

Quality, Defensibility, and the Electronic Medical Record

Several Elements of an EMR System May Contribute to Defensibility and Should Be Considered

The development of the electronic medical record (EMR), or the electronic health record (EHR), has the potential to revolutionize many aspects of documentation management for health care organizations of all types. Aside from its service to billing and reimbursement, is medical record quality a quality and compliance issue? Medical records documentation problems contributed to the development of 6,702 physician professional liability or medical malpractice cases with indemnity payments of \$382 million from 1985 to 2005, according to just one database of professional liability claims.¹

Medical records documentation has a direct impact on compliance investigations. For example, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and the Department of Justice (DOJ) used medical records documentation in prosecution of the Tenet Healthcare Corporation/Redding Memorial Hospital case in 2005. Medical record documentation that supports or contraindicates billing for services is commonly studied by investigators.

In the case of Redding, the DOJ and OIG found a lack of medical necessity for cardiac procedures performed from 1988 to 2002, and investigators noted 13 medical malpractice lawsuits against physicians between 1988 and 2002. Tenet faced exclusion of the facility and reached a divestiture agreement with the OIG, in addition to paying a \$54 million settlement with the DOJ.²

A variety of laws, rules or statutes and regulations can be implicated through inadequate medical records documentation. These can include:

- Medicare Conditions of Participation (CoP):
 - Patient Rights (*Interim final rule*, 64 FR 36069, July 2, 1999),



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The views expressed in this article are those of the author and do not necessarily reflect the official policy or position of the Air Force, the Department of Defense, or the U.S. government.

- Quality Assessment, Performance Improvement (*Final rule*, 68 FR 3435, January 24, 2003),
- Authentication of Verbal Orders (42 C.F.R. §482.24(c)(1));
- False Statements Concerning Health Care (18 U.S.C. §1035);
- Schemes to Defraud Health Care Programs (18 U.S.C. §1347);
- Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. §299c-21); and
- Federal False Claims Act (31 U.S.C. §§3729-3732).

This article focuses on the aspects of an EMR that can contribute to and hamper quality and defensibility of medical decision making, treatment, and continuity of care.

EMR is a rapidly developing field. As such, a comprehensive body of literature regarding EMR successes and failures is still emerging. Much of the information provided in this guide is given not from a retrospective review of past history but a prospective view of what EMR can and should do to assist the health care provider. This guide may be of particular interest to physicians and health care organizations considering an EMR acquisition. While it does not endorse any particular EMR product, it does provide the reader information on certain aspects of an EMR that can be of particular benefit to complete and comprehensive medical records development.

DEVELOPMENT OF THE ELECTRONIC MEDICAL OR HEALTH RECORD

EMR products of various types have developed simultaneously with the emergence of technology that supports the creation of a contemporaneous electronic record of patient encounters and captures in the same media pre-encounter data (such as patient registration) and post-encounter information (such as consulting reports or laboratory tests).

Arguably, the early development of some types of EMR and increased acceptance of practice management systems (PMS) were propelled by the implementation of computerized claims filing. As federal, state,

and private payer sources began to accept, and then require, electronic submissions of claims, medical practices began to use PMS that supported electronic billing.

The passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) included a timeline for development of transaction sets and code standards that could be universally applied for all electronic transactions between government payers and health care providers. HIPAA also provided privacy and security standards for the protection of personal health information (PHI) that may be stored in EMR systems.

HIPAA's security standards recognized in part that vast quantities of electronic patient information could be generated and disseminated by EMRs, sometimes to the detriment of the patient if not adequately protected. HIPAA's privacy provisions were designed to protect the health information rights of individual patients.³

The use of computerized billing systems/PMS is now virtually universal in medical practices and health care organizations that bill federal, state, and managed care companies. At the same time, the use of personal data devices and computers has dramatically increased to encompass most health care providers and organizations. With improvements in technology there also have been improvements in functionality; devices are increasingly user friendly and are now used by physicians, nurses, and support staff.

There are barriers to use of an EMR, however. Cost of implementation, complexity of systems and the process of evaluating them, and the ability of a system to decrease practice expense and recoup initial investment are some common reasons physicians and health care organizations may not have selected an EMR. Implementation of an EMR with effective positive results is also complex and requires cooperation and consistency among all parties. Finally, the universe of vendors (estimated at over 1,000 in the United States alone) provides a staggering number of choices and complexity.

QUALITY OF CARE AND EMR

Many schools of thought equate an EMR with improved quality of care. Easily accessible health records and patient information may speed care and reduce the potential for medical errors. Automated systems such as computerized drug reconciliation programs or medication adverse event warnings can provide physicians with immediate access to drug contraindications. Easily missed data such as drug allergies can be readily accessed or searched for in electronic files with appropriate database management. Patient identification with a specific record or data can be verified more easily using unique identifiers, reducing the possibility of misdiagnosis.

The Medicare Physician Quality Reporting Initiative (PQRI) lists 100+ quality measures that may lead to improvements in quality of care. EMR is seen as a logical progression of a system that allows physicians to identify measures they wish to track and provides payments for those that successfully monitor and report on measures. Physician order entry and the use of electronic prescriptions is one example of a quality measure used in pay-for-performance (P4P) systems.⁴

An EMR system cannot in and of itself improve quality of care, but it can improve the capture and flow of data to health care providers who make decisions regarding patient care, and it may decrease the time needed to identify, locate, and disseminate information that will contribute to correct medical decision making.

EMR AND DEFENSIBILITY OF DOCUMENTATION

The use of any comprehensive information management system that accurately captures data is a “double-edged sword” when it comes to defensibility. Accurate EMR data collection systems may provide the physician with a wealth of data and information regarding a patient’s health and condition. Accurate capture of all data means the physician is increasingly responsible for accurate decisions using the data. In an environment where all information is readily

available, health care providers will be expected to access and use the data accurately and comprehensively.

Physicians and other caregivers also may be held responsible for failing to review or use data captured by an EMR. For instance, computerized systems will almost certainly record medical tests ordered, day and time the test was ordered, the test results, and the day and time the test was reviewed by the health care provider. A delay in review, a failure to review, or a failure to recognize problems and act on test results also will be recorded or will appear as a gap or time lag in the information flow.

Several elements of an EMR system may contribute to defensibility, if properly utilized and implemented by health care organizations and physicians. These elements should be included in the capability sets of a practice-based EMR. This list is not all inclusive.

Accurate Capture of Patient Identification/Ability to Distinguish between Patients

An EMR should include systems to capture and record patient identification using two or three elements. This can allow the EMR to distinguish between patients with the same name by using other data such as birth date to ensure the correct patient record is being presented along with the patient. Patient identification should be recreated on each page of data accumulated by the EMR.

Accurate Capture of Medical Problem, Treatment, Medication, and Allergy Lists

Use of problem and medication lists that are regularly updated decreases the opportunity for missed diagnosis or medication errors. EMR systems should allow capture of this information and should share the data for health care provider review at each patient visit. Some EMR systems allow patients to update and share this data (and basic registration) via Internet-based systems. It should be noted, however, that submitted data must

be reviewed and approved by staff members, who then authorize insertion into the medical record. The patient does not have direct access or the ability to permanently change the record. Other EMR systems allow staff members to print off the data, and then ask patients to verify the data on check-in and sign that they have verified the data.

As an aside on good patient-staff communications, patients are frequently angered by being asked to complete a blank form on medications and problems at each visit. Using a printed list of medication and problem information is a far superior process. A complete list lessens the chance that important medications will be forgotten and fosters trust that the practice is aware of and records the various health issues of each individual. Allergies should be collected and reviewed in this process, with recognition that new allergies may develop over time even in adult patients.

Identification of Tests Previously Ordered, or Results Not Yet Received

The EMR should flag tests ordered and in need of review and should identify tests for which results are not yet available. Staff and health care providers are then readily aware of any outstanding information needed for the current patient visit.

Identify Consulting Reports or Consulting Referrals Completed or Not Yet Complete

The EMR also should track and flag consulting reports received since the last visit, or referrals ordered but not yet complete. This allows the health care provider to review the consultation information prior to the patient visit or begin a search to learn why reports are not yet available.

Track Prescriptions and Sample Medications and Reconcile Medications

An effective EMR will track prescriptions for each patient and include software that allows quick review of medications for contraindications. Allergy data also should be a

factor in the prescription/medication review process. A medication reconciliation should occur with each new prescription written and ideally is an automated process that provides alerts to the health care provider when potential problems are identified.

Record Subjective and Objective Findings and Analysis along with Review of Systems Data Needed for Billing and Reimbursement

The system should allow entry of findings and review of systems (ROS) data. Advanced systems will automatically select a Current Procedural Terminology®, Version 4 (CPT®-4) Evaluation and Management billing code that is then verified and accepted, adjusted, or rejected by the physician or provider responsible for the visit. This process can improve regulatory compliance by identifying the correct code based on data entered during the visit. The system should allow complete capture of the medical plan of treatment based on the visit findings.

New Laboratory Orders, Diagnostic Studies, Treatments, Prescriptions, Sample Medications, and Refills

The EMR should capture new tests, prescriptions, sample medications issued, or refill data and send data to the appropriate location in the system. For instance, a new prescription written should automatically populate the medication list with that information (and complete a new medication reconciliation with flags to the provider for any contraindications noted).

Sample medications given should show up as a “sample medication” addition to the medication list or as a separate list of samples given. From a risk management perspective, sample medication lists allow contact with patients in the event of a medication recall. There are approximately four to six major Food and Drug Administration (FDA) recalls each year.

Follow-up Appointments

The system should capture follow-up visit information and ensure staff members at the front desk are alerted to schedule follow-up visits.

Patient Education/Informed Consent

The EMR should generate appropriate patient education information on ordered medications, tests, or procedures and print that information to be given to the patient along with verbal instructions. The system should alert physicians or providers that informed consent is required prior to procedures or surgeries and also may print consent documents for patient review.

Plan of Treatment

Systems should capture the plan of treatment for the patient and populate reminders for tests, procedures, and appointments based on the plan of care recorded.

Physician or Provider Signature

The EMR should generate a final electronic document that is prepared for physician or provider review and electronic sign off. Advanced systems create a task list for the originating provider, and the task is not recorded as complete until it is reviewed and signed off electronically.

Appointment Management Information

Advanced systems also will contribute regular reports on provider productivity, numbers of patient visits by type, billing and reimbursement tracked a variety of ways, and tests ordered. Data on patient wait time, patient treatment time, and number of patients seen should be readily available.

Consultation and Test Follow Up and Management

Reminder systems should be included in an EMR that will identify patients needing referral or consultation. A reminder system should be included that notifies providers of the completion of tests, or reminds them of follow-up needs.

This should not be considered a comprehensive list of all data elements needed in an effective EMR. It is a list of common operational tasks the EMR should address and can easily be added to or enhanced with additional elements.

It is relatively easy to list common tasks that will improve defensibility. It is much more difficult to set up, operate, and maintain an EMR that includes these capabilities.

IMPLEMENTING DEFENSIBLE EMR

Management of Old Paper Records

What does a paperless medical practice do with old paper medical records? Colonel Dennis Marquardt, RN (USAF, retired), notes:

The paper record is a valuable piece of the patient's history that must be preserved. The length of time will probably be a combination of state laws, how much of the record was scanned or transferred into the EMR, and facility policy. ...The "rub" for risk managers is to make sure that past medical history is available to the provider, and that current encounter information is being recorded in the EMR.⁵

Some practices scan all older files into the new EMR system prior to going online. This can be a time-consuming job, but it creates a more comprehensive EMR end product. Other practices will record only certain critical information and maintain the old paper record as a second reference. In the event this is done, management of the older record and the new EMR simultaneously is important. Col. Marquardt goes on to note:

...the provider will probably not read through the paper copy and EMR during the short encounter time with the patient. This, however, does not relieve the provider (or the organization) of the responsibility

ty or accountability for the information contained in the paper record regarding past medical history.⁶

Coordination of information is vitally important if paper records are maintained as a reference and a new EMR is used as the current recordkeeping system. Extra care is needed to ensure physicians use the older record as an “encyclopedia” and the new record as the current system of up-to-date documentation. Although a reference to information contained in an older paper record may be appropriate, making such reference may extend the period of time the paper record must be maintained as well. A reference to an older document may make that document an important piece of future defensibility.

Garbage In, Garbage Out

For many years, computer programmers have used the acronym GIGO (Garbage In, Garbage Out) to describe the capabilities of computer systems. Simply put, the computer system is able to produce information equal to the quality of data given it. Good and careful input should create meaningful and useful output. Poor input will create poor output.

Because of this quality, the EMR takes on an importance not only to quality of care but to regulatory compliance. A large multispecialty group implemented EMR and then undertook a retrospective study of effectiveness six months later. The retrospective study determined that less than half of the records created during the previous six months contained sufficient documentation to support the evaluation and management (E&M) billing code assigned the service. Ineffective implementation and monitoring created a compliance issue, management problem, and defensibility concern.

If paper documentation systems are not pristine, do not expect the EMR system to improve documentation or defensibility. Health care providers are likely to migrate

current bad documentation habits to the EMR platform. Successful implementation of an EMR system should include development of printed copies of documentation templates that will be used during a transition period. Physicians should use the paper system and learn what documentation is needed during a transition period. Compliance and documentation should be monitored. When good documentation is being consistently recorded, it is time to begin the process of transition to the EMR framework.

Once transition has occurred, it is important to monitor effectiveness and compliance. A system of routinely checking documentation patterns is highly recommended, especially during the first 12 to 24 months of operation. The practice may be well served to conduct regular, at least annual, checks of billing and documentation patterns for all health care providers. Properly set up, these checks also can meet recommendations of the OIG for a regular review of documentation and regulatory billing compliance.⁷

EMR Data Longevity

Statutory limits usually are applied to the retention of medical records documentation, with most documents maintained a minimum of seven to 10 years and pediatric records until the age of majority.

EMR provides the ability to store vast amounts of data without traditional paper record limitations. In addition, EMR systems will track user activity and changes. These are positive considerations in favor of EMR systems. They also put users on notice that all data entered (including incorrect data) and all use of the record (including alterations) will be permanently recoverable.

An entire field of litigation experts now focuses almost exclusively on the impact of EMR and other computerized systems. EMR users should take special care in the management of information, as the information and any changes made to it will be permanently available with sufficient research and expertise. Future litigation almost certainly

will require submission of both individual plaintiff patient information and the ability to track all use of that information.

CONCLUSION

EMR is a burgeoning field of activity in health care today. Most information readily available about EMR systems is produced by vendors, with some material available from organizations that now provide vendor certifications.⁸

For many reasons, EMR is an attractive choice to physicians and health care organizations. With effective implementation, EMR offers speed and ease of access, multiple user capability, decreased storage costs and staff costs, and clinical support systems that can assist physicians and other users, such as physicians desk reference (PDR)-based medication reconciliation processes to avoid adverse medication incidents. The field is new, and studies on comparative functionality of EMR systems are very limited if available at all.

Defensibility of EMR documentation is also being tested in the courts even as various systems are being tested by users. Certain elements of good documentation, electronic or manual, are readily recognizable. Time and usage will identify other process steps that will improve defensibility.

Physicians should be aware that EMR documents are permanent and that user access is easily tracked. Poor documentation input will result in poor documentation output. EMR systems alone do not guarantee “better” documentation. Effective implementation of the EMR system is arguably the most important step in the documentation pro-

cess. Inadequate training and adherence to system use likely will result in inadequate documentation and limit defensibility.

Endnotes:

1. Physician Insurers Association of America (PIAA), Data Sharing Project, compilation of data on professional liability case indemnity payments for all specialties involving medical records problems, Report 052, 2006.
2. HHS, Office of Inspector General (OIG), *OIG News*, Dec. 11, 2003, *OIG and Tenet Healthcare Corporation Reach Divestiture Agreement to Address Exclusion of Redding Medical Center*, www.hhs-oig.gov.
3. HHS, Office of Civil Rights, *The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Frequently Asked Questions*, contains information on HIPAA privacy standards, www.hhs.gov/ocr/hipaa.
4. HHS, Centers for Medicare & Medicaid Services (CMS), *Physician Quality Reporting Initiative, PQRI Overview*, www.cms.hhs.gov/pqri.
5. Dennis Marquardt, Col, USAF (Ret), *The Electronic Medical Record: EMR Factors to Consider*. Research article and personal interview. Col. Marquardt is the Chief, Performance Improvement/Risk Management at a large Air Force outpatient medical facility in Texas, a former Commander (chief executive officer) of two military hospitals, a vice president of Patient Care, a chief nurse executive, a consultant to the Air Force Surgeon General for Ambulatory Care Services, a consultant for Flight Nursing to the Air Combat Command Surgeon General, and the former chief operating officer/risk manager for the largest civilian multispecialty clinic in North Texas.
6. *Ibid.*
7. HHS, Office of Inspector General (OIG), *Compliance Program Guidance*, www.oig.hhs.gov/fraud/complianceguidance.html.
8. Organizations, such as the Certification Commission for Healthcare Information Technology (CCHIT), are independent organizations providing certification of EMR systems and tracking incentives offered for use by health care providers. Visit www.cchit.org for more information.

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