Department: Legal	Effective Date: 08/07/2019
Unit: Privacy	Most Recent Revision Date: 07/22/2020
Policy Title: HIPAA Designated Record Set Policy	Applies to: ☑ MCS Healthcare Holdings, LLC ☑ MCS Advantage, Inc. ☑ MCS Life Insurance Company ☐ MCS General Insurance Agency
Approved by: Corporate Compliance Committee	

POLICY

1. The Designated Record Set includes, as it relates in whole or in part to making decisions about the patient:

   a. *Inpatient/Outpatient Medical Records* - Examples include, but are not limited to, the following:
      i. Advanced Directives
      ii. Physician/Non-Physician Practitioner Orders
      iii. Telephone Consultations
      iv. Emergency Room Record (i.e. Triage, Assessment and Examination, etc.)
      v. Ambulance Record
      vi. Consent Forms
      vii. Discharge Summary Reports
      viii. History and Physical Reports
      ix. Progress Notes
      x. Ancillary Reports
      xi. Therapy Notes
      xii. Operative, Surgery or Procedure Reports
      xiii. Nurses Notes/Assessments
      xiv. Medication Administration Record (MAR)
      xv. Intake/Output Records
      xvi. Visit Sheets
      xvii. Consults
      xviii. Authorizations/Consents
      xix. Patient Submitted Documentation
      xx. Source data not interpreted or summarized in the medical record (i.e. EKG
      xxi. strips, fetal monitor strips, etc.)

   b. *Financial/Billing Records* – Examples include, but are not limited to, the following:
      i. Detailed Bills
      ii. UB 04, HCFA 1500
      iii. Insurance information
      iv. Records of Payment
      v. Adjustments Advanced
      vi. Eligibility information
      vii. Enrollment Records

   c. Other records used to make decisions about patients – Examples include, but are not limited to, the following:
      i. Audiotapes not transcribed (e.g. dictation tapes, taped sessions with patients/family that would not be considered psychotherapy notes)

ii. Videos/photographs of patients
iii. Utilization review worksheets

d. *Business Associate Records* - Records maintained by a Business Associate that fall within the definition of Designated Record Set, that are not merely duplicates of information maintained by MCS, and which are required to determine compliance with HIPAA regulations.

2. The Designated Record Set does not include health information generated, collected, or maintained for purposes that do not include decision making about the patient or which is exempt from disclosure to the patient/ Such information includes, but is not limited to:
   a. Research records while the individual is part of a clinical trial, while the clinical trial is in progress.
   b. Data collected and maintained for peer review purposes
   c. Data collected and maintained for performance improvement purposes
   d. Data collected and maintained for compliance purposes
   e. Data collected and maintained for quality control purposes
   f. Risk Management records
   g. Appointment and surgery schedules
   h. Birth and death registers
   i. Surgery registers
   j. Cancer Registry information
   k. PHI that may not be released because it is covered by the Clinical Laboratory Improvements Amendments of 1988 (CLIA).
   l. Psychotherapy Notes
   m. Substance Abuse Treatment Records (pertaining to 42 CFR Part2)
   n. Information compiled in reasonable anticipation of or for use in a civil, criminal, or administrative action or proceeding.
   o. All employee health records
   p. Source data interpreted or summarized in the individual's medical record (for example, Pathology slides; diagnostic films; electrocardiogram tracings from which interpretations are derived; photographs; fetal monitor strips, etc.)

3. The Designated Record Set contents can be maintained in either paper (hardcopy) or electronic formats, including digital images and scanned documents, and can include Patient identifiable source information, such as photographs, films, digital images, fetal monitor strips, and a written or dictated summary or interpretation of findings.

4. A beneficiary does not have a right to access the documents that are not considered part of the Designated Record Set for any purpose. As such, workforce members must pay particular attention to those records that are not included in the Designated Record Set and which are not available for patient inspection and amendment. Any questions regarding requests for those types of records should be referred to the Privacy Officer.

DEFINITIONS

1. Authorization: refers to a written permission from an individual that gives a Covered Entity or employer permission to use or disclose Protected Health Information (or other confidential medical information) for specified purposes, which are generally purposes other than managing treatment, payment, or health care operations.

2. Business Associate (BA): a person or organization that receives protected health information from MCS to provide services to or on behalf of MCS, or a person or organization that performs a professional service for MCS that involves the use of protected health information.

3. Covered Entity (CE): A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted standards under HIPAA.

4. Designated Record Set: Is defined as a group of records maintained by or for a covered entity that comprises:
   - The medical records 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
   - other records that are used, in whole or in part, by or for the covered entity to make decisions about individuals.

5. Disclosure: Refers to the release, transfer, access to, or divulging of information in any other manner outside the entity holding the information.

6. Health Care Operations: refers to certain administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment.

7. Individual: Refers to the person subject of the Protected Health Information.

8. Payment: encompasses the various activities of health care providers to obtain payment or be reimbursed for their services and of a health plan to obtain premiums, to fulfill their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care.

9. Personal Representative: an individual with the legal authority to act on behalf of an incompetent adult, an unemancipated minor, or a deceased individual, or the deceased estate, in making health care decisions or in exercising the patient's rights related to the individual's protected health information and HIPAA Privacy Rules.

10. Protected Health Information (PHI or ePHI): Means individually identifiable health information that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. "Individually identifiable" means that the health or medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

11. Treatment: means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another.

12. Workforce: Refers to employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

REFERENCES

Federal

- Health Insurance Portability and Accountability Act of 1996 – Pub.L. 104–191 (110 Stat. 2033)
- Individual Protection and Affordable Care Act – Pub.L. 111-148 (124 Stat. 119)
- American Recovery and Reinvestment Act of 2009 – Pub.L. 111–5

State

- Individual's Bill of Rights and Responsibilities – Public Law No. 194 of August 15, 2000, as amended.
- Puerto Rico Health Insurance Code – Public Law No. 194 of August 29, 2011, as amended – Chapter 14.

RELATED MCS POLICIES

- CA-SP-014: Verification of a Person's Identity
- MCS-Policy-024: Individual's Privacy Rule Rights
- MCS-POLICY-065: Minimum Necessary Policy
- MCS-Policy-088: HIPAA Complaints Policy
- CA-COMP-085: Disciplinary Actions for Non-Compliance of HIPAA Regulations

POLICY REVISIONS

DATE	CHANGE(S)	REASONS
08/07/2019	New Policy	To document compliance with 45 CFR 164.501
07/22/2020	Updated to reflect organizational changes.	Annual revision