Specialized Patient Records

Specialized Patient Records are certain types of health information that require special handling:

- Substance abuse and mental health care
- Home care
- Therapeutic and emotional information

They have many strict legal requirements. Here is an outline of some key concepts and key terminology to understand and be aware of surrounding specialized patient records and health information.

Drug and Alcohol Abuse:

- Two federal laws
 - o Drug Abuse Prevention, Treatment, and Rehabilitation Act
 - Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation
 Act of 1970
- Rules and regulations have been promulgated
- Apply to all treatment programs that receive federal assistance
 - Includes entities whose sole purpose is substance abuse diagnosis and treatment
 - o General medical facilities with specialized unit and staff may also be included

CONFIDENTIALITY:

Patient Identification

- Regulations restrict disclosure of patient-specific information
 - Prohibit identification of patient's presence (or past presence) in facility
 - Disclosure requires patient consent or court order
 - Unconditional obligation not to identify patients treated
- Those involved in substance abuse treatment should adopt uniform method of answering inquiries

Patient Notice

- Patients must be given notice
 - Of federal confidentiality requirements
 - Upon admission or shortly thereafter
 - Written summary of federal law and regulations
- Programs may develop own notice or use sample
- Documentation in patient record is essential
 - Confirm notice given and time frame

RELEASE OF INFORMATION

- Federal regulations govern
- Three categories under these regulations
 - 1. Disclosure with written patient authorization
 - 2. Disclosure without patient authorization but pursuant to the regulation
 - 3. Disclosure made subject to a valid court order

1. Disclosure with Written Patient Authorization

- Release of information form required to include
 - Name of program or person permitted to make disclosure
 - Identification of patient
 - Name of program or person to which disclosure may be made
 - Purpose of the disclosure
 - Amount and type of information to be disclosed
 - Signatures of person authorized to consent
 - Notice that authorization may be revoked
 - Expiration date
- O Who may authorize disclosure?
 - Adult patient
 - Minor child where law permits minor to consent to treatment
 - If state law requires parental consent, form must be signed by parent or guardian and minor patient
- Form must conform with federal regulations
 - Failure to comply invalidates authorization
 - Any missing element makes form invalid
- Notice prohibiting re-disclosure
 - Federal regulation strictly prohibits
 - The person or facility that receives the patient information cannot release to another
- Written notice must accompany any release of patient information
- Must use statement listed in regulation
- Additional efforts to ensure compliance may be considered (e.g., stamp on pages)

2. Disclosure Without Written Patient Authorization

- Limited exceptions under regulations
 - Medical emergencies
 - Medical personnel providing emergency care
 - FDA notice to patients of error or dangerous drugs
 - Research activities
 - Qualified researcher conducting approved work
 - Security ensured and re-disclosure prohibited
 - Audit activities
 - By qualified organizations only

- Limit use with disclosure back to program only
- Ensure security of information and destruction post-audit

3. Disclosures Pursuant to Legal Process

- Discovery requests
 - To produce and disclose patient-specific information for use in litigation
 - Without a court order, do not disclose
- Subpoena or subpoena duces tecum
 - Command to appear and/or present documents and other things
 - Alone, it does not authorize disclosure

MISCELLANEOUS ISSUES:

- Court order authorizing disclosure
 - That is otherwise prohibited by statute or regulation
 - Only issued on finding of good cause
 - Application procedure is set by regulation
- Components of valid order
 - Limit disclosure to essential parts of record
 - Limit disclosure to persons who need to know
 - Include measures to protect patient (e.g., sealing records)
- Closure or acquisition of program
 - o Patient consent to transfer record needed, or
 - o Patient identifying information must be purged
 - o Unless statute of limitations requires keeping record for set time beyond closure
- If transfer authorized, then record must be sealed and specifically labeled
 - Held in confidence until retention period ends
 - Upon expiration, records are destroyed
- Regulations designed to protect vulnerable patients
- Enforcements and penalties
 - All federally assisted programs will comply
 - Violations will be reported to the U.S. attorney or FDA (methadone programs)
 - o Penalties upon conviction \$500 to \$5000 fines

MENTAL HEALTH AND DEVELOPMENT DISABILITY CARE:

- Settings for care
 - o Inpatient psychiatric facilities
 - Residential treatment facilities
 - Therapist offices
- Need to protect health information similar
 - Two main differences
 - Additional requirements for record content
 - More stringent privacy protection

- Unique settings and circumstances
 - Change in supervision
 - Seclusion, restraint use, passes, and discharge
 - Significant legal events
 - Commitment orders, interaction with police
 - Restrictions of patient rights
 - Suicide attempts
 - Proper documentation is necessary
- Medicare conditions of participation
 - Establish standards for documentation
 - Records of assessment, diagnosis, plans, progress, discharge and summary must comply
- State mental health code requirements
 - May require written plans for each patient
 - Document restraint use and reasons for use
 - Explain limitations on patient rights
 - Restrictions on visitors or phone use
 - Document special treatments (electroshock therapy)
- Joint Commission requires documentation
 - Of patient's legal status
 - o Involvement of family members in treatment
- Two separate records exist
 - Official record as required by law
 - Clinician's psychotherapy notes
 - HIPAA and ARRA address
 - Mental health professional's record
 - Documents and analyzes contents of conversation
 - No legal requirement that this be part of official record
 - May not be subject to discovery
- Patient identification
 - The fact that patient is or was a patient may not be disclosed without patient consent
- Release of information
 - o Patient-specific information is confidential
 - May not be disclosed unless
 - Patient authorizes
 - Without authorizations, under limited situations
 - By court order
 - Laws of the state must be reviewed to determine governing requirements

HOME HEALTH:

- Subject to multiple requirements
 - o Medicare conditions of participation
 - State law and regulations
 - Accrediting standards
- If agency receives Medicare funds, conditions of participation govern
 - Detail qualifications for staff and rights of patients
 - Notification to patient of rights
 - Confidentiality of all clinical records
 - Advise patients of disclosure policies and procedures
- State law: statutes and regulations
 - Frequently follow Medicare regulations
 - May also address confidentiality and disclosure
 - o State-administered Medicaid programs may contain specific regulations
 - Licensing regulations
 - Tennessee requires detailed content, retention, and security safeguards
 - County requirements may also be in place
 - Departments of Health and/or Social Services
- Accrediting standards and professional guidelines
 - o Do not have the force of law
 - Establish standard of care in negligence case
 - Joint Commission
 - o Community Health Accreditation Program
- HIM should be familiar with legal, regulatory, and accreditation expectations

GENETIC INFORMATION:

- Information obtained from a genetic test or DNA sample
- Looking into patient's future health
- Human Genome Project
 - Funded by Congress
 - o Research available on GenBank website
- Information used to assist patient
 - o Increase diagnostic surveillance
 - Identify whether one is a gene carrier; impact on offspring
- Regulations to prevent potential misuse
 - HIPAA prohibits insurance company from
 - Considering information as preexisting condition
 - Charging higher premiums based on genetic info
 - Executive order at federal level prohibits
 - Use by federal agency in hiring or promotion

- Requesting or requiring genetic test results from applicants or employees
- State laws may prohibit genetic discrimination
 - Missouri, California, Arizona, Maryland, Wisconsin
- Federal law (GINA) includes additional protections
 - Strengthens HIPAA and state law
 - Prohibits insurance company misuse of genetic information
 - Cannot determine eligibility or use to set premiums
 - Cannot require genetic testing
 - o Prohibits employer and labor union misuse
 - Cannot use genetic information in hiring, firing, assignment decisions
 - Cannot request or purchase genetic information

HIV INFORMATION:

- Public health threat
- Background Information About HIV/AIDS
 - Retrovirus suppresses immune system
 - Transmitted through sexual contact, exposure to blood, or blood components, passed from mother to child in utero or through breast milk
 - Disease may progress to AIDS and death
- Climate of fear and misunderstanding
 - No vaccine and no cure
- Federal and state laws to address
 - Testing requirements
 - Confidentiality concerns
- Tests to detect HIV antibody/antigen
 - Enzyme-linked immunosorbent assay (ELISA)
 - Detects presence of HIV in serum or plasma
 - IF ELISA is positive, this must be confirmed
 - Western Blot assay
 - Radioimmunoprecipitation assay (RIPA)
 - Indirect immunofluorescence assay (IFA)
 - Confirmation of positive test is considered seropositive HIV
- Voluntary Testing
 - Consent for testing
 - State and federal requirements
 - Obtain written, signed consent from patient
 - Delivery of pretest information and counseling
 - State laws require providers to give information
 - Test types, methods used, and meaning of results
 - Transmission of disease and risk reduction
 - Disclosure of results posttest counseling

- Test results, their meaning, and importance
- Methods to reduce spread and notification of partner
- Referral to care and support groups
- Reporting of positive results to public health authority
- Mandatory Testing
 - Forced testing no right to refuse
 - Court-ordered testing
 - States empower courts to protect public good
 - Order requires clear and convincing evidence
 - Reasonable belief that person is infected and poses a threat to others
 - Mandated by state laws (vary)
 - Target groups that may threaten public health
 - Prisoners, convicted sex offenders
 - Employees in defined and limited situations
- Anonymous Testing
 - Fear of testing and discrimination
 - State laws to encourage testing
 - System that assigns unique identifier
 - Identifier replaces name and signature
 - On consent forms
 - On blood sample
 - Identifier and not name is reported to public health authority with test result
 - Cannot be used for blood donation eligibility

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