Clinic and Ministry Health Care. Organizations which utilize the Shared EMR as its EHR application are referred to as Tier 1 participants. Organizations which access the Shared EMR for patient care information as "read-only" are referred to as Tier 2 participants.

<u>Source Records</u>: Source records may include diagnostic images, video, voice files, and e-mail. The Organization must determine which of these data elements, electronic-structured documents, images, audio files, and video files, if any, to include in the Designated Record Set and/or Legal Health Record (e.g., pathology slides, diagnostic films, electrocardiogram tracings from which interpretations are derived).

Background:
The purpose of this guidance is to provide assistance to Shared EMR Tier 1 participants in identifying and defining the Legal Health Record (LHR) which is created and maintained in the Organization's Shared Electronic Medical Record (EMR) application. It is strongly recommended that Tier 1 participants create and maintain an Organizational LHR policy and supporting procedures for creation, maintenance, retention, access, use, and disclosure of its LHR.

<u>Legal Health Record vs. Designated Record Set</u>: The HIPAA Privacy Rule addressed for the first time the concept of the designated record set (DRS) and legal health record (LHR) for health care organizations. The Privacy Rule defined the DRS to include information beyond the traditional health record documents (e.g., financial, billing, insurance, etc.).   While similar to the DRS, the LHR is actually a subset of the DRS, including financial, billing, insurance and other related documents. In general, rarely are financial and billing records disclosed unless specifically requested. The DRS is generally broader than the LHR because it addresses all protected health information. The LHR is generally the information used by the patient care team to make decisions about the treatment of a patient. The DRS contains protected health information along with business information unrelated to patient care.

There are currently no federal or state regulations which identify the requirements for the legal health record. The most definitive source of information on the establishment of the legal health record is provided by the American Health Information Management Association (AHIMA). AHIMA regularly researches and addresses all issues related to the LHR and updates its body of knowledge as applicable. The creation of this guidance relied heavily on the AHIMA practice brief "*Fundamentals of the Legal Health Record and Designated Record Set*" which was updated and republished in February of 2011.
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Distribution: Ministry Health Care and all wholly owned Ministry Organizations, including Ministry Door County Medical Center and Ministry Saint Elizabeth's Medical Center, except Agape. Agape Community Center will be provided notification of and access to all Ministry Administrative Guidance and will determine applicability and the need to implement.

Values: This Position Statement has been reviewed for support of the Ministry Health Care Values.

Key Words and Terms: Custodian of the health record, designated record set, electronic health record, legal health record, personal health record

Applicable Joint Commission Standards:
- IM.02.01.01 – Privacy of Health Information
- IM.02.01.03 – Security and Integrity of Health Information
- IM.02.02.01 – Management of Health Information

Applicable Federal/State Regulations:
- HIPAA 45 CFR 165.501 – Designated Record Set

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MINISTRY HEALTH CARE

Attachment A: Health Record Matrix Components of DRS/LHR SAMPLE

The matrix below is a tool Organizations can use to help identify and track the paper and electronic portions of the health record during an EHR implementation and ongoing maintenance. Organizations can customize this matrix to their needs and add specific items that should be considered when implementing an EHR. It is up to each individual Organization to determine what health information is considered part of their Legal Health Record and their Designated Record Set.

Type of Application/ Document/ File	Name of Application/ Document/ File	Primary Source	Primary Source System Implementat ion Date	Part of Designated Record Set	Part of Legal Health	Reviewed by/Decision Made by (Authorizing Body) & Date
Nursing	ICU nursing assessment	Electronic nursing documentation system		Yes	Yes	Standard of care/ documentation
Nursing	I & O worksheet	Paper		No	No	Information transferred to Vitals Record
Physician Orders	Congestive heart failure standing order set	Computerized physician order entry system		Yes	Yes	Standard of care/ documentation
Emergency Department	Emergency department treatment record	Paper		Yes	Yes	Standard of care/ documentation
Advance Directives	Power of Attorney for Health Care	Paper	External	Yes	Yes	AHIMA Guidance 2009
Discharge Summary Transcribed Report	Discharge summary	Transcription system		Yes	Yes	Standard of care/ documentation
Payment	EOB	Patient Financial System		Yes	No	Standard business record documentation

Attachment B: The following table provides examples of those documents that are not generally included in the Legal Health Record.

Outside the DRS/LHR	Examples
Health information generated, collected, or maintained for purposes that do not include decision making about the individual	Data collected and maintained for research Data collected and maintained for peer review purposes Data collected and maintained for performance improvement purposes Appointment and surgery schedules Birth and death registers Surgery registers Diagnostic or operative indexes Duplicate copies of information that can also be located in the individual's medical or billing record
Psychotherapy notes	The notes of a mental health professional about counseling sessions that are maintained separate and apart from the regular health record
Information compiled in reasonable anticipation of or for use in a civil, criminal, or administrative action or proceeding	Notes taken by a covered entity during a meeting with the covered entity's attorney about a pending lawsuit
Clinical Laboratory Records	Requisitions for laboratory tests (may need to adjust of the requisition serves as the order) Duplicate lab results when the originals are filed in the individual's paper chart
Employer records	Pre-employment physicals maintained in human resource files The results of HIV tests maintained by the infectious disease control nurse on employees who have suffered needle stick injuries on the job
Business associate records that meet the definition of Designated Record Set but that merely duplicate information maintained by the covered entity	Transcribed operative reports that have been transmitted to the covered entity
Education records	Records generated and maintained by teachers and teachers' aides employed by a school district or patients in acute care hospitals, institutions for the developmentally disabled and rehabilitation care centers
Source (raw) data interpreted or summarized in the individual's medical or health record	Pathology slides Diagnostic films Electrocardiogram tracings from which interpretations are

Outside the DRS/LHR	Examples
	derived
Versions	Management of multiple revisions of the same document. By versioning, each iteration of a document is tracked.
Metadata	Data that provides a detailed description about other data. "Information about a particular data set or document that describes how, when, and by whom it was collected, created, accessed, or modified and how it is formatted.
Audits	Results of reviews to identify variations from established baselines or used to track an individual's activity in an electronic system (e.g., view, print, edit).
Pending reports	Reports that have been initiated by a member of the health care team but not yet authenticated and may not be available for viewing by staff until completed. An EHR system will keep these documents in a pending or incomplete status.
Miscellaneous records	▪ Adoption Records ▪ Guardianship Papers (may be disclosed if situation warrants – professional judgment).
Quality improvement/peer review records	▪ Medical Staff Case Reviews
Registry information	▪ Birth Registers ▪ Death Registers ▪ Surgery Registers ▪ Cancer Registers ▪ Trauma Registers
Research records	▪ Records Maintained for Research Purposes
Risk management records	▪ Incident/Variance Reports
Schedules	▪ Surgery Schedules ▪ Appointment Schedules
Triage/nurse call records	▪ Audiotape recordings of Calls ▪ Triage Log of Call