Compliance Issues for Rural Health Clinics

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Documentation

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Importance of Documentation in Medical Records

- Rural health clinics (RHC) must report revenue codes and HCPCS codes and charges for all services on separate lines outside of the qualifying visit line—a significant change to RHC billing. Proper documentation to support these charges for qualifying visits, items, and services is now more important than ever.

If It's Not Documented, It's Not Done

- Document EVERYTHING to prevent fraud or False Claims Act violations
  - It is fraudulent to either document services that were not performed or to submit claims for services without appropriately documenting those services.

- Missing clinical notes or test results, (dates, signatures, orders, care or service rendered), incomplete or illegible documents, or improper billing and coding can be interpreted as fraud or abuse and lead to a false claim with the government resulting in penalties.

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Requirements for Medical Records

- Federal
  - The Federal regulations governing the certification of RHCs were published in the "Federal Register" on July 14, 1978, 43 FR 136. Conditions for certification under those regulations are the subject of these guidelines.

State

Medical records shall be maintained in accordance with the following guidelines:
https://chfs.ky.gov/agencies/dph/dafm/lhpb/.../MedicalRecordsManagement.docx

Content

1. The medical record shall contain sufficient information to identify and assess the patient and furnish evidence on the course of the patient's health/medical care.
2. The record shall include accurate and legible documentation of any local health department activity involving or affecting the patient's health to include but not be limited to assessment, tests, results, and treatment. Red or fluorescent allergy stickers may be displayed on the front of a medical record to alert the health care provider of a potential emergency that can interfere with a patient's medical care or treatment. Allergies may also be written in red within a medical record.
3. All medical records must be maintained in a standard format with entries and forms filed in chronological order with the most recent on top.
4. Each form/document filed within the record shall include the patient's name, identification number and clinic identifier. (The computer generated 1 or 2 label may be used.)
5. Each entry in the record shall contain the date of service, description of service, provider's signature and title.

NOTE:A service providers' legend must be maintained which contains the signature, title of provider, provider's initials and employee ID number. It is to be retained permanently and kept current of new certifications or license privileges. (See "Scope of Practice" in Administrative Reference (AR) Personnel Section for instructions on updating license/certification of personnel.)

Records System Compliance

- A RHC that has an electronic health record (EHR) system may be part of a larger EHR system or may participate in a systematic exchange of patient health care information to promote good patient care.
  - In either insistence, only the appropriate RHC staff may have access to the medical records of RHC patients.

- The RHC's written clinical records policies and procedures reflect that it is part of a larger system or exchange, when applicable.
  - Even when the RHC participates in a larger EHR system, the clinical records for all RHC visits must still meet the requirements of the RHC Patient Health Records Condition
  - Must be readily retrievable and distinguishable from other information in the shared EHR system.

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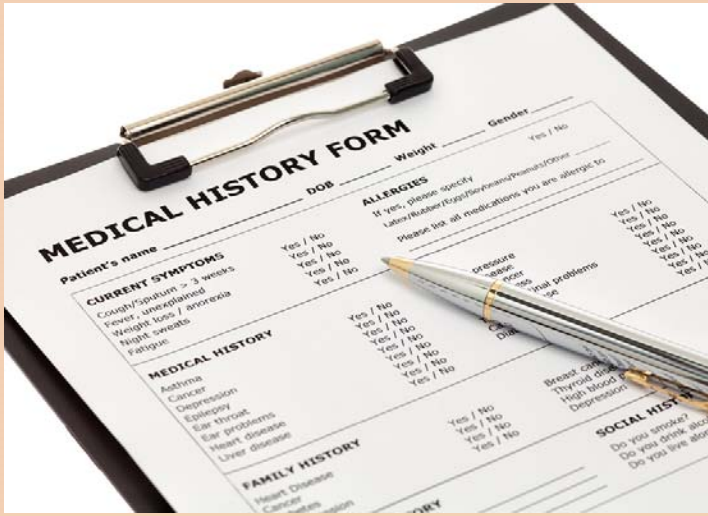
Records System Compliance

- The RHC must also comply with the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules at 45 CFR Parts 160 and 164 when sharing clinical record information that is Protected Health Information.
- However, CMS does not interpret or assess compliance with HIPAA requirements, and thus surveyors also are not authorized to assess HIPAA compliance.
- If surveyors suspect a serious breach of HIPAA, they should refer their concerns to the regional U.S. Department of Health & Human Services Office of Civil Rights.

Complete and Accurate

- All clinical records entries must be legible, i.e., able to be read clearly and unambiguously. Any entries or information contained in the clinical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events.

- The clinical record must also be complete, i.e., it must contain for each patient at least the information required at § 491.10(a)(3). Implicit in the requirement for the record to be complete is an expectation that all entries of required information are made into the clinical record promptly, so that it is available to subsequent caregivers.



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Complete and Accurate

- The RHC must ensure that all clinical records are accurately written.
  - All clinical records must contain the correct information for the correct patient.
  - The identity of the patient must be clear through use of identifiers such as name, date of birth, etc.
  - The RHC may have a system in place that assigns a unique patient identifier to each patient, such as a medical record number or financial identification number.
    - If the RHC has such a system in place, its clinical records policies and procedures must address the manner in which the unique identifiers are generated and assigned to each individual patient.
    - The RHC must also take steps to ensure the accurate identity of the patients if using unique identifiers.

Complete and Accurate

- Entries in the clinical record may be made only by individuals authorized by the RHC in accordance with its written policies and procedures to do so, and must be dated, timed, and authenticated by the individual making the entry.
- When authenticating the entry, the author indicates by his/her signature/authentication that the entry is accurate.
- Entries made on behalf of a practitioner by authorized individuals must also be promptly dated, timed, and authenticated by the practitioner.
  - A clinic policy stating that a practitioner must disapprove an entry within a specific time period or the entry is by "default" authenticated is **no**t acceptable; the practitioner must affirmatively authenticate each entry.

Complete and Accurate

- The RHC must have in place a method to identify the author of each entry and to ensure that entries are not made by any individual using another individual's identity. For example, if the RHC uses an EHR system that requires individuals to use passwords or card keys to access the system, individuals may not share their passwords or card keys with other individuals. Likewise, if the RHC uses a paper clinical record system and authorizes the use of rubber stamps for signatures, the individual whose signature the stamp represents must not allow any other individual to use it.

Readily Accessible

- The clinical record must be readily accessible to RHC staff. The RHC must have a clinical record system that allows clinical staff timely access when needed to all open records, i.e., records of all RHC patients who, per clinical record policy, are considered to still be active RHC patients. The clinical records policies and procedures must also address how long closed clinical records will be readily accessible to staff (This is distinguishable from the 6 year retention of closed records requirement at §491.10(c)).

- The RHC's clinical record system must be systematically organized to facilitate completion, storage, and retrieval of records in manner that supports timely provision of evaluation or treatment services to RHC patients.

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Policies and Procedures for Medical Records

- The RHC must maintain a complete, comprehensive and accurate clinical record (also referred to as a medical record) for each RHC patient.
  - The RHC must use the information contained in each clinical record in order to ensure the delivery of appropriate care to each RHC patient.

Staffing Necessary for Medical Records

- A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized
  - That individual is responsible for developing and implementing, with approval of the RHC's professional staff and leadership, written clinical record policies and procedures.

What Should Medical Records Contain?

- Identification and social data
- Evidence of consent
- Forms
- Pertinent medical history
  - Include allergies and adverse reactions to medications
- Assessment of the health status and health care needs of the patient,
- Brief summary of the episode, disposition, and instructions to the patient;
- Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;
- All physician's orders,
- Reports of treatments and medications and other pertinent information necessary to monitor the patient's progress;
- Signatures of the physician or other health care professional.
- Signature log

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Medical Record Recommendations

- Maintain individual patient charts.
- Use problem and medication lists.
- Sheets must be attached.
- Physician writing must be legible.
- No financial data in charts. (Insurance info is OK)
- Must have written policies regarding retention, confidentiality, and release of information.

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Retention of Medical Records

§ 491.10(c) Retention of records. -The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

- Clinical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks.
- RHC must be able to promptly retrieve the complete medical record of every individual evaluated or treated at the RHC 6 years after the latest entry made into the patient's record.
- Clinical records must be maintained within the RHC.
- Although RHCs are expected to comply with other Federal or State law requirements calling for longer retention periods, compliance with these other requirements is not assessed as part of the Federal RHC survey.

Annual Review of Policies and Procedures Regarding Medical Records

An annual evaluation is a requirement that must be fulfilled to maintain RHC status. The goal is Review the operations of the RHC on an annual basis and show improvement. This includes Medical Records! CFR 491.11

The Evaluation must be completed once every 12 months.

By following Section CFR 491.11, you can complete the annual review or have someone with RHC experience facilitate the review of your RHC. One person should NOT be an employee of the clinic.

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Sec. 491.11 Program evaluation.

a) The clinic or center carries out, or arranges for, an Annual Evaluation of its total program.
b) The Evaluation includes review of: 1)The utilization of clinic or center services, including at least the number of patients served and the volume of services;
   1) The utilization of clinic or center services; including at least the number of patients served and volume of the services;
   2) **A representative sample of both active and closed clinical records**; and
   3)The clinic's or center's health care policies.

c) The purpose of the Evaluation is to determine whether:
   1) The utilization of services was appropriate;
   2) The established policies were followed; and
   3) Any changes are needed.
   d) The clinic or center staff reviews the results of the Evaluation and takes corrective action if necessary

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Annual Review of Policies and Procedures Regarding Medical Records

The Evaluation includes review of:

The clinic's or center's health care policies.

- The policies are developed with the advice of a group of professional personnel that includes one or more Physicians and one or more Physician Assistants or Nurse Practitioners. *At least one*

member is not a member of the clinic or center staff.

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HIPAA/HITECH/Part 2

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HIPAA/HITECH/Part 2

- Protection of record information.
- The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.
  - Written policies and procedures govern the use and removal or records from the clinic and the conditions for release of information.
- The patient's written consent is required for release of information not authorized by law.

Fraud, Waste and Abuse Compliance

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The Basics Requirements of a Compliance Program

1. Written Policies, Procedures and Standards of Conduct
2. Compliance Officer, Compliance Committee and High Level Oversight
3. Effective Training and Education
4. Effective Lines of Communication
5. Well-Publicized Disciplinary Standards
6. Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks
7. Procedures and System for Prompt Response to Compliance Issues

42 C.F.R. §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi); Internet-Only Manual ("IOM"), Pub. 100-16, Medicare Managed Care Manual Chapter 21; IOM, Pub. 100-18, Medicare Prescription Drug Benefit Manual Chapter 9

Compliance Headache Areas

- Coding and Billing are complicated
  - This is one of the bigger risk areas for compliance issues among healthcare providers
  - They must be complete and accurate, and represent reasonable and necessary services
  - If coding and billing are not done carefully and accurately…

False Claims Act

What does it prohibit?

Cannot knowingly submit a false claim for payment to the federal government.
Must report and repay an overpayment within 60 days.

What are the penalties?

- Repayment plus interest
- Civil monetary penalties of $5,500 to $11,000 per claim
- 3x damages
- Exclusion from Medicare/Medicaid

18 United States Code § 1347

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Anti-Kickback Statute

What does it prohibit?

Soliciting, receiving, offering or paying remuneration (including any kickback, bribe, or rebate) in return for referrals for (or the purchasing, ordering, arranging or recommendation of) services that are paid in whole or in part under a federal health care program (which includes the Medicare program).

What's the penalty?

Any person who knowingly accepts such remuneration will be fined up to $25,000, imprisoned up to 5 years, or both. Significant civil monetary penalties may also apply. Further, conviction results in mandatory exclusion from participation in federal health care programs.

42 United States Code § 1320a-7b

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Stark Statute (Physician Self-Referral Law)

What does it prohibit?
A physician making a referral for certain designated health services payable by Medicare to an entity in which the physician (or a member of his or her immediate family) has a financial relationship (ownership, investment interest or compensation arrangement), unless an exception applies. Also prohibits Medicare and other claims for those services.

What's the penalty?
Any individual/entity who knowingly participates in a prohibited referral arrangement may be fined, among other amounts and penalties:

Up to a $15,000 fine for each fraudulent claim
Up to a $100,000 fine for entering into an arrangement or scheme

42 United States Code § 1395nn

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OIG Penalties

- The Office of Inspector General ("OIG") may seek civil monetary penalties for wide variety of behavior
  - For example – penalty may be enforced against an organization that offers something of value to a Medicare beneficiary, knowing that this would likely influence the beneficiary's selection of a provider or supplier which may be paid at least in part by Medicare.
- If the OIG excludes an individual or entity, that individual or entity is out – no more payments for services from any federal health program. 42 United States Code § 1395y(e)(1)(B), Code of Federal Regulations Part 1001

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Emergency Preparedness

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Emergency Preparedness

- NEW regulations as of 2017!
  - Implementation Date Nov. 15th 2017
  - Old Regime 491.6(c):
    - Training staff in handling emergencies
    - Placing exit signs in appropriate locations
    - Taking other appropriate measures consistent with conditions of the area where the clinic is located
  - New regime is much more detailed and can be found in the CFR: **§491.12**
  - For CAHs new rules are listed at **§485.625**

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Emergency Preparedness

- §491.12 (a) – Emergency Preparedness Plan
  - Emergency Preparedness Plan must be created and updated every year
  - CMS gives some RHCs some leeway
    - Must have a strategy to address the various emergency events the clinic is at risk for
    - Must analyze RHC capability during and after emergency including delegations of authority and succession plans
    - Must include a process to cooperate with the broader community on emergency preparedness

Emergency Preparedness

§491.12 (b) Policies and Procedures

- Policies/procedures must be updated annually
- Policy on evacuation w/ exit signs, staff responsibility and a means to shelter in place
- System to preserve patient info

§491.12 (c) Communication Plan

- Must be updated annually
- Include contact info for all staff, contractors, physicians, volunteers, gov't emergency preparedness staff, other RHCs, etc.
- Must include primary and alternate means of communication with all
  - Info about the condition of RHC and patients
  - Info about ability of the RHC to provide assistance

§491.12 (d) Training and Testing

- Yearly training all staff and contractors
- Yearly full-scale community-based exercise

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Any questions?

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