CMS Conditions of Participation CAHs 2026 Part 2 of 5



Patient Rights, Advance Directives, Consent, Interpreters, Grievances, Exercise of Rights, Disclosures, Privacy, Safety, Ligature Risks, Abuse and Neglect, Confidentiality, Restraints and Seclusion and Visitation

Speaker



- Laura A. Dixon, Esq.
- BS, JD, RN, CPHRM
- President, Healthcare Risk Education and Consulting, LLC
- ldesq@comcast.net
- Email questions to CMS:
  Acute hospitals: qsog_hospital@cms.hhs.gov.

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DISCLAIMER

The information provided during this program/webinar is informational only. It is not intended to be legal advice or to establish an attorney-client relationship. Please consult with your in-house counsel or professional legal representative for advice.

Objectives

- Recall: CMS recently added Patient Rights to the Conditions of Participation for CAHs
- Recall: CMS has restraint standards that CAHs must follow
- Describe: a hospital must have a grievance policy and procedure in place
- Recall: interpreters should be provided for patients with limited English proficiency and hearing impairment
- Describe: visitation requirements including policies and permitted limitations



Patient Rights

New Regulations

New Regulations

This content is from the eCFR and is authoritative but unofficial.

Displaying title 42, up to date as of 8/28/2025. Title 42 was last amended 8/26/2025.

Title 42 —Public Health
Chapter IV —Centers for Medicare & Medicaid Services, Department of Health and Human Services
Subchapter G —Standards and Certification
Part 485 —Conditions of Participation: Specialized Providers

ENHANCED CONTENT - TABLE OF CONTENTS

Subpart F Conditions of Participation: Critical Access Hospitals (CAHs) 485.601 – 485.649
§ 485.601 Basis and scope.
§ 485.603 Rural health network.
§ 485.604 Personnel qualifications.
§ 485.606 Designation and certification of CAHs.
§ 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.
§ 485.610 Condition of participation: Status and location.
§ 485.612 Condition of participation: Compliance with hospital requirements at the time of application.
§ 485.614 Condition of participation: Patient's rights.
§ 485.616 Condition of participation: Agreements.
§ 485.618 Condition of participation: Emergency services.
§ 485.620 Condition of participation: Number of beds and length of stay.
§ 485.623 Condition of participation: Physical plant and environment.
§ 485.625 Condition of participation: Emergency preparedness.
§ 485.627 Condition of participation: Organizational structure.
§ 485.631 Condition of participation: Staffing and staff responsibilities.
§ 485.635 Condition of participation: Provision of services.
§ 485.638 Conditions of participation: Clinical records.
§ 485.639 Condition of participation: Surgical services.
§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.
§ 485.641 Condition of participation: Quality assessment and performance improvement program.
§ 485.642 Condition of participation: Discharge planning.
§ 485.643 Condition of participation: Organ, tissue, and eye procurement.
§ 485.645 Special requirements for CAH providers of long-term care services ("swing-beds")
§ 485.647 Condition of participation: psychiatric and rehabilitation distinct part units.
§ 485.649 Condition of participation: Obstetrical services.

Overall

- Presently – there is no established section in the current Appendix W
- Recent regulatory changes added in Patient Rights
- Regulation follows the regulations of Appendix A for Acute hospitals

Condition: Patient Rights

- CAH must protect and promote each patient's rights
- Standard : Notice of rights
- 1. Must inform each patient/representative of rights before providing or discontinuing care whenever possible
- 2. Must establish a process for prompt resolution of grievance and notify each patient who to contact to file grievance
  - Governing body must approve and be responsible for effective operation
  - Must review and resolve grievance unless delegated in writing to committee

Grievances – cont'd

(#2 continued)

- Grievance process must include mechanism for timely referral of concerns regarding quality of care/premature discharge to appropriate Utilization and Quality Control Quality Improvement Organization; at a minimum
  - Hospital must establish clearly explained procedure for submission of patient's written or verbal grievance
  - Process must specify time frames for review and provision of response
  - In its resolution hospital must provide patient with written notice of decision with name of hospital contact person, steps taken to investigate, results of process and date of completion

Standard: Exercise of Rights

- 1. Patient has a right to participate in development and implement of plan of care
- 2. Patient/representative has right to make informed decisions regarding their care
  - Can request or refuse care as long as not medically unnecessary or inappropriate
- 3. Right to formulate advance directives and have them followed
- 4. Right to have family member/representative and physician be promptly notified of their admission

Standards: Privacy & Confidentiality

- Privacy
  - Personal privacy
  - Receive care in safe setting
  - Free from all forms of abuse or harassment
- Confidentiality
  - Confidentiality of record
  - Right to access records orally or in writing and in form/format requested
  - As agreed upon between hospital and patient
  - Must not frustrate effort to access
  - Must seek to meet requests as quickly as possible

Standard: Restraint or Seclusion

- Right to be free from physical or mental abuse and corporal punishment
  - Free from restraint or seclusion as means of coercion, discipline, convenience or retaliation by staff
  - Only imposed to ensure immediate physical safety of patient, staff and others
  - Discontinued at earliest possible time
- Lists what is a restraint and is not restraint
  - Manual or medication
  - Not – dressings, helmets, escorts

Restraint or Seclusion – cont'd

- Seclusion- involuntary confinement alone physically prevented from leaving
  - Only for violent or self-destructive behavior
- Restrain or seclusion may only be used when less restrictive interventions ineffective for protection
- Type/technique must be least restrictive intervention
- Must have written policies and procedures on use consistent with current standards of practice

Standard: Staff Training

- Patient has a right to safe implementation of restraint or seclusion by trained staff
- Must provide patient-centered, trauma informed competency-based training and education on use of both
  - Includes medical staff
  - Contracted personnel
- Training must include alternatives to use restraint and/or seclusion

Standard: Death Reporting

- Must report to CMS by phone, fax, electronically as determined by CMS not later than close of business on next business day after knowledge of death
  - Death occurs while in restraint or seclusion
  - Death that occurs within 24 hours after removed from restraint/seclusion
  - Death known to hospital that occurs within 1 week after restraint/seclusion
  - Reasonable to assume use contributed directly or indirectly to death

Death in Soft Wrist Restraints

- Must record in internal log or other system
  - Any death that occurs while in such restraints
  - Death within 24 hours after removed from such restraints
- Staff must document in the record date and time death
  - Reported to CMS if not soft restraints
  - In internal log, etc., if soft wrist restraints
- Death documented as follows:
  - Entry no later than seven days after death
  - Document name, date of birth and death, attending or other LP responsible for care, medical record number and primary diagnosis electronically or other form

Advance Directives C0812

- Standard: Compliance with federal laws and regulations
  - PSDA – Patient Self Determination Act – is a federal law
- Right to make advance directives
- Staff must comply with their advance directives
- Right to refuse treatment
- May have a DPOA or a **support person**/patient advocate

Advance Directives – cont'd

- May designate a support person – to exercise visitation rights
- If patient incapacitated and DPOA – must give DPOA information to make informed decisions and consent for the patient
- Must also seek the consent of the patient's representative when informed consent is required for a care decision

Advance Directives – cont'd

- Must provide information to the competent patient when admitted
- *Should* consider giving to outpatient as applicable
  - ED
  - Observation
  - Same Day surgery
- Document in medical record
- If incapacitated, give to family or surrogate
- Has conscience objector clause

Advance Directives – cont'd

- Cannot require one
- Must ensure staff educated on the P&P
- Includes the right to make a psychiatric advance directive or mental health declaration
  - Give consideration even if no state specific law
- Must provide community education
  - EX – post on your website

Standard: Visitation

- Moved from Tag C-1054
- Must have policies and procedures regarding visitation
  - Must inform the patient of rights and any restrictions or limitation in advance providing care
  - Inform who they want to have as visitor
  - May not restrict or limit based on protected classes
  - Must ensure equal privileges



Reasonable Restrictions

- Infection control issues
- Interfere with the care of other patients
- Court order restricting contact
- Disruptive or threatening behavior
- Substance abuse treatment plan
- Patient undergoing care or interventions
- Restriction for children under certain age
- Roommate needs rest/privacy

Training and Survey Procedures

- Need to train staff on the P&P
- Need to determine role staff will play in controlling visitor access
- Surveyor will:
  - Verify you have a P&P
  - Review policy to determine if restrictions
  - Documentation staff is trained
  - Ensure staff aware of P&P on visitation
    - Can describe the policy for the surveyor

Support Person

- Maybe someone other than DPOA in Advance Directive
- Can be friend, family member or other individual who supports the patient during their stay
- Can exercise patient's visitation rights on their behalf if patient unable to do so
- Must accept designation if given orally or in writing
  - Writing best
- TJC calls person "Patient advocate"

Incapacitated Patient

- When patient incapacitated
  - No advance directives on file
  - Must accept individual who tells you they are the support person
  - Expected to accept without demanding supporting documentation
  - Must allow person to
    - Exercise rights
    - Give them notice of patients' rights

More Than One Support Person

- If two individuals claim to be the support person – can ask for documentation
  - Includes same sex partners, friends, or family members
  - Need policy on how to resolve this issue
- Any refusal to recognize support person must
  - Be documented in the medical record
  - Along with specific reason for the refusal

Additional Visitation Requirements

- Patient can withdraw consent and change their mind
- Must document in the medical record that the notice was given
- Surveyor:
  - Will look at the standard notice of visitation rights
  - Will review medical records to make sure documented
  - Will ask staff what is a support person and what it means

Prohibited Visitation Actions

- Must not restrict visitors based on
  - Race
  - Color
  - Sex/Gender identity/orientation
  - Religion, etc.
  - EX: If a unit is restricted to two visitors every hour the patient gets to pick their visitors not the hospital
- Hospitals urged to develop culturally competent training programs

Notice

The following is informational only as CMS has not developed interpretive guidelines nor survey procedures for patient rights section. This information is from Appendix A for acute hospitals. However, as the regulations follow that for Acute hospitals, this information may assist in develop of processes until CMS has developed guidance.

Protect & Promote Rights

- **Condition:** Hospital must protect and promote patient's rights
- Applies to all M/M participating hospitals
  - Short/Long term > Children's
  - Acute > Surgical/Specialty
  - Psychiatric > Rehab and Cancer
- Applies to all parts and locations
  - Inpatient
  - Outpatient
  - Provider-based

Notice of Rights

- Standard: Right to notification and exercise of rights
  - Privacy and safety
  - Confidentiality of medical records
  - Restraint issues (50 pgs. of standards)
  - Grievances
  - Advance directives
  - Visitation rights

Rights and Grievance Process

- Must ensure the notice of rights met
- In a manner the patient will understand
  - Limited English proficiency (LEP)
  - Low health literacy
    - 20% of patients read at a fifth-grade level
- Must have P&P to ensure patients have information to exercise their rights

Notice of Patient Rights

- Must inform each patient
  - Of patient's rights
  - In advance of furnishing/discontinuing care
  - Why – to protect and promote each patient's rights
- Ensure patients have information on their rights
  - Includes inpatients and outpatients

Designation of Representative

- Take reasonable steps to determine patient's wishes on designation
- If not incapacitated and has a representative
  - Must provide representative with the notice of patient rights in addition to the patient
  - Patient can do orally or in writing (author suggestion)

Designation – Incapacitated Patient

- If incapacitated – notice of rights given to the person who presents with an advance directive
  - I.e., DPOA
- If no advance directive
  - Spouse
  - Domestic partner
  - Parent of minor child
  - Other family member

Designation of Representative

- Cannot ask for supporting documentation unless
  - More than one person claims to be representative
- If refuse the request
  - Must document such in the medical record
- States can specify a state law for doing this
- Hospital must adopt P&P

Notice of Patient Rights

- Confidentiality and privacy
- Pain relief
- Refuse treatment and informed consent
- Make/Have Advance directives
- Right to get copy of IM Notice or detailed notice
- Right to be free from unnecessary restraints
- Right to determine who visitors will be

Notify Patient of Their Rights

- Information given to the patient's representative when appropriate
  - Document reason: patient unconscious – support person – guardian – DPOA – parent of minor, et. al.
- Consider
  - Copy on the back of the general admission consent form and acknowledgment of Notice of Privacy Practice
  - Include sentence that patient acknowledges receipt of rights
  - Right to contact the BFCC QIO or state agency of problems (Family and Beneficiary Centered Care)



Grievances

Question 1

Benton Hospital's grievance process requires patients to mail in any complaint or grievance they may have regarding their hospital stay. Letters are to be addressed "To Whom it May Concern" only. Individual names are not provided on the "patient rights" form given to the patient on admission.

Is this process sufficient under CMS?

- Yes – individual instructions are provided to a patient
- No – contact information to file a grievance – name, etc., is not provided

Grievance Process

- Must have a process for prompt resolution
  - Inform each patient to whom to file a grievance
  - Provides definition – include in your policy
- Consider using CMS's definition of grievance in your policy (next slide)

Definition

- A formal or informal written or verbal complaint
  - When the verbal complaint about patient care is not resolved at the time by staff present
  - By a patient, or a patient's representative
  - Regarding patient's care, abuse, or neglect, issues
  - Related to the hospital's compliance with the CMS CoP
  - A Medicare beneficiary billing complaint related to rights

Grievances – cont'd

- Have process to deal with minor requests in more timely manner than a written request
  - Does not require written response
  - Examples: change in bedding, housekeeping of room, and serving preferred foods
- If complaint cannot be resolved at the time of the complaint or requires further action for resolution – then it is a grievance
- All requirements for grievances must be met

Another Person Complains

- Someone other than patient complains
  - Contact the patient – confirm person is authorized representative
  - Get the patient's permission to discuss protected health information with designed person – HIPAA
  - Document patient's permission was obtained
    - Some facilities get a HIPAA compliant form signed

Grievance or Not

- Grievance
  - Written complaint
  - Complaint telephoned in after discharge
  - Any/all complaints abuse, neglect, patient harm
    - Unless would have been routinely handled by staff
  - If patient asks to have it considered a grievance
- Not a grievance
  - Patient satisfied but family not
  - Billing – unless quality of care
  - Comments in patient satisfaction questionnaire
    - Unless ask for resolution or treat as grievance

Examples

- Grievance
  - Patient to nurse – "I am missing some money my purse. I think one of the staff took it"
  - Email from patient to Risk Manager – "My doctor failed to diagnose my condition"
  - Reason – needs investigation
- Not a grievance
  - Patient to nurse – "My food is cold"
  - Satisfaction survey – Anonymous – "Your rooms are cold"
  - Reason – can/could have resolve it now

Survey Procedure

- Will review the hospital policy
  - Assure grievance process encourages all personnel to alert appropriate staff concerning grievances
- Ensure grievances involving situations that place patients in immediate danger are resolved in a timely manner
- Conduct audits and PI – ensure facility is following its grievance P&P

Survey Procedure – continued

- Will interview patients
  - Confirm they know how to file a complaint or grievance
    - Including right to notify state agency (State department of health and BFCC QIO with phone numbers)
    - Add email address and address of both
- Hospital - document the information given to the patient

Prompt Resolution

- Must establish a process for prompt resolution
- Inform each patient whom to contact to file a grievance by name or title
- Operator must know where to route calls
- Make form accessible to all



Governing Board Duties

- Must approve and is responsible for effective operation of the grievance process
  - Elevates issue to higher administrative level
- Have a process to address complaints timely
- Coordinate data for PI
  - Look for opportunities for improvement
- Most boards will delegate this to hospital staff

Board Responsibility

- Must review and resolve grievances
  - Unless delegates the responsibility in writing to the grievance committee
- Grievance process reviewed and analyzed thru hospital's PI program
- Grievance committee must be more than one person
  - Needs adequate number of qualified members to review and resolve

Grievance Process

- Process must include a mechanism for timely referral of patient concerns regarding the quality of care or premature discharge to the appropriate QIO
  - Each state has a state QIO under contract from CMS and list of QIOs[1]
- QIO are CMS contractors – review appropriateness and quality of care to Medicare beneficiaries

[1]http://www.qualitynet.org/dcs/ContentServer?pagename=Medqic/MQGeneralPage/GeneralPageTemplate&name=QIO%20Listings

Check Website for Changes

www.keproqio.com/bene/qualityofcarecomp.aspx

Telephone, Fax Numbers and Mailing Addresses				
Region 1 Connecticut Massachusetts Maine New Hampshire Rhode Island Vermont	**Region 4** Alabama Florida Georgia Kentucky Mississippi North Carolina South Carolina Tennessee	**Region 6** Arkansas Louisiana New Mexico Oklahoma Texas	**Region 8** Colorado Montana North Dakota South Dakota Utah Wyoming	**Region 10** Alaska Idaho Oregon Washington
Toll-free Phone 888-319-8452 **Local Phone** 216-447-9604 **TTY** 855-843-4776 Toll-free Fax** **Mailing Address** 5700 Lombardo Center Dr. Suite 100 Seven Hills, OH 44131	**Toll-free Phone** 888-317-0751 **Local Phone** 813-280-8256 **TTY** 855-843-4776 Toll-free Fax** **Mailing Address** 5201 West Kennedy Blvd. Suite 900 Tampa, FL 33609	**Toll-free Phone** 888-315-0636 **Local Phone** 216-447-9604 **TTY** 855-843-4776 Toll-free Fax** **Mailing Address** 5201 West Kennedy Blvd. Suite 900 Tampa, FL 33609	**Toll-free Phone** 888-317-0891 **Local Phone** 813-280-8256 **TTY** 855-843-4776 Toll-free Fax** **Mailing Address** 5700 Lombardo Center Dr. Suite 100 Seven Hills, OH 44131	**Toll-free Phone** 888-305-6759 **Local Phone** 813-280-8256 **TTY** 855-843-4776 Toll-free Fax** **Mailing Address** 5700 Lombardo Center Dr. Suite 100 Seven Hills, OH 44131

Beneficiary & Family Centered Care QIOs

- Beneficiary and Family Centered Care (BFCC)-QIOs will manage:
  - **All beneficiary complaints**
  - Quality of care reviews
  - EMTALA
  - And other types of case reviews
- Ensures consistency in the review process while taking into consideration local factors important to beneficiaries and their families

Grievance Procedure

- Hospital must have a clear procedure for the submission of a patient's written or verbal grievances
- Surveyor will
  - Review your information to make sure it clearly tells patients how to submit a verbal or written grievance
  - Interview patient to make sure information provided tells them how to submit a grievance



Policy and Procedure

- Must have a P&P on grievance
  - Specific time frame for reviewing and responding to the grievance
  - Grievance resolution that includes the patient with a written notice of its decision, IN MOST CASES
- Written notice to the patient must include
  - Steps taken to investigate the grievance
  - Results
  - Date of completion

7-Day Rule

- 7 days considered appropriate
  - If not resolved or investigation not completed within 7 days
  - Must notify patient still working on it and hospital will follow up



Investigation Time

- Most complaints not complicated and do not require extensive investigation
  - Will look at time frames established
- Document if grievance so complicated it requires an extensive investigation
  - Facility must respond to the substance of every grievance

Response

- Explanation to the patient
  - In a manner the patient/legal representative would understand
    - Remember the issue of low health literacy
- Written response must contain
  - Elements required in this section
    - Not statements that could be used in legal action against the hospital
  - Steps taken to investigate the complaint
- Surveyors will review the written notices to make sure they comply with this section

Grievances

- If patient emailed a complaint – may email back response
  - Check hospital policy on security – may not allow since email is not encrypted
- Maintain evidence of compliance with the grievance requirements
- Grievance considered resolved when patient is satisfied with action

- OR –

- If hospital has taken appropriate and reasonable action

Policy and Procedures

- Must maintain records and files of the investigation
  - Hospital
  - Physician office
  - Other covered entity
- Complaint coordinator or patient advocate must investigate the complaint
- All interested persons must be afforded an opportunity to submit evidence relevant to the grievance

Policy and Procedures – cont'd

- Patient or person always has the option of filing a complaint with the OCR at anytime
- OCR has a section on how patients can file a civil rights complaint
  - It can be sent via email, fax, regular mail or via the OCR Complaint Portal at https://ocrportal.hhs.gov/ocr/smartscreen/main.jsf



Exercise of Patient Rights
Consent
Advance Directives

Exercise of Rights

- Standard: Exercise of rights
- Right to participate in the development and implementation of their plan of care (A-0130)
  - Includes inpatients and outpatients
  - Includes discharge planning and pain management
- Requires hospital to actively include the patient in developing their plan of care including changes

Patient Representative

- Hospital expected to take reasonable step to determine patient's wishes on designation of a representative with same requirements
  - Same as if patient competent and has a representative
    - Must involve **both** in development and implementation of a plan of care
- If incapacitated and AD – listed person is involved
- If incapacitated and no AD
  - Who claims to be patient representative
  - Cannot ask for supporting documentation unless two claims to be the representative

Patient Representative – cont'd

- Document refusals to let someone be the representative in the medical record
  - Same requirement to follow any specific state law
- Need P&P and should teach staff this section
- Policy must facilitate expeditious and non-discriminatory resolution of disputes about whether the person is the patient's representative

Participate in Plan of Care

- If patient refuses – document
  - Includes refusal of legal representative if a minor patient or incompetent
- Plan of care is frequently cited
  - Participation in interdisciplinary plan does not eliminate the need for a nursing plan of care (Tag 396)
  - Patients needing post-hospital care are given choices: home health, IPR (inpatient rehab), LTC or LTCH in writing
  - Includes choice to pain management, patient care issues, and discharge planning

Patient Rights

- Make informed decision regarding care
- Be informed of diagnosis
- Request or refuse treatment
  - Right to sign out AMA
  - Remember EMTALA requirements if patient is transferred
  - Have patient sign the transfer agreement



Informed Consent

- 3 sections in the manual on informed consent
  - Patient rights – informed decisions
  - Medical records
  - Surgical services
- Patient has the right to make informed decisions
- Same provisions for patient representative
  - If competent patient has a patient representative – give information to both regarding information to make an informed decision about the care

Patient Representative & Consent

- Hospital must obtain the written consent of the patient representative of a patient not incapacitated
  - Continues throughout the inpatient hospitalization or the outpatient encounter
- Same for patient who is incapacitated
  - Whether they have a DPOA
  - If not – then to patient representative
- If no advance directives – hospital cannot ask representative for supporting documentation unless two people claim to be the representative

Rights: Informed Consent

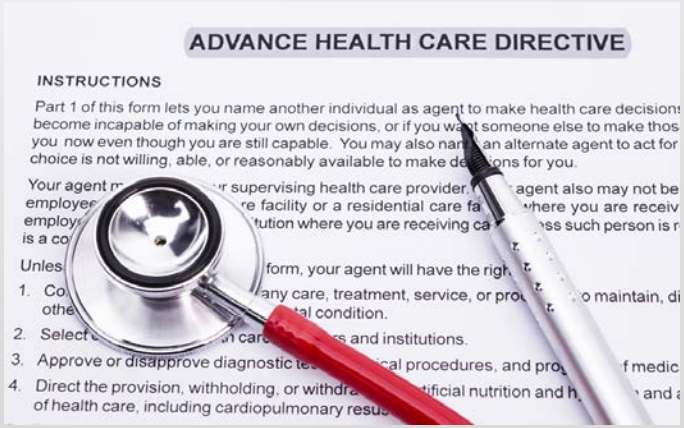
- Delegate the right to make informed decisions to another (DPOA, guardian)
- An informed consent for surgery or a treatment
- Be informed of health status and to be involved in care planning and treatment
- Informed decision on discharge planning to post acute care
- Request or refuse treatment
  - P&P to assure patient's right to request or refuse treatment

Rights: Disclosures to Patients

- Two disclosures that must be in writing
  - 1. If physician owned hospital
  - 2. If a doctor or an ED physician is not available 24 hours a day to assist in emergencies
    - Include in notice to patients and post sign in the ED
    - Must be signed acknowledgement from the patient
  - Provide information at beginning of inpatient stay or visit
    - Physicians who refer patients to the hospital they have an ownership interest must disclose
    - Plus – that hospital requires this as a condition for the physician being credentialed or privileged
  - Give to patients at first opportunity and have P&Ps

Advanced Directives

- Patient has the right to make and have advance directives followed if they become incapacitated
  - Staff must provide care consistent with the directives
  - P&P must include delegation of patient rights to the representative if the patient incompetent
  - Patient may designate in AD a support person to make decisions on visitation



Advance Directives – continued

- Policy should have clear statement of any limitations such as conscience objections
  - Minimum: clarify any difference between facility wide and those raised by individual doctors
- Must provide written information to the patient on rights under state law, at time of admission as an inpatient
  - *Should* provide same notice to **3 types of outpatients:** ED, observation or same day surgery
  - Document whether or not they have an AD

Advance Directives – continued

- Cannot condition treatment on whether a patient has one
- Not a mechanism for patient to demand inappropriate or medically unnecessary care
- Ensure compliance with state laws on AD
  - Inform patients they may file with state survey and certification agency
- Provide and document advance directives education and try and get a copy and place on chart
- Must train staff on P&P and community education

Additional Rights

- Right for DPOA to make medical decisions when patient incapacitated
  - I.e. – informed consent or pain management
- Disseminate policy on advance directive
  - Identify state authority permitting an objection
  - Includes Psychiatric or behavioral health AD
- Visitation regulations is a new patient rights

Notification of Admission

- Right to have a family member or representative notified and their physician notified on admission if not aware
  - Must now ask every patient on admission and document
  - Must do so promptly when patient responds affirmatively
- If incapacitated – identify family member or representative to promptly notify
- If someone comes with patient/arrives after and asserts they are the patient's representative – hospital accepts
  - Same if two people claim to be their representative & follow state law





Privacy
Safety
Ligature Risks

Personal Privacy

- Standard: Privacy and Safety
- Patient has a right to personal privacy while within the hospital
  - To receive care in a safe setting
  - Be free from all forms of abuse or harassment
  - To respect, dignity, and comfort
  - Privacy during personal hygiene activities
    - Toileting – bathing – dressing
    - Examinations – pelvic exam

Video/Electronic Monitoring

- Need consent for video/electronic monitoring
  - Must be clinical need
  - Make sure patient aware and can see camera
    - Cameras in patient rooms (sleep lab, ED safe room)
    - Not applicable to cameras in hallways or lobbies
  - Include in general admission consent form that all patients sign on admission or make sure patients are aware
  - May use to monitor patients
    - Violent and/or self destructive
    - In both restraint and seclusion

Personal Privacy & Confidentiality

- Person not involved with care may not be present during exam without consent
- Information in directory may not be disclosed without informing patient in advance
  - Visitor must ask for the patient by name
- Can use information for payment and healthcare operation
- Must have P&P – restrict access to MR to those who need to know

Uses & Disclosures

- Incidental uses and disclosures permissible
  - Names on spine of chart
  - Names on outside of rooms
  - Whiteboards that list patient present in OR or PACU
- Take reasonable safeguards
  - Ask waiting patients to stand back a few feet from a counter used for patient registration
  - Speak quietly if patient in semi-private room
  - Passwords on computers
  - Limit access to areas with white boards

Survey Procedure

- Surveyor will
  - Conduct observations to determine if privacy provided during exams, treatments, surgery, personal hygiene activities, etc.
  - Look to see if names with patient information is posted in plain view
  - Ask if patient names are posted in public view
    - No white boards with patient names and other PHI

Safety

- The right to receive care in a safe setting including
  - Environmental safety
  - Infection control
  - Security – i.e., preventing infant abductions
  - Preventing patient falls
  - Medication errors
  - Very broad authority for patient safety issue
- Right to respect for dignity and comfort

Examples: Care in a Safe Setting

- Hand washing between patients
- P&P to manage unwanted visitors or contraband materials
- P&P on background checks on staff





Question 2

Baker Hospital has a busy ER that frequently sees patients with behavioral health issues. Pt. R presents with suicidal ideation and is placed in a room close to the nurses' station. He is not placed on suicide precautions, but the room is cleared of sharps and the waste basket.

Five hours after admission and with a plan to transfer to a behavioral health facility, Pt. R cannot be located. Around the same time, EMS brings a patient to the ER who was hit by multiple vehicles after running into traffic on a major interstate. The patient dies shortly after admission and is eventually identified as Pt. R.

What citations – if any – might Hilltop be issued?

Ligature Risk – New Guidelines

- Patients at risk include inpatients and outpatients
- Recognize not all risks can be eliminated
  - Should be able to demonstrate how identify patients at risk
  - Identify what steps taking to minimize risks
- Following nationally recognized standards and guidelines
- Examples potential risks:
  - Ligatures >Access to medications
  - Sharps >Breakable windows
  - Harmful substances >Plastic bags <Oxygen tubing.

Guidelines

- Consider 3 main elements to ensure safety re: ligature risks:
- 1. Patient risk assessment
- 2. Staffing/monitoring
- 3. Environmental risks noncompliance to include risk which do not pose an immediate jeopardy should be corrected ASAP
  - Within timeframe noted by CMS, SA or AO

Patient Assessment

- CMS recognizes there are numerous models/versions of patient screening and assessment tools
- Does not endorse or require particular tool
- Type should determine risk of harm
- Appropriate to patient population, care setting, staff competency
  - OB or post-partum
  - Emergency department

Psychiatric Hospitals/Units

- All patients should be screened for suicidal ideation
- Behavioral health patients in acute – screened if primary reason for evaluation/treatment
- Guidelines list out several resources:
  - 2018 report: Recommended standard care for people with suicidal risk
  - From National Action Alliance for Suicide Prevention
  - www.actionallianceforsuicideprevention.org

Staffing/Monitoring

- Provide appropriate level of education and training re:
  - Identify patients at risk of harm
  - Environmental patient risk factors
  - Mitigation of strategies
- Includes:
- Employees – Volunteers – Contractors – per diem
- Any others providing care via arrangement

Staff – cont'd

- Have flexibility to tailor training to services provided and populations
- CMS expects education and training for all new staff initially upon orientation and when policies and procedures change
- *Recommends* ongoing training at least every 2 years after initial

Environmental Risks

- Should implement environmental risk assessment strategy
- Provide care in safe setting
- May not be the same in all hospital or units
- Implement as per specific care environment and population
- Consider possibility the unit may care for patients at risk of harm
  - Example – post OD on step-down unit

Survey Procedures

- Will review and analyze incident/accident reports
  - Any patterns
  - Will expand review if suspect more widespread or pervasive problems with safe environmental issues
- Will observe patient care environments and other areas frequented by patients for unattended items (new)
- Utility or housekeeping carts with hazardous items
  - Cleaning agents/solutions
  - Brooms
  - Tools, etc.

Survey Procedures – cont'd

- Will review policies and procedures and interview staff on how hospital
  - Trains staff on assessment of care environment
  - Upon hire
  - Before providing care or working independently
  - Whenever policies/procedures change
  - Identify processes to keep staff current on meeting patient needs and ID risks, and how to report

Survey Procedures – cont'd

- Will review policies and procedures and interview staff
- How hospital defines continuous visual observation or 1:1 monitoring
- Policy should include ability of assigned staff member to immediately intervene when patient at risk
- Will observe and interview staff where infants and children are inpatients
  - Appropriate security protections in place and functioning
- All new

Survey Procedures – cont'd

- Will review policies and procedures regarding
  - Curtailing unwanted visitor
  - Contaminated materials
  - Unsafe items that pose safety risks to patients and staff
- Will access security efforts to protect vulnerable patients
  - Newborns – children – elderly
  - Those at risk for suicide/intentional harm
  - Enough security, appropriate mechanisms in place and followed to protect patients

Survey Procedures – cont'd

- Will determine if there is a policy for assessing and reassessing patients identified as being at risk for suicide or harm (new)
  - Following nationally accepted standards of practice
- Will review policies and interview staff
  - Verify processes are established to protect vulnerable patients
  - Ensure care provided in safe setting

Ligature – General Information

- Definition: Anything that can be used to attach a cord, rope, or other material for the purpose of hanging or strangulation
  - Includes shower rails, shoelaces, belts, sheets, towels, coat hooks, pipes, radiators, window and door frames, ceiling fixtures, etc.
  - Observe housekeeping carts or utility carts
    - Mops/brooms
    - Cleaning agents/disinfectants



Ligature – General Information

- Want a ligature free environment especially in behavioral health units
- Safety risks include furniture that can be thrown, sharp objects, plastic bags for suffocation, oxygen tubing, breakable windows, etc.



Ligature Risks - Generally

- Psych patients in non-psych setting must also be protected such as the ED, ICU, med-surg. etc.
- Identify patients at risk for self harm
  - Protection measures such as 1:1 monitoring with continuous observation
  - Removal of sharp objects from the room or equipment that can be used as weapons
- Any deficiencies must be corrected within 60 days from receipt of the report
- Follow up surveys will be done

Ligature Risks - Requirements

- Provide education and training for staff and volunteers, including contractors and agency staff
  - Upon orientation and when changes are made and recommend every two years
- Identify environmental safety risks for patients
  - All sections of the hospital
  - Ligature free/resistant environment for psych units and psych hospitals
- Patient risk assessment and strategies

2024 Edition



BEHAVIORAL HEALTH DESIGN GUIDE

https://www.bhfcllc.com/design-guide

Kimberly N. McMurray, AIA, EDAC, NCARB, MBA

Behavioral Health Facility Consulting, LLC

Founders and Authors Emeritus:
James M. Hunt, AIA
David M. Sine, DrBE, CSP, ARM, CPHRM

Freedom from Abuse/Harassment

- Patient has a right to be free from all forms of abuse, harassment and neglect
  - Must have process to prevent
  - Criminal background checks as required by state law
  - Must provide ongoing (yearly) training: abuse, harassment, and neglect
  - Have proactive approach to identify events that could be abuse
  - Must have P&P
  - Adequate staffing section

Abuse – Definition

- Abuse: the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish
  - Includes staff neglect or indifference to infliction of injury or intimidation of one patient by another
  - Include state laws in your P&P on abuse and neglect



Neglect – Definition

- Neglect: The failure to provide goods and services
  - Necessary to avoid physical harm
  - Mental anguish
  - Or mental illness
- What to do:
  - Investigate all allegations of abuse or neglect
  - Do not hire persons with record of abuse or neglect
  - Report all incidents to proper authority, board of nursing, etc.

Other Considerations

- Includes freedom abuse from other patients and visitors
  - Hospital must have a mechanism in place to prevent this
- Effective abuse program includes prevention
  - Adequate number of staff who have been screened
  - Identify events that could lead to or contribute to abuse
  - Protect during investigation
  - Investigate and report and respond

Other Considerations – cont'd

- Have a policy in place for investigating allegations
- Make sure staffing sufficient across all shifts
- Ensure appropriate action taken if substantiated
- Make sure staff know what to do if they witness abuse and neglect
- Include in policy and training any state or accreditation requirements



Confidentiality

Access and Confidentiality of Clinical Records

Confidentiality

- Standard: Confidentiality of patient records
- Patients have a right to confidentiality of their medical records (A0147)
  - Sufficient safeguards to ensure access to all information
  - HIPAA compliant authorization or MR release form
  - Minimal necessary standard
    - Abstract out information on child abuse record
- MR kept secure and only viewed by staff involved in care
  - Do not post patient information where it can be viewed by visitors

Patient Records – Access

- Right to access the information contained within their medical records
- Right to inspect their record or to get a copy
  - Upon oral or written request
  - In the form or format requested by the patient
    - Electronic copy
    - If not - paper copy or other form agreed by the hospital and patient
  - You cannot frustrate the efforts of the patient to get their medical records

Access to Records

- Patient has a right of access to their **current** medical records within a reasonable time
  - Update medical records policy
  - Educate nurses, doctors, and other staff
  - Have a process for patients who want to review their current medical records

Timely Receipt and Content

- Right to get records timely
  - HIPAA: 30 days unless stored off site then 60 days at the latest
  - CMS says "timely"
  - State law may be more stringent
- Right to entire medical record
  - Can request a specific portion
- Record must include the discharge planning documents

Patient Rights & OCR

- CMS: with technology expect request completed fewer than 30 days
- Cannot frustrate efforts of patients to get their medical records
- Section overlaps with requirements from OCR
- OCR's lengthy memo on access to records

OCR Rights & HIPAA

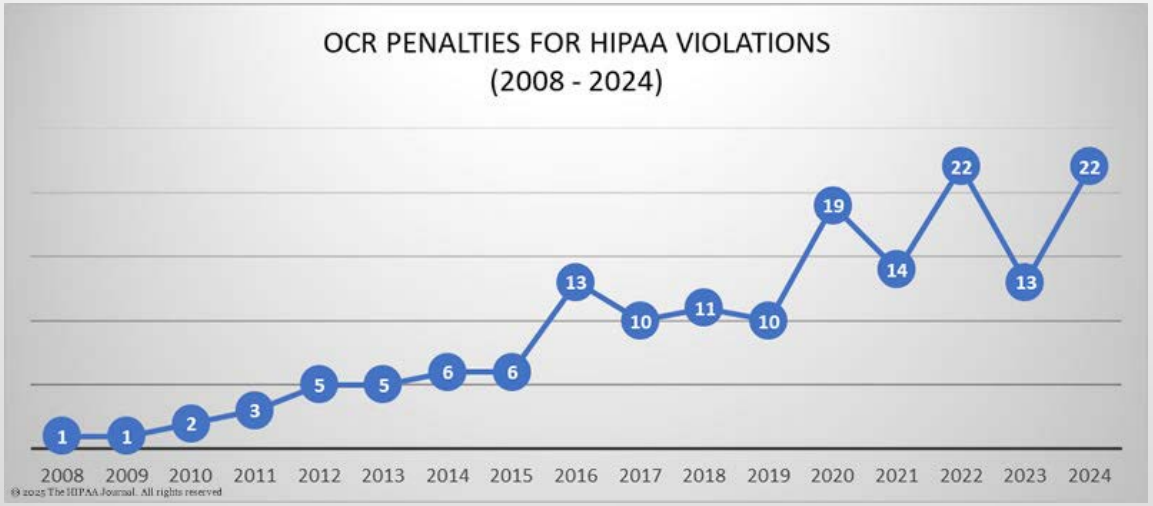
- Access to their information
- Right to inspect medical records
- Can allow email to make requests or fax
  - Verify patient's identity
- Cannot require person to request records in person
- Cannot require patient to mail the authorization

OCR Rights – cont'd

- Can request a paper or electronic copy
- Can request copies of x-rays
- Must send to patient within 30 days of request
  - 30-day extension available if archived offsite and not readily accessible
- Hospital
  - Can charge for records – but no retrieval fee
  - When hospital may deny the request
  - Cannot refuse to give copies because hospital bill not paid

Timely Access & OCR Complaints

- Patients who do not get records timely can file a complaint with OCR
- OCR fining hospitals who fail to get patients their records timely



- https://www.hipaajournal.com/wp-content/uploads/2024/08/the-hipaa-journal-ocr-penalties-hipaa-violations-jan25.jpg

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

August 24, 2023

UnitedHealthcare Pays $80,000 Settlement to HHS to Resolve HIPAA Matter over Patient Medical Records Request

OCR settles forty-fifth HIPAA Right of Access investigation

Today, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) has announced a settlement with UnitedHealthcare Insurance Company ("UHIC"), a health insurer that provides insurance coverage to millions of individuals across the U.S., concerning a potential violation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's right of access provision. The rule requires that patients be able to access their health information in a timely manner. This investigation marks the 45th Right of Access case to be resolved via voluntary settlement. UHIC agreed to implement a corrective action plan and pay $80,000 to resolve this investigation.

"Timely access to health information is one of the cornerstones of HIPAA. OCR will continue to ensure that covered entities with a record of delaying or denying access requests will be subject to enforcement," said OCR Director, Melanie Fontes Rainer. "Health insurers are not exempt from the right of access and must ensure that they are taking steps to train their workforce to ensure that they are doing all they can to help members' access to health information."

Failure to Give Access - $160,000

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

January 4, 2024

HHS' Office for Civil Rights Settles Multiple HIPAA Complaints with Optum Medical Care Over Patient Access to Records

This Settlement Marks the 46th Enforcement Action in the OCR Right of Access Initiative

On December 15, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), announced a settlement with Optum Medical Care of New Jersey (formerly known as Riverside Medical Group and Riverside Pediatric Group). Optum Medical Care is a multi-specialty physician group serving patients throughout New Jersey and Southern Connecticut. The settlement resolves multiple complaints filed with OCR concerning potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's Right of Access provision. The HIPAA Right of Access provision requires that individuals or their personal representatives have timely access to their health information for a reasonable cost. OCR's investigation revealed that Optum failed to provide access within 30 calendar days. Optum has agreed to implement a corrective action plan to ensure timely access for patients to their records and pay $160,000 to resolve this matter. The agreement marks OCR's 46th Right of Access enforcement action.

"Health care providers must make responding to parents' or patients' request for access to their medical records in a timely manner a priority," said OCR Director Melanie Fontes Rainer. "Access to medical records is a fundamental right under HIPAA, and one for which OCR receives thousands of complaints each year. This is

Other Rules re: Access to Records

- If patient incompetent – then to the personal representative
  - Should sign as the personal representative – DPOA, guardian, parent
- Reasonable cost for copying, postage or summary
  - No retrieval fee allowed under federal law

"Open Records" Access

- With limited exceptions – gives patients immediate access to health information in record at no charge
- Includes:
  - Notes
  - H&P
  - Diagnostic
  - Progress notes plus more
- In the medical records CoPs



Proposed New Regulations* – Highlights

- https://www.hipaajournal.com/new-hipaa-regulations/
  - Allow patients to inspect PHI in person and take notes or photos of PHI
  - Changing maximum time to provide access to PHI from 30 days to 15 days
  - When individuals should be provided ePHI without charge
  - Wording change – expand ability of CE to disclose PHI to avert threat to health/safety when harm is "seriously and reasonably foreseeable"
    - Currently – when "serious and imminent"



Restraint and Seclusion

Restraints

- Patients have a right to be free from physical or mental abuse, and corporal punishment
- Includes restraint and seclusion (RS)
  - Only be used when necessary
  - Not as coercion, discipline, convenience or retaliation
  - Only used for patient safety and discontinued at earliest possible time
- Guidelines apply to all hospital patients even those in behavioral health

Right to be Free From Restraint

- Consider adding it to your patient rights statement if not already there
- Must give patients a copy of their rights
  - Staff should document or have patient sign that they received their rights
  - Could include information in admission packet
- Do not consider using R&S as routine part of fall prevention

Leadership's Role

- Leadership is responsible for creating a culture that supports right to be free from R&S
- Leadership must ensure:
  - Systems and processes in place to eliminate inappropriate R&S and monitors use thru PI process
  - R&S only used for physical safety of patient or staff
  - Hospital complies with all R&S requirements

Restraints Protocols

- CMS previously did not recognize or allow the use of protocols
- No longer banned by the new regulations but still need separate order for R&S
- Order must contain information for staff on how to monitor and apply like intubation protocol
  - Must document individualized assessment, symptoms and diagnosis that triggered protocol
  - Need MS involvement in developing and review and quality monitoring of their use

Restraint Standards

- If a patient becomes violent or has self destructive behavior (V/SD) in the ICU or ED, CMS has one set of standards that apply
- Decision to use R&S is not driven from diagnosis
  - Rather – from assessment of the patient



Restraint Standards Medical Patients

- Joint Commission calls it behavioral health and non-behavioral health
- CMS calls it violent and or self destructive (V/SD) and non-violent and non-self destructive
- CMS: "It is not the department in which the patient is located but the behavior of the patient"



Definition

- "Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely"
  - Mechanical restraints include belts, restraint jackets, cuffs, or ties
  - Manual method of holding the patient is a restraint
  - Therapeutic holds to manage V/SD patients
- Time limits on length of order apply – i.e. four hours for an adult

Drug or Medication

- Drug or medication used
  - Manage the patient's behavior
  - Restrict the patient's freedom of movement
  - Not a standard treatment or standard dosage for the patient's condition
- Use of PRN drug is only prohibited if medication meets definition of drug
  - Ativan for ETOH withdrawal symptoms is okay
  - Phenergan to control activity → restraint

When a Drug is Not a Restraint

- Medication is within pharmacy parameters set by the FDA and manufacturer for use
  - Use follows national practice standards
- Used to treat a specific condition based on patient's symptoms
- Standard treatment would enable patient to be effective or increase functioning

Restraints Do Not Include

- Forensic restraints
  - Handcuffs, shackles, or other restrictive devices
  - Applied by law enforcement or police
  - Closely monitor and observe for safety reasons
- Orthopedically prescribed devices, surgical dressings or bandages, protective helmets
- Methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests

Restraints Do Not Include

- Protecting the patient from falling out of bed
  - Cannot use side rails to prevent patient from getting out of bed IF patient cannot lower
  - Then it becomes a restraint
- Striker beds or the narrow carts – use of side rails are not a restraint
- IV board - unless tied down or attached to bed
- Postural support devices for positioning or securing
- Device used to position a patient during surgery or while taking an x-ray

Restraints Do Not Include – cont'd

- Recovery from anesthesia is part of the surgical procedure and is medically necessary
- Mitts – ***unless*** tied down or pinned down or so bulky or applied so tightly patient cannot use or bend their hand
  - "Boxing gloves"



- Padded side rails can be put on when as a seizure precaution
- Giving child a shot to protect them from injury

Restraints Include

- Physically holding a patient for forced medications
- Tucking in a sheet so tight patient could not move
- Use of enclosed bed or net bed
  - Unless patient can freely exit the bed such as the zipper inside the bed
- Freedom splint that immobilizes limb
- Remember: is it not "the thing" – rather "what the thing does" to the patient in restricting movement

Is This a Restraint?



Restraints

- Devices with multiple purposes –
  - Side rails or Geri chairs – when cannot be easily removed by the patient
  - Restrict the patient's movement constitute a restraint
- Seat belt in a wheelchair is an exception and allowed
- Patient can lower side rails when they want – not a restraint but document
- If a patient can remove a device - is not a restraint

Restraints - continued

- Stroller safety belts, swing safety belts, highchair lap belts, raised crib rails, and crib covers
  - Okay if age or developmentally appropriate
- Use of these safety interventions must be addressed in your policy
- Holding an infant or toddler is not a restraint

Weapons

- CMS does not consider the use of weapons in the application of restraint or seclusion as a safe, appropriate health care intervention
  - Security staff can carry – per hospital policy and state/federal law
  - Use of weapons security is law enforcement action
    - Not healthcare intervention
  - Okay if patient is arrested and use by law enforcement
- Weapons include pepper spray, mace, nightsticks, Tasers, stun guns, pistols, etc.

Assessment

- Should do comprehensive assessment
  - Assess to reduce risk of slipping, tripping or falling
  - To identify medical problems that could be causing behavioral changes
    - Increased temp – hypoxia – low blood sugar – electrolyte imbalance – drug reactions, etc.
  - Use of restraint is not considered routine part of a fall prevention program

Question 3

Dayton Hospital's restraint and seclusion policy requires an initial assessment, is only for the behavioral health unit and a provider's order. What, if anything, would you recommend be added to the policy? (check all that apply)

- Patient re-evaluation for every shift
- Be applied throughout the facility
- Review and approval by the Board, Medical Staff and Nursing leadership
- Nothing specific – more – that is sufficient

Seclusion – Definition

- Involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving
- May only be used for the management of violent or self-destructive behavior (V/SD behavior) that jeopardizes the immediate physical safety of the patient, a staff member, or others
- Being on a locked unit with others or for time out if patient can leave area **not** seclusion

Determine Reason for R&S

- Surveyor will look for evidence that staff determined the reason for the R&S
  - Should be documented and be specific
  - Consider a field on the order sheet to include this
- Usually – to prevent danger to the patient or others



Possible Reasons to Restrain

- Danger to self
- Maintain therapeutic environment
- Prevent patient from removing vital equipment
- Physically attempting to harm others or property
- Demonstrated lack of understanding to comply with safety directions

Less Restrictive

- Restraints only used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm
- Type or technique used must be least restrictive
  - Is what the patient doing a hazard?
  - Allowing sundowners to walk or wander at night
- Request from patient or family member is not sufficient basis for using if not indicated by condition of patient

Less Restrictive Requirements

- Must assess patient
- Must document
  - Restraint is least restrictive intervention to protect patient safety
  - Based on assessment
  - Effect of least restrictive intervention
- Train staff on what is least restrictive interventions

Least Restrictive Restraint to More

▪ Side-rails……..	▪ Net bed
▪ Hand mittens……	▪ Soft extremity restraint
▪ Lap board……..	▪ Geri chair
▪ Roll belt/lap belt……	▪ Vest restraint
▪ 2-point soft restraint..	▪ 3- or 4-point soft
▪ Wrap IV site ……..	▪ Arm board
▪ Hand mitten……..	▪ Soft wrist restraint
▪ Freedom splint is a restraint!	

Alternatives

- Should be considered along with less restrictive interventions
  - What are other things you could do to prevent using R&S
    - A sitter or family member stay with patient
- Distractions – watching video games, working on a laptop computer
- Try nonphysical intervention skills
- Consider having a list of alternatives in the toolkit

Possible Alternatives

Bed sensor	Lower chairs
Close to nurse's station	Allow wandering, if possible
Activity apron	Food/hydration
E-Z release hugger (if can release)	Low beds or mattress on floor
Reality orientation/familiarize patients to room	Encourage family visits
Verbal instructions/support	Pain/discomfort relief
Frequent visits with patient (hourly except night shift)	Diversion activities such as TV, CDs, DVDs, music therapy, picture books, games
Skin sleeves	Provide structured, quiet environment
Sensor alarm	Exercise/ambulate
Posey lateral wedges	Toileting routine
Access to call cord	

Restraints and Licensed Practitioners

- LPs can write orders for restraints
- Any practitioner permitted by State law and hospital policy having the authority to order restraints or seclusion for patients
  - Within the scope of their licensure
  - Consistent with granted privileges may
  - NP, PA, licensed resident, but not a medical student
- Must specify who in your P&P

Notify Doctor ASAP

- Any established time frames must be consistent with ASAP (not in 1 or 3 hours)
- Hospital MS policy determine who is the attending physician
- P&P should address the definition of asap
- RN or PA who does 1 hour face-to-face must notify attending physician and discuss findings
- Be sure to document if licensed practitioner or nurse notifies physician

Restraints Order Needed

- Order must be received for the restraint from the physician or other licensed practitioner responsible for the care of the patient
- Policy & procedure – include:
  - If an emergency
  - Category of who can order - PA, NP, resident
    - Cannot be medical student
- PRN order prohibited if medication used as a restraint

3 Exceptions to PRN

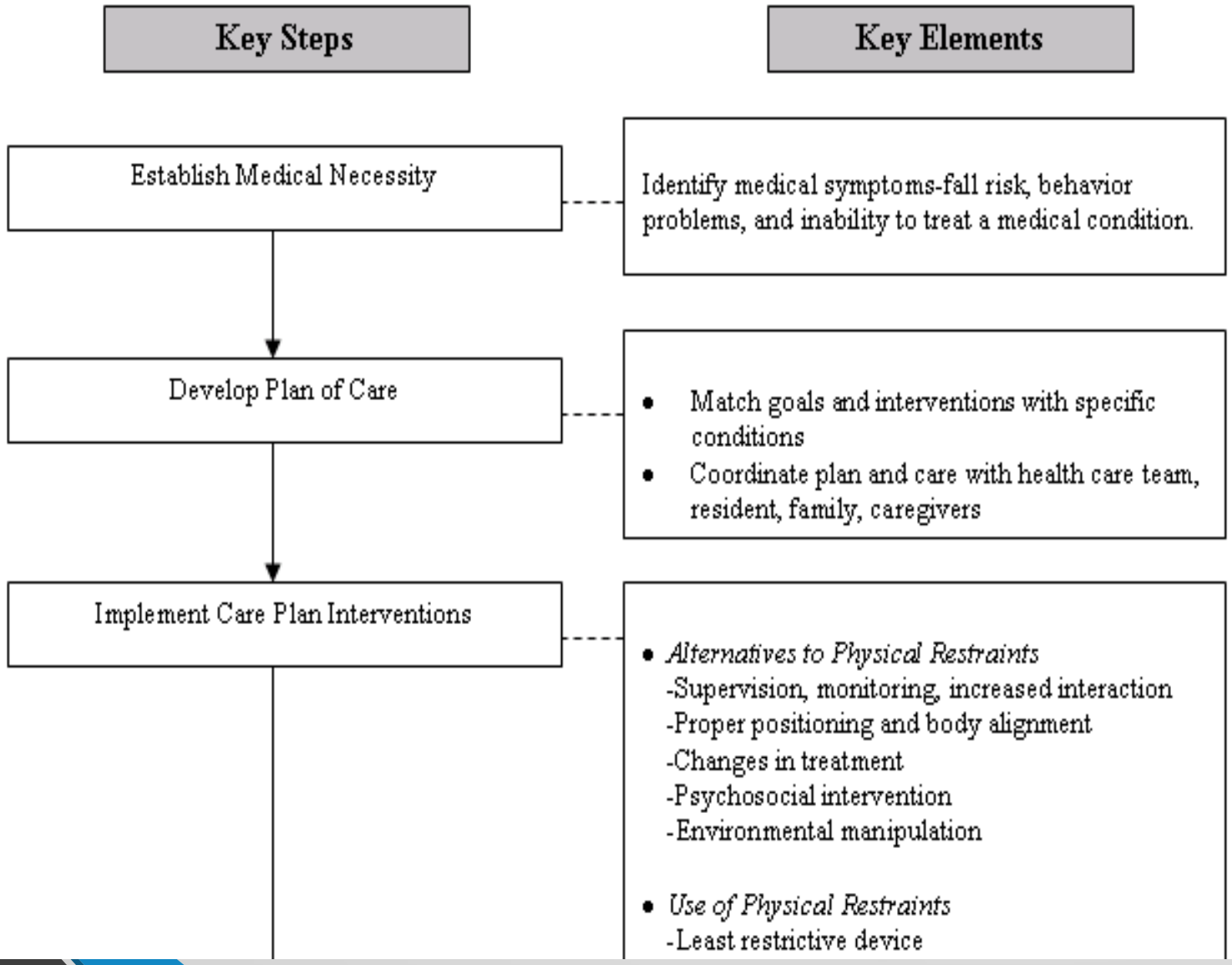
- Geri chair – for patient to be safely out of bed
  - Patient sitting up to eat meal
- Raised side rails – status requires all 4 rails up
  - Seizure precautions
  - Air mattress
- Repetitive self-mutilating behavior
  - Lesch-Nyham Syndrome →



Plan of Care

- Restraints must be used in accordance with a written modification to the patient's plan of care
  - What was the goal of the plan of care?
  - Use of restraint should be in modified plan of care
- Care plan should be reviewed and updated in writing
  - Within time frame specified in P&P
  - Plan reflects a loop of assessment → intervention → evaluation → reevaluation

Physical Restraints: Development of Plan of Care



Plan of Care – continued

- Orders are time limited – include in the plan of care
- For patient who is V/SD – consider debrief as part of plan of care
  - Not mandated by CMS
- Can add information on debrief to R&S toolkit

End at Earliest Time

- Must be discontinued at the earliest possible time
  - Regardless of the time identified in the order
- If discontinue and still time left on clock and behavior reoccurs – will need to get a new order
- **Temporary release** for patient care is okay (feeding, ROM, toileting)
  - **Trial release** is seen as a PRN order and not permitted

Policy – End at the Earliest Time

- Restraints only used while unsafe condition exists
- Hospital policy should include
  - Who has authority to discontinue restraints
  - Circumstances under which restraints to be discontinued
  - Who allowed to take them off
  - Based on determination that patient's behavior no longer a threat to self, staff, or others (put this in your P&P)
  - Procedures to follow when staff need to apply in an emergency
- Surveyors will look at hospital policy

Patient Assessment

- Staff must assess and monitor patient's condition on ongoing basis
- Physician or LP must provide ongoing monitoring and assessment also
  - Determine is if R&S can be removed
- Removed "continually monitored" except for V/SD patients
  - Says at an interval determined by hospital policy

Intervals of Patient Assessment

- Based on patient's need, condition and type of restraint used (V/SD or not)
- CMS does not specify time frame for assessment
  - TJC: every 2 hours for medical patients and every 15 minutes for behavioral health patients
  - CMS says this may be sufficient
  - BUT – waking patient up every 2 hours in night might be excessive
- Frequency of evaluations and assessment must be in your hospital P&P
  - Document to show compliance

Documentation

- Consider special documentation sheet for assessment parameters
  - Including frequency of assessment
  - Hospital policy should address each of these
- If doctor writes a new order or renews order need documentation that describes patient's clinical needs and supports continued use
  - Fluids offered, vital signs
  - Toileting offered, mental status, circulation
  - Removal of restraint and ROM and repositioning

Documentation – continued

- Should include:
  - Attempts to reduce restraints
  - Skin integrity
  - Level of distress or agitation, et. al.
  - Patient's behavior and interventions used
  - Clinical response to the intervention
  - Symptoms and condition that warranted the restraint

Documentation – Behavior

- Document behavior in descriptive terms to evaluate the appropriateness of the intervention
  - Patient attempting to bite the nurse on her arm
  - Patient picked up chair and threw it against the window
  - "The aliens are here in my room and trying to take me away"



Restraint Toolkit

- Have with documentation sheet
  - With the requirements
  - Order sheet
    - Some facilities have separate order sheets for V/SD (behavioral health) and nonV/SD (non behavioral health)
  - Manufacturer instructions for the restraints
  - Articles, etc.

Document Type of Restraint

TYPE OF RESTRAINT OR SECLUSON: (CHECK ALL THAT APPLY)

☐ 4 Side Rails ☐ Elbow Immobilizers ☐Soft Wrist Restraint(s) ☐Hand Mitt(s)

☐ Soft Wrist Restraint(s) ☐Vest ☐Soft Ankle Restraint(s) ☐ Papoose Board

☐Other_____

CATEGORY OF ORDER: (CHECK ALL THAT APPLY)

☐ Initial order ☐ Continuation order ☐Verbal order

I have assessed the patient, attempted or considered alternative(s), determined the need for restraints, and have notifie

_____ and have obtained an order for the application of restraints.

Print Name of L.I.P.

RN Signature _____Date:_____ Time: _____

Print Name_____

LICENSED INDEPENDENT PRACTITIONER (LIP) to COMPLETE
(Physician, Resident, Advanced Practice Nurse, or Physician Assistant)

In accordance with Centers for Medicare and Medicaid (CMS) Conditions of Participation, Standard 482.13(e)(3) (ii)
I have personally evaluated this patient (within one hour of application if this is an initial order) and have determined the need to use/continue the use of restraints/seclusion as specified by this order.

I have notified _____on Date _____Time_____

Print Name of Attending Staff Physician

L.I.P. Signature_____ Date_____ Time _____

Print Name _____

Log and QAPI

- Hospital takes actions thru QAPI activities
- Leadership should assess and monitor use to make sure medically necessary
- Consider log to record use of restraints/seclusion
  - Shift – date – time – staff who initiated
  - Date and time each episode initiated – type of restraint used
  - Whether any injuries of patient or staff
  - Age and gender of patient

Restraint Review Form

Medical Record Number: _____ Restraint Date: _____ Review Date: _____

Complex/Unit: _____ Review By: _____

Restraint Time In: _____ Restraint Time Out: _____

Criteria #	Criteria	Answer
117	All episodes of restraints are ordered/ countersigned by the physician Responsible Person:	Yes / No / NA
118	When emergency use of restraint is ordered, the physician visits within one (1) hour to authorize continued use. Responsible Person:	Yes / No / NA
119	Each episode of restraint has a specific time limit documented in the order by the physician. Responsible Person:	Yes / No / NA
120	Each episode of restraint has a written order limited to one (1) hour by the physician. Responsible Person:	Yes / No / NA
121 (A)	Each episode and re-evaluation of restraint is documented in the patient's medical record by the physician. Responsible Person:	Yes / No / NA
121 (B)	Each episode and re-evaluation of restraint is documented in the patient's medical record by the nurse. Responsible person:	Yes / No / NA

Use as Directed

- Restraints and seclusion must be implemented in accordance with safe, appropriate restraining techniques
  - As per hospital policy in accordance with state law
- Use according to manufacturer's instructions and include in your policy as attachment
  - Maintain copies of these
- Follow any state law provision or standards of care and practice
- Complete incident report if any injury to patient

Use As Directed By Manufacturer













One Hour Rule

- Standard for behavioral health patients or V/SD
- Time limits for R&S used to manage V/SD behavioral and drugs used as restraint to manage them
- Must see (face-to-face)
  - Evaluate the need for R&S
  - Within one hour after the initiation of this intervention

One Hour Rule – continued

- Originally – physician had to see and evaluate the patient
  - AHA sued CMS over this provision
- Now - face-to-face evaluation can be done by physician, LP or a RN trained under 482.13 (f)
  - Physician does not have to come to the hospital to see patient
  - Telephone conference may be appropriate
  - (Training requirements are detailed and discussed later)
- Evaluation done to rule out possible underlying causes of contributing factors to the patient's behavior

One Hour Rule Assessment

- Must see the patient face-to-face within 1-hour after the initiation of the intervention, unless state law more restrictive
- Practitioner must evaluate
  - Patient's immediate situation
  - Reaction to the intervention
  - Medical and behavioral condition
  - Need to continue or terminate the restraint or seclusion
- Must document this and change documentation form to capture this information

Assessment – continued

- Includes physical and behavioral assessment
  - Review of systems,
  - Behavioral assessment, as well as
  - Patient's history, drugs and medications and most recent lab tests
- Consider other causes: drug interactions, electrolyte imbalance, hypoxia, sepsis etc.
- Document change in the plan of care
- Staff must be trained in all the above

Time Limited Orders

- Time limits apply- written order is limited to
  - 4 hours for adults
  - 2 hours for children (9-17)
  - 1 hour for under age 9
- Related to R&S for violent or self-destructive behavior
  - And safety of patient or staff



PHYSICIAN ORDERS

RESTRAINTS FOR VIOLENT/SELF-DESTRUCTIVE PATIENT

Date of Restraint Order – Single Episode: _____

An evaluation of patient's condition and necessity for restraints must be completed within 1 hour of application of any type of restraint.

Alternatives to restraints attempted:

- ☐ Family involvement
- ☐ Relaxation techniques
- ☐ Verbal de-escalation
- ☐ Redirection/Reorientation
- ☐ Decreased stimulation

- ☐ **NO ALTERNATIVES / IMMINENT RISK**
- ☐ Anticipation of toileting/hydration needs
- ☐ Discomfort assessed/relieved
- ☐ Sitter / 1:1 Observation
- ☐ Other _____

Date/Time of Face-to-Face (must be within 1 hour of restraints initiation) _____

Pre-existing Conditions that would present greater risk:

- ☐ Pre-existing medical conditions
- ☐ Physical disability
- ☐ History of sexual abuse
- ☐ History of physical abuse
- ☐ Other

1. **The patient's immediate situation:**
2. **The patient's reaction to intervention:**
3. **The patient's medical and behavioral condition:**
4. **Do restraints need to be continued?** ____ **Yes – order will be obtained**
   ____ **No – RN will remove restraint & document discontinuance on flowsheet**

Authorized RN/MD/LIP: _____ _____
(Signature) **(Date/Time)**

- ☐ **Restraint Plan discussed with multidisciplinary team and care plan is modified.**
- ☐ **Family notified of restraint policy and intent to apply restraints.**

Restraint Initiation (use least restrictive possible):

Renew Order

- Original order for both violent or destructive may be renewed up to 24 hours
  - Then physician reevaluates
  - Nurse evaluates patient and shares assessment with practitioner when need order to renew
  - Unless state law if more restrictive
- After the original order expires
  - MD or LP must see the patient and assess before issuing a new order

Non-Violent Non-Destructive

- Each order for non-violent or non-destructive patients may be renewed as authorized by hospital policy



Need Policy on R&S*

- Will interview staff to make sure they know the policy
- Consider training on policy in orientation and during the annual in-service and when changes made
- Surveyor to look at use of R&S and make sure it is consistent with the policy
  - Major area in the survey process

Staff Education

- All staff having direct patient contact must have
  - Ongoing education and training
  - Proper and safe use of restraints
  - Able to demonstrate competency
- Yearly education of staff as when skills lab is done
  - Document competency and training
- P&P should identify what categories of staff responsible for assessing and monitoring the patient (RN, LPN, Nursing assistant)

Staff Education – continued

- Standard: Patients have a right to safe implementation of restraint/seclusion by trained staff
  - Training plays critical role in reducing use
- Staff, including agency nurses, must be trained AND demonstrate competency in the following:
  - Application of restraints (how to put them on)
  - Monitoring
  - How to provide care to patients in restraints

Staff Education – Training

- Training must be done before performing any of these functions
- It must occur in orientation before new staff can use them on a patient
- Must occur on periodic basis consistent with hospital policy
- Use a form
  - Document that each of the education requirements have been met

Staff Education

- Consider yearly during skills lab
- Hospital must require appropriate staff to have
  - Education
  - Training
  - Demonstrated knowledge based on the specific needs of the patient population in at least:
- Techniques to identify staff and patient behaviors
- Events and environmental factors that may trigger circumstances that require R/S

Question 4

What would you recommend for annual staff training for use of restraints, seclusion, agitated patients? (check all that apply)

- De-escalation techniques for all disruptive and/or behavioral health patients
- CPR
- Self-defense training
- General first aid
- Is for clinical staff only
- Involves all personnel – including security

De-escalation & Training

- Teach staff what is de-escalation
  - Not just staff on the behavioral health unit
  - Avoid confrontation and approach in a calm manner
  - Active listening
  - Validate feelings - "you sound like you are angry"
- Some facilities have personal de-escalation plan that lists triggers:
  - Not being listening to, feeling pressured, being touched, loud noises, being stared at, arguments, people yelling, darkness, being teased, etc.

Personal De-escalation Plan

Patient Name:_____
Date:_____

PROBLEM BEHAVIORS: What type of behaviors are problems for you?

- ❑ Losing control
- ❑ Feeling unsafe
- ❑ Injuring yourself
- ❑ Assualtive behavior
- ❑ Running away
- ❑ Suicide attempts
- ❑ Restraints/Seclusion
- ❑ Feeling suicidal
- ❑ Drug or alcohol abuse
- ❑ Other:_____

TRIGGERS: What type of things (triggers) make you feel unsafe or upset?

- ❑ Not being listened to
- ❑ Lack of privacy
- ❑ Feeling lonely
- ❑ Darkness
- ❑ Being teased or picked on
- ❑ Feeling pressured
- ❑ People yelling
- ❑ Arguments
- ❑ Being isolated
- ❑ Contact with family_____
- ❑ Being touched
- ❑ Loud noises
- ❑ Not having control
- ❑ Being stared at
- ❑ Particular time of day/ night:_____
- ❑ Particular time of year:_____
- ❑ Other:_____

WARNING SIGNS: Please describe your warning signs, for example what other people may notice when you begin to lose control?

- ❑ Sweating
- ❑ Clenching teeth
- ❑ Wringing hands
- ❑ Bouncing legs
- ❑ Squatting
- ❑ Crying
- ❑ Not taking care of self
- ❑ Singing inappropriately
- ❑ Eating more
- ❑ Breathing hard
- ❑ Clenching fists
- ❑ Loud voice
- ❑ Rocking
- ❑ Cant sit still
- ❑ Isolating/ avoiding people
- ❑ Hurting myself
- ❑ Sleeping less
- ❑ Being rude
- ❑ Racing heart
- ❑ Red faced
- ❑ Sleeping a lot
- ❑ Pacing
- ❑ Swearing
- ❑ Hyper
- ❑ Hurting others or things
- ❑ Eating less
- ❑ Laughing loudly/ giddy
- ❑ Other:_____

_____

Staff Education – cont'd

- Choose the least restrictive intervention
  - Based on an individualized assessment of the patient's medical, or behavioral status or condition
- Safe application and use of all types of R&S used in the hospital
  - Including training in how to recognize and respond to signs of physical and psychological distress
  - For example, positional asphyxia

Staff Education – cont'd

- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary
- Monitoring the physical and psychological well-being of the patient who is restrained or secluded including
  - Respiratory and circulatory status
  - Skin integrity
  - Vital signs
  - Special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation

First Aid

- Use of first aid techniques
  - Plus – CPR certification
    - Including required periodic recertification (206)
- All staff who apply, monitor, access, or provide care to patient in restraint must have education and training in first aid technique and certified in CPR
  - To render first aid if patient in distress or injured
  - Develop scenarios and first aid class to address these

Training Documentation

- Hospital must document in personnel records that the training and competency successfully completed
- Security guards respond to V/SD patients so would need to train
  - Many give an 8-hour CPR course
  - Do not want someone going into the room of a V/SD patient without training to prevent injury to staff and patient

Training Cost

- Individuals doing training program must be qualified
- Trainers must have high level of knowledge
  - Document their qualifications
- Train-the-trainer programs are done by many facilities



Educating Physicians and LPs

- Physician and other LP training requirements must be specified in hospital policy
- At a minimum:
  - Physicians and other licensed practitioners
  - Authorized to order R or S by hospital policy in accordance with State law
  - Must have a working knowledge of hospital policy regarding the use of restraint or seclusion
- Hospitals have flexibility to determine what other training physicians and LPs need

Stricter State Laws

- Requirements will be superseded by existing state laws that are more restrictive
  - State laws can be stricter but not weaker or they are preempted
- States are always free to be more restrictive
  - Many states have a state department of mental health which has standards for patients that are in a behavioral health unit

1:1 Monitoring R *and S*

- For behavioral health patients (violent/self-destructive per CMS) that are a danger to self or others
- Cannot use R&S together unless
  - Patient visually monitored in person face to face or
  - By audio and video equipment
- Person monitoring patient must be assigned and a trained staff member
  - Must be in close proximity to the patient
  - Must be documentation in the medical record

Documentation

- Documentation to include
  - Least restrictive interventions used
  - Conditions or symptoms that warranted RS
  - Patient's response to intervention
  - Rationale for continued use
- Include in hospitals P&P
- Modify assessment sheets to include information
- Consider sitter policy – ensure they do not leave patient unsupervised

Deaths – Reporting

- Standard: Hospital must report to CMS each death that occurs while a patient is in restraint or in seclusion at the hospital
  - Every death that occurs within 24 hours after the patient has been removed from R&S
- Each death known to the hospital
  - Occurs within 1 week after R&S
  - Where reasonable to assume
  - Use of restraint or placement in seclusion
  - Contributed directly or indirectly to a patient's death
- Must document date and time reported to CMS

“Reasonable to Assume”

- “Reasonable to assume” includes, but is not limited to:
  - Deaths related to restrictions of movement for prolonged periods of time, or
  - Death related to chest compression, restriction of breathing or asphyxiation

Additional Reporting

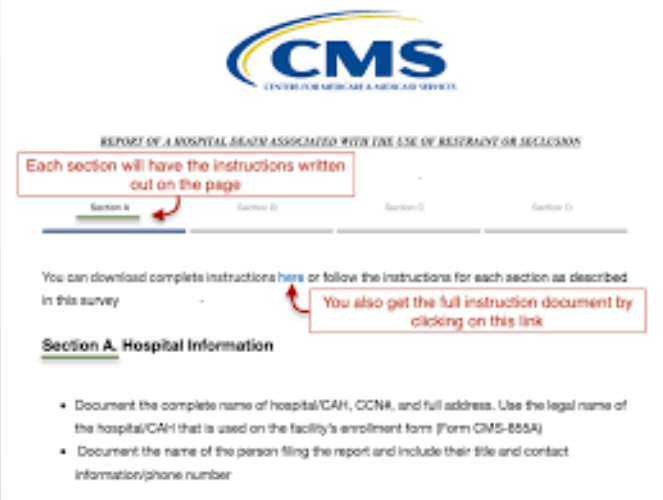
- Standard: When no seclusion used and only restraints are soft, cloth-like material
- Must record in internal log/similar system
  - Death while in such restraints
  - Death within 24 hours after removed
- Must document date and time death record in the log or system

Internal Log

- Will need to include information in internal log
- Log must be done asap – no later than 7 days
  - Must include patient's name, date of birth, date of death, attending physician, primary diagnosis, and medical record number
  - Name of practitioner responsible for patient could be used in lieu of attending if under care on non-physician practitioner
    - CMS could request to review the log at anytime
- Still required to report death within seven days
- May need to rewrite policies and procedures and train all staff

Deaths – Reporting

- Must be reported to CMS regional office by telephone
  - No later than the close of business the next business day following knowledge of the patient's death
  - Must use the electronic form
  - https://www.cms.gov/files/document/qso-20-04-hospital-cah-dpu.pdf.



Electronic Restraint Reporting Form

- Form CMS-10455 requires more information than paper form
- Asks for information such as:
  - Primary diagnosis, cause of death, reason for the use of restraint/seclusion, events or circumstances leading up to death, circumstances surrounding the death, how R&S was associated with the death, type of R/S used, and length of time in R/S, etc.
  - To determine whether an onsite survey is indicated to investigate the circumstances surrounding the patient deaths associated with the use of restraints and/or seclusion



OCR Section 1557 Interpreters

OCR Section 1557

- OCR 1557 changes August 2020
  - If CMS identifies a violation can notify the OCR to investigate – discrimination
- Cannot:
  - Segregate, delay or deny services based on patient's color, race, or national origin
  - Force a hospital/provider to do procedure against religion
    - Abortion – sex reassignment surgery
- January 2025 Executive Order 14168 – "gender identity" no longer recognized

Interpreters

- Must offer a timely qualified interpreter when oral interpretation is a reasonable step to provide a patient with meaningful access
- Language services are provided free of charge
  - May not require a patient to have their own interpreter
  - Cannot rely on child to interpret with exception
  - Cannot use low quality video remote interpreting services
  - May not delay or deny effective language assistance services to patients with LEP

- Resources at https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html

Interpreters Requirements

- Must ensure interpreters available
  - Ensure communication needs of patients are met
- Need "qualified" interpreters
  - "Certification" NOT required
- Document interpreter was used
  - See TJC Patient Centered Communications Standards



Signs and Taglines

- Post a sign in several languages
  - 15 languages under OCR 1557
    - 17 languages in 5 states: CO, MD, RI, VA and DC
  - Include in yearly skills lab and make sure staff knows and understand P&P
  - Review your policy and procedure
- Taglines – notify patient of the availability of language assistance services
  - Publish and place in prominent locations
- If own physician practices – ensure interpreters present in prescheduled appointments

Certification Optional

- National Board of Certification for Medical Interpreters and CCHI or the Certification Commission for Healthcare Interpreters – two credentials
  - **CHI stands for Certified Healthcare Interpreter** -best (Spanish, Mandarin & Arabic)
  - And entry level **Core Certification Healthcare Interpreter** (CoreCHI)

§1557 Grievance Procedure

- Must adopt a grievance procedure (P&P)*
  - Whoever the hospital designates must investigate any grievances alleging noncompliance with Section 1557
  - Must provide for prompt and equitable resolution of the grievance
  - Let the patient know what they did and when they did it
  - Changes August 2020 - have a process

* See appendix

Final Discussion

DW is a 66-year-old with a long history of autism disorder in which he does not tolerate loud noises, bright lights or touching without warning to him. DW was a passenger in a car that was "T-Boned" at high speed. The driver – his sister and caretaker, was killed in the impact. DW is brought to the ER in an unconscious state, on a precautionary backboard and cervical color. He regained consciousness shortly after arrival and becomes very combative – pulling on the collar and swinging at the staff. Attempts to quiet him verbally were unsuccessful so he is placed in 4-point restraints and medication administered. DW becomes quiet but still appears agitated.

Final Discussion – cont'd

Thirty minutes later, DW's brother-in-law arrives and explains DW's autism condition. He is able to speak with DW and get him calmed, explains to DW what is occurring – C-collar and backboard and the why of their use; DW agrees to be compliant. The brother-in-law also demands the restraints be removed immediately – they cause increased agitation to DW. The staff refuse due to the prior episode of violence.

What citations, if any, might the hospital face? (check all that apply)

- Violation of patient rights – unnecessary restraint
- Inappropriate use of restraints – punishment for hitting the staff
- No citations – it was necessary for staff safety

Thank You



- Laura A. Dixon, Esq.
- BS, JD, RN, CPHRM
- President, Healthcare Risk Education and Consulting, LLC
- ldesq@comcast.net

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Appendix

Resources

and

Internet Links

Office of Civil Rights

www.hhs.gov/civil-rights/index.html

Civil Rights

I would like info on. . .

- Final Rule on Section 1557
- Limited English Proficiency (LEP)
- Civil Rights Clearance for Medicare Providers



We Translate

Get help in other languages including Español, 繁體中文, Tiếng Việt, 한국어, Tagalog, Русский, Kreyòl Ayisyen, Français, Português, Polski, 日本語 , Italiano, Deutsch, فارسی.

Civil Rights Information for Individuals and Advocates

We enforce laws against discrimination based on race, color, national origin, disability, age, sex, and religion by certain health care and human services providers and health insurance plans.

Filing a Civil Rights Complaint

You may file a civil rights complaint with OCR if you feel a health care provider or government agency discriminated against you (or someone else) unlawfully.

Civil Rights for Providers of Health Care and Human Services

Understand which entities must comply with civil right laws and how to comply.

Newsroom

Read the latest news releases and bulletins and an archive of past releases.

Special Topics

Read about special topics in civil rights: Child welfare services, HIV/AIDS, limited English proficiency, community living and more.

HIPAA - Health Information Privacy

Find guidance and more information about the HIPAA Privacy Rule, including what information is protected and how

OCR Section for Providers



Limited English Proficiency Resources

Limited English Proficiency (LEP)

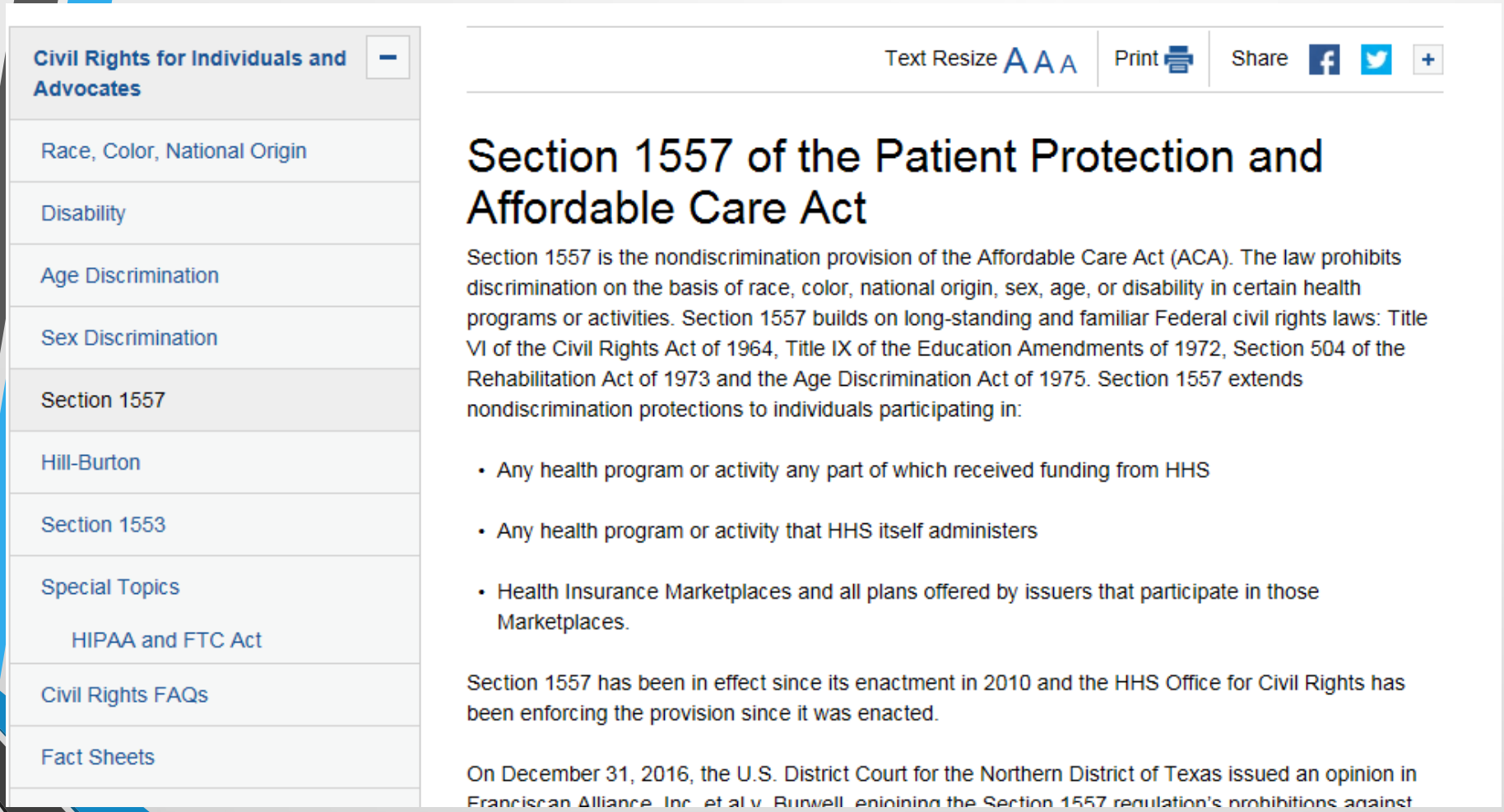
If English is not your primary language and you have difficulty communicating effectively in English, you may need an interpreter or document translation in order to have meaningful access to programs funded by the Department of Health and Human Services (HHS). Title VI of the Civil Rights Act of 1964 requires recipients of Federal financial assistance to take reasonable steps to make their programs, services, and activities by eligible persons with limited English proficiency.

LEP Resources

www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html

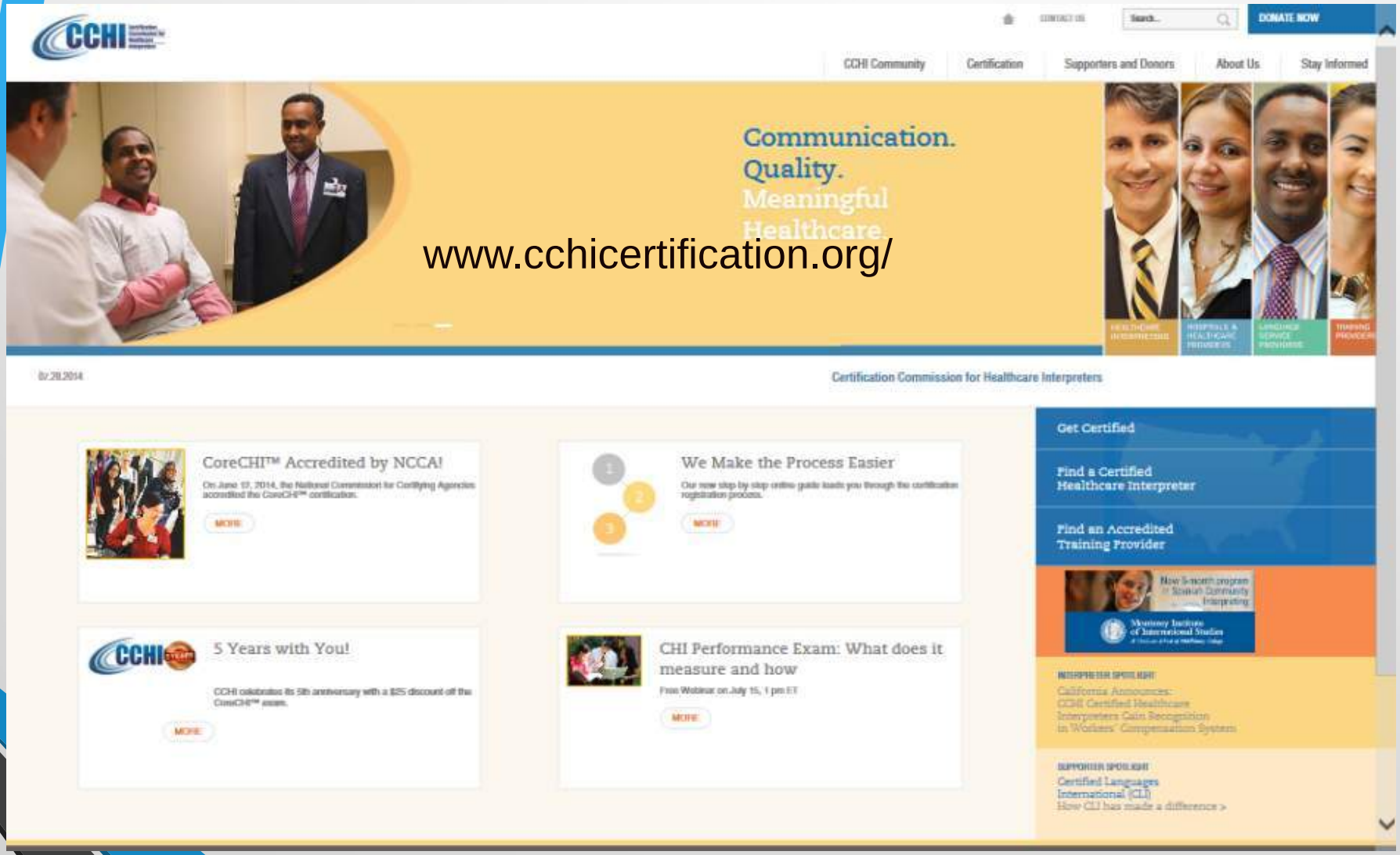
- Revised HHS LEP Guidance
  - FAQs
  - Summary
  - Fact Sheet
- Understand Discrimination on the Basis of Race, Color or National Origin
  - Fact Sheet about Title VI Discrimination - PDF - 2013
- Read about OCR's LEP Enforcement Success Stories
- Federal, State, and Non-Governmental Resources
- HHS Language Plan (2013) - PDF – The plan established a strategy for ensuring meaningful access by individuals with LEP to HHS administered programs and activities in accordance with Executive Order 13166.
  - OCR Blog Post: HHS Continues to Improve Access for LEP Individuals - 12/1/2015

Resources on OCR Website on 1557



www.hhs.gov/civil-rights/for-individuals/section-1557/index.html

CCHI Certification Commission





LANGUAGE ACCESS REQUIREMENTS

GET CERTIFIED LOGIN

LANGUAGE ACCESS REQUIREMENTS | INTERPRETER CERTIFICATION | HOSPITAL CASE STUDIES | BILINGUAL STAFF

http://cchicertification.org/healthcare-administrators/language-access/

Accurate and effective communication is the most fundamental component of the healthcare encounter between patient and provider. Hospitals and healthcare providers are mandated to meet the communication needs of an increasingly diverse population.

When you don't have CCHI certified healthcare interpreters, you risk:

- Loss of federal funding due to unqualified interpreters (The High Costs of Language Barriers in Medical Malpractice),
- The Joint Commission accreditation,
- Non-compliance with Section 1557 of the Affordable Care Act (read more here),
- Office for Civil Rights investigation,
- Patient compliance, safety and higher readmission rate.

National Board of Certification for Medical

THE NATIONAL BOARD OF CERTIFICATION FOR MEDICAL INTERPRETERS

https://nbcmi.memberclicks.net/

Member Login | Search our site

HOME | ABOUT US | GET CERTIFIED | RECERTIFICATION | WEBINAR | GET INVOLVED | CONTACT US



Welcome Interpreters!

Medical interpreters are a key component of the care team when assisting persons with limited English proficiency. Since 2010, the National Board of Certification for Medical Interpreters (National Board) has helped thousands of interpreters further their careers through its excellent credentialing program, by which professional medical interpreters demonstrate they have met nationally set standards to ensure patient safety and compliance with federal guidelines and requirements. Once a candidate passes the certification exams from the National Board, they are bestowed the **CMI Credential** (Certified Medical Interpreter).

The careful vetting process and high standards held by the National Board are just some of the reasons employers and care providers prefer working with CMIs--knowing they will be compliant with regulatory guidelines, provide complete and accurate interpretation, and promote patient safety.

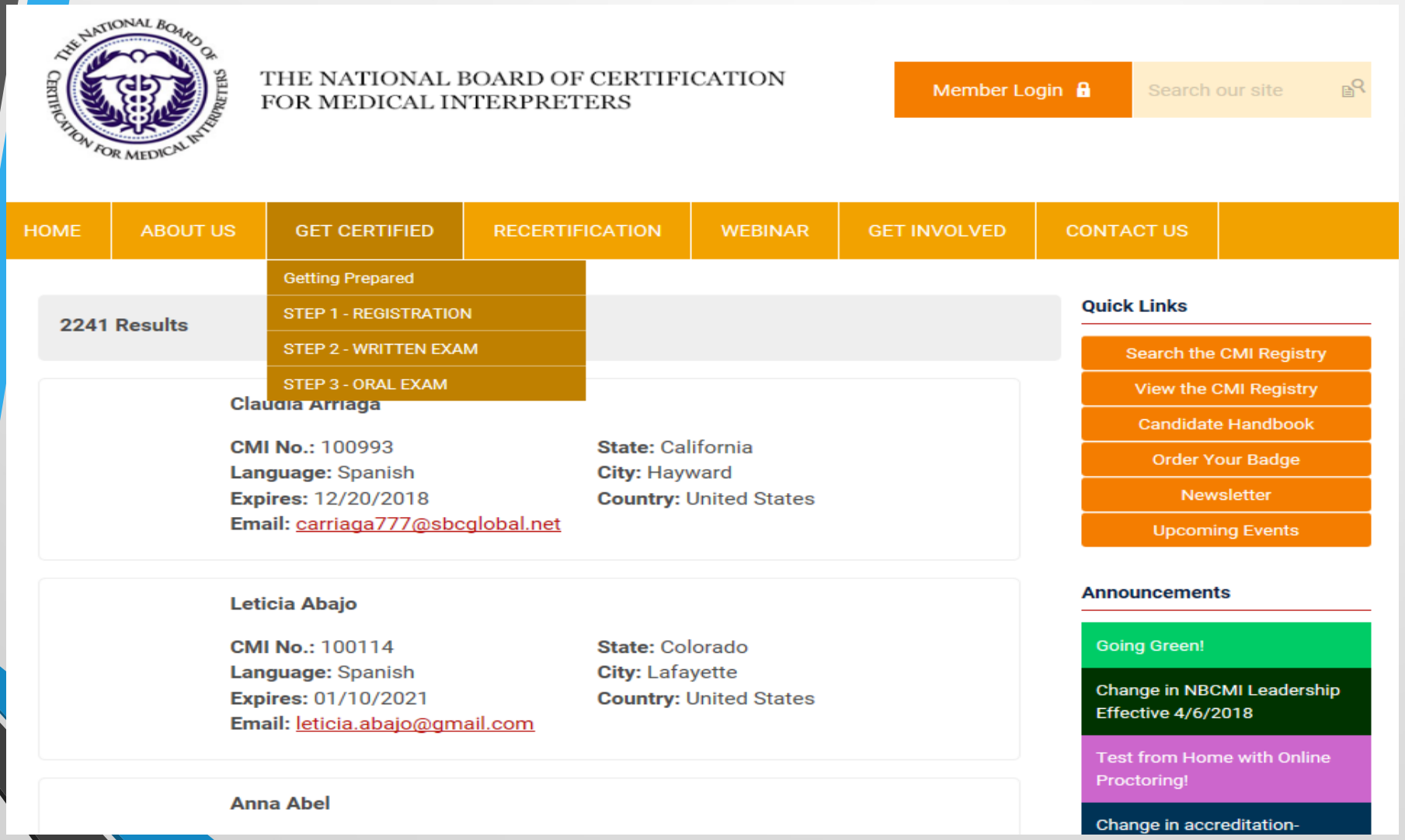
Quick Links

- Search the CMI Registry
- View the CMI Registry
- Candidate Handbook
- Order Your Badge
- Newsletter
- Upcoming Events

Announcements

- Going Green!
- Change in NBCMI Leadership Effective 4/6/2018
- Test from Home with Online Proctoring!
- Change in accreditation- Bringing all CMI exams under the same standards

HR Can Check Registry



Interpreters – Federal Rule: "Qualified"

https://www.govinfo.gov/content/pkg/FR-2020-06-19/pdf/2020-11758.pdf (see page 86; or pg. 37245)

Department's Office for Civil Rights, that the health program or activity will be operated in compliance with section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in an Exchange or approval to operate a State Exchange.

(b) *Duration of obligation.* The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing section 504 at 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing section 504 at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under section 1557 and this part.

§ 92.5 Enforcement mechanisms.

(a) The enforcement mechanisms provided for, and available under, Title VI of the Civil Rights Act of 1964 (42 seq.), Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2 of this part.

(b) Insofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the statutes cited in paragraph (a) of this section or provided by the Architectural Barriers Act of 1968 (42 U.S.C. 4151 *et seq.*); the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008 (42 U.S.C. 12181 *et seq.*), Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d), the Coats-Snowe Amendment (42 U.S.C. 238n), the Church Amendments (42 U.S.C. 300a–7), the Religious Freedom Restoration Act (42 U.S.C. 2000bb *et seq.*), Section 1553 of the Patient Protection and

(iii) The nature and importance of the entity's health program, activity, or service; and

(iv) The resources available to the entity and costs.

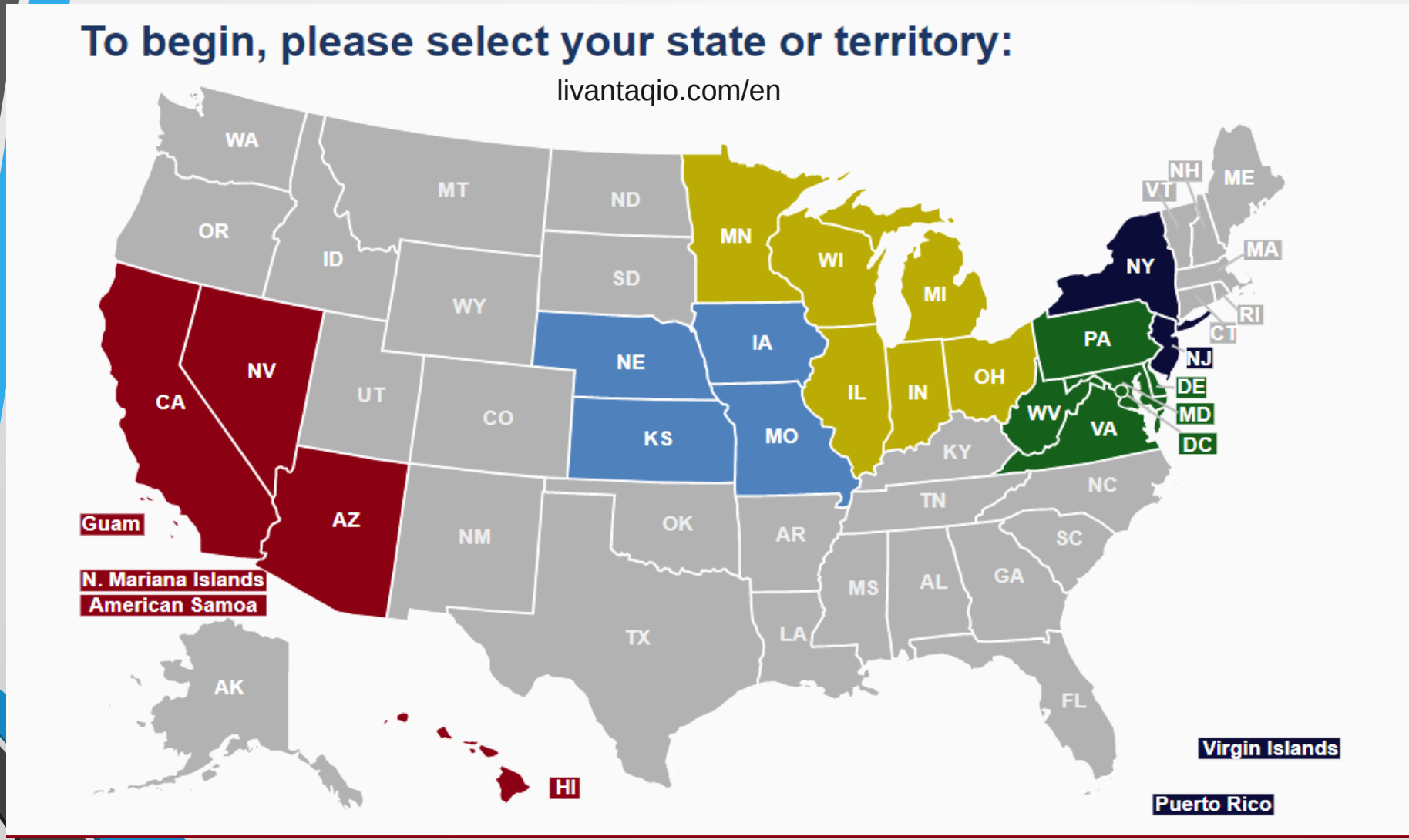
(2) *Language assistance services requirements.* Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of language assistance services, such services must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. Language assistance services may include:

(i) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency; and

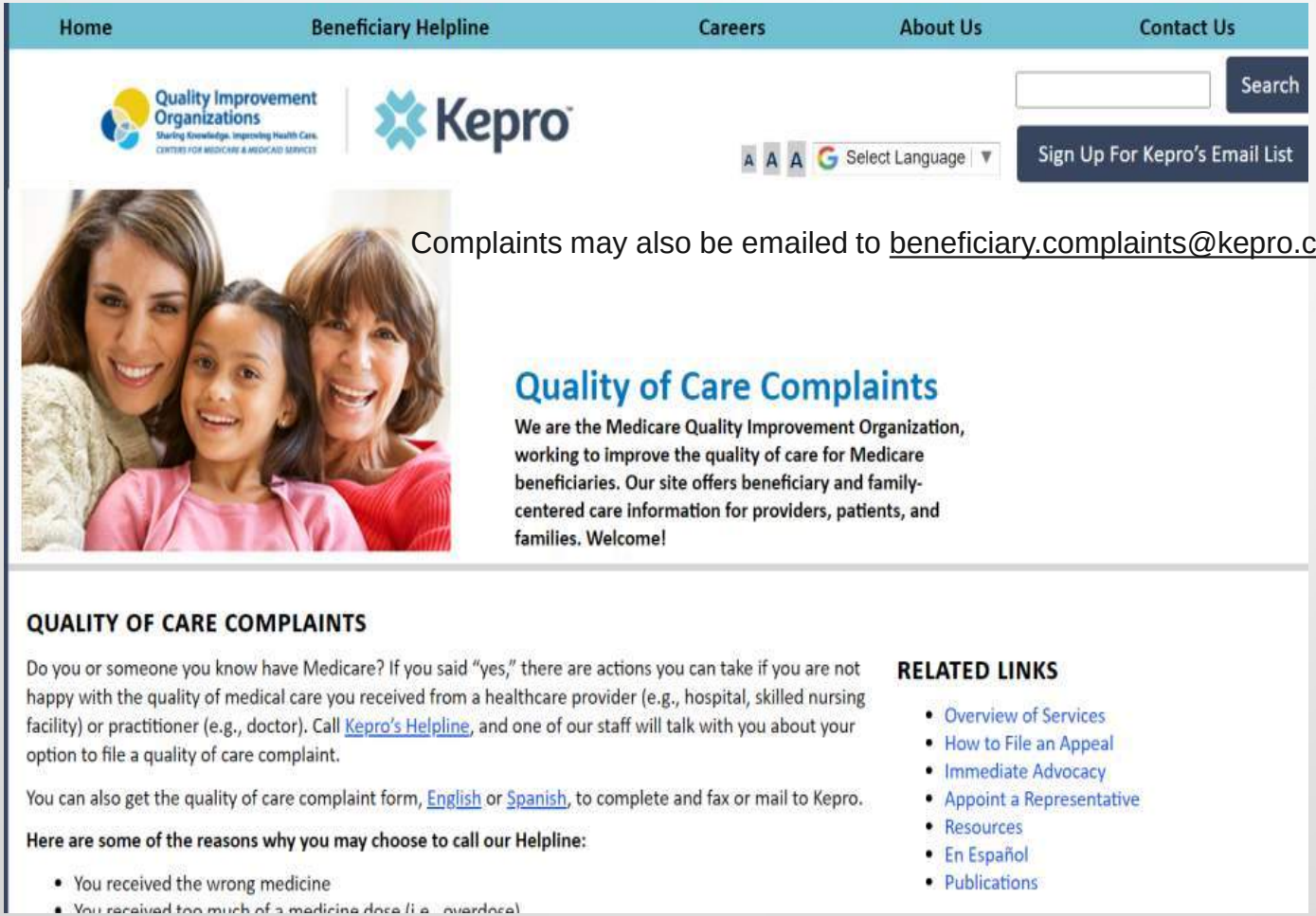
(ii) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English.

Document last modified: 3/4/2021

KEPRO and Livanta QIOs



Quality of Care Complaints Kepro



Complaints may also be emailed to beneficiary.complaints@kepro.com

MEDICARE QUALITY OF CARE COMPLAINT FORM

1. BENEFICIARY NAME:

2. MEDICARE NUMBER (HICN):

3. SEX: ☐ **MALE** ☐ **FEMALE** | **DATE OF BIRTH:**

4. RACE/ETHNICITY *(Completion of this section is voluntary) How would you describe your race? Please mark one or more boxes.*
How would you describe your race? Please mark one or more boxes.

☐ American Indian or Alaska Native ☐ White ☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ Hispanic or Latino

5. BENEFICIARY'S AUTHORIZED REPRESENTATIVE'S NAME *(IF APPLICABLE)*:

6. CONTACT INFORMATION FOR PRIMARY CONTACT:

https://ivantaqio.com/assets/files/cms10287english.pdf

STREET/APT.

CITY | **STATE** | **ZIP**

PHONE | **ALTERNATE PHONE**

7. Briefly describe the incident or your concerns: Include dates and times, persons involved, and description of what happened. Include attachments, if appropriate.

8. May we reveal your identity during the review of your complaint? ☐ YES ☐ NO
If you check "no" we cannot review your complaint as a written beneficiary complaint. However, based on the circumstances of your complaint, we may choose to review your complaint as a general quality of care review.

9. Check "yes" here if you authorize the QIO to forward your address or other contact information to the entity that conducts beneficiary satisfaction surveys. If you check "yes", you will be contacted by telephone or postal mail to

Sample Grievance Policy

Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

It is the policy of [Name of Covered Entity] not to discriminate on the basis of race, color, national origin, sex, age or disability. [Name of Covered Entity] has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 1557 of the Affordable Care Act (42 U.S.C. § 18116) and its implementing regulations at 45 C.F.R. pt. 92, issued by the U.S. Department of Health and Human Services. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. Section 1557 and its implementing regulations may be examined in the office of [Name and Title of Section 1557 Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email], who has been designated to coordinate the efforts of [Name of Covered Entity] to comply with Section 1557.

Any person who believes someone has been subjected to discrimination on the basis of race, color, national origin, sex, age or disability may file a grievance under this procedure. It is

www.hhs.gov/sites/default/files/section-1557-sample-grievance-procedure.pdf

Proposed Updates 2023

- Allowing patients to inspect PHI in person and take notes or photographs of their PHI
- Changing the maximum time to provide access to PHI from 30 days to 15 days
- Restricting the right of individuals to transfer ePHI to a third party to only ePHI that is maintained in an EHR
- Confirming that an individual is permitted to direct a covered entity to send their ePHI to a personal health application if requested by the individual

Proposed Updates – continued

- When individuals should be provided with ePHI without charge
- Requiring covered entities to inform individuals that they have the right to obtain or direct copies of their PHI to a third party when a summary of PHI is offered instead of a copy
- The Armed Forces' permission to use or disclose PHI to all uniformed services has been expanded
- A definition has been added for electronic health records

Proposed Updates – continued

- Wording change to expand the ability of a covered entity to disclose PHI to avert a threat to health or safety when harm is "seriously and reasonably foreseeable" (currently when harm is "serious and imminent")
- A pathway created for individuals to direct sharing of PHI maintained in an EHR among covered entities
- Covered entities will not be required to obtain a written acknowledgment from an individual that they have received a Notice of Privacy Practices
- https://www.hipaajournal.com/hipaa-updates-hipaa-changes/

New Ligature Risk Assessment Guidelines

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality

Ref: QSO-23-19-Hospitals

DATE: July 17, 2023

TO: State Survey Agency Directors

https://www.cms.gov/files/document/qso-23-19-hospitals.pdf

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Ligature Risk and Assessment in Hospitals

Memorandum Summary

- ***Patients in Medicare-certified hospitals have a right, by regulation, to receive care in a safe setting.***
- ***Hospitals can demonstrate compliance with this standard through appropriate patient assessments, adequate staffing and monitoring, and mitigation of environmental risks.***

Background:

Medicare-certified hospitals have a regulatory obligation to care for patients in a safe setting under the Medicare Hospital Conditions of Participation at §482.13(c)(2). The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person similarly situated as the patient would consider to be safe. Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity, and comfort would also be components of an emotionally safe environment.

The focus of ligature risk management should be to place patients in an environment, with appropriate monitoring, reflective of their specific medical and psychiatric needs. Based on their

Training on How to Fill Out the Restraint Form



OCR Privacy Website

HHS.gov Health Information Privacy U.S. Department of Health & Human Services

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- Covered Entities and Business Associates
- HIPAA Enforcement Highlights
- Frequently Asked Questions



HIPAA Access Guidance and FAQs

New guidance and FAQs clarify HIPAA's Right to Access requirements.

HIPAA for Individuals

Filing a HIPAA Complaint

HIPAA for Professionals

HIPAA for Professionals

Privacy +

Security +

Breach Notification +

Compliance & Enforcement +

Special Topics +

Patient Safety +

Covered Entities & Business Associates

Training & Resources

FAQs for Professionals

Other Administrative Simplification Rules

HIPAA for Professionals

To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, included Administrative Simplification provisions that required HHS to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security. At the same time, Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information.

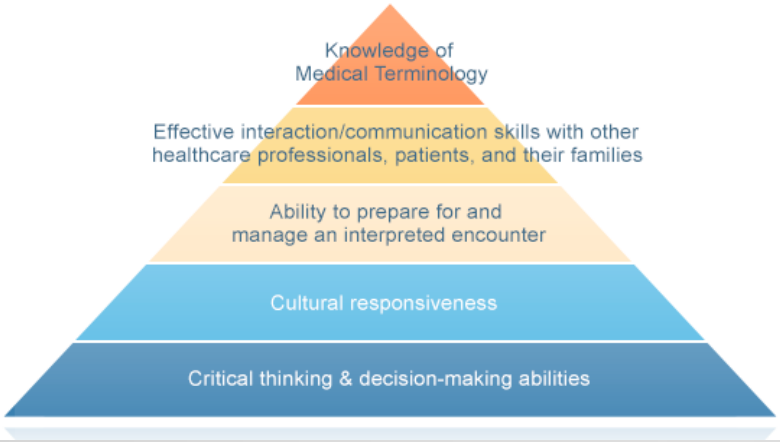
- HHS published a final Privacy Rule in December 2000, which was later modified in August 2002. This Rule set national standards for the protection of individually identifiable health information by three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct the standard health care transactions electronically. Compliance with the Privacy Rule was required as of April 14, 2003 (April 14, 2004, for small health plans).
- HHS published a final Security Rule in February 2003. This Rule sets national standards for protecting the confidentiality, integrity, and availability of electronic protected health information. Compliance with the Security Rule was required as of April 20, 2005 (April 20, 2006 for small health plans).
- The Enforcement Rule provides standards for the enforcement of all the Administrative Simplification Rules.
- HHS enacted a final Omnibus rule that implements a number of provisions of the HITECH Act to strengthen the privacy and security protections for health information established under HIPAA, finalizing the Breach Notification Rule.
- View the Combined Regulation Text (as of March 2013). This is an unofficial version that pr... all the HIPAA regulatory standards in one document. The official version of all federal regulations is

top

CoreCHI: Entry Point for Interpreters

1. The Core Certification Healthcare Interpreter™ (CoreCHI™) is the entry point into professional certification for healthcare interpreters regardless of the language(s) in which they interpret. ***CoreCHI™ is THE one certification every interpreter of every language needs to have and can have today.*** This certification tests medical interpreters of any language on the core professional knowledge as well as critical thinking, ethical decision-making, and cultural responsiveness skills needed to perform the interpreter's duties in any healthcare setting.**It focuses on the role of the healthcare interpreter** and measures the interpreter's knowledge, abilities and skills related to:

- universal protocols and safety precautions,
- being a partner in a patient's care team,
- culturally-determined patient's behavior which may negatively impact the outcome of the healthcare encounter,
- ethical decision-making,
- U.S. health care system and medical terminology, etc.



CCHI certification of interpreters helps facilitate HR tasks to ensure that individuals who provide language services have specific qualifications and competencies required to perform their job functions in a safe and efficient manner.

www.cchicertification.org /healthcare-providers/ensure

CCHI Website

- Hospital can go to their website and find a certified interpreter
- HR can verify interpreter's certification status
- Click on access interpreter registry

