CMS RURAL HEALTH CLINICS CONDITIONS for CERTIFICATION 2021

Part 2 of 2

Staff and Responsibilities, Provision of Services, Medical Records, Program Review and Emergency Preparedness

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Introduction

Why We are Here Today

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		A. BUILDING _____ B. WING _____	

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. *(See reverse for further instructions.)* Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE

FORM CMS-2567 (02/99) Previous Versions Obsolete

If continuation sheet Page _____ of _____

Also Called State Operation Manual

State Operations Manual
Appendix G - Guidance for Surveyors: Rural Health Clinics (RHCs)

Table of Contents
(Rev. 200, 02-21-20)

Condition

Staffing and Staff Responsibilities

Question

- Our clinic has experienced difficulty obtaining and/or maintaining adequate staff due to COVID-19.
  - Yes
  - No
  - Prefer not to answer

Staffing & Responsibilities 81

- Clinic has staff that includes one or more physicians to carry out responsibilities
  - May be owner, employee or contracted
  - Includes definitions of “physician” already covered
  - If have only one physician – must be MD/DO
  - Must have sufficient practitioners to provide services
    - Based on volume and within standards of care
- If not responsible for medical supervision nor direction – may have a contract with a physician or third-party entity, i.e., locum tenens

Staffing 82

- Staff must include one or more PA or NP
  - May be owner, employee, contractor
  - At least one must be an employee
    - Others can be contractors
- Definitions include education requirements
- Must be licensed and practice within scope of practice

Nurse Practitioner

- Currently licensed RN meeting State requirements and
  - Currently certified by ANA or National Board Pediatric Nurse Practitioners and Associates – OR
    - Satisfactorily completed formal 1 academic year education program
    - Successfully completed formal program and given an awards degree/diploma/certificate upon successful completion

  -OR-

  - Successfully completed RN program and worked in expanded role

Physician Assistant

- Meets State requirements and meets at least one:
  - Currently certified by National Commission on Certification of Physician Assistants to PCP; OR
  - Satisfactorily completed accredited education and supervised practice program

  -OR-

  - Successfully completed a PA program and worked in expanded role

Waiver for Sufficient Practitioners

- Existing RHC can request a waiver to employ a NP or PA
  - Initial applications not eligible
- CMS grants one-year waiver if:
  - Clinic submits written request
  - Demonstrates inability, despite reasonable efforts, to hire in previous 90-day period
  - Request submitted 6 months or more after date previous waiver expired
  - Deemed granted unless denied by RO within 60 calendar days

Optional Staffing 83

- Not required to have on staff:
  - Nurse midwife
  - Clinical social worker
  - Clinical psychologist
- May be
  - Owner
  - Employee
  - Contracted

Ancillary Personnel

- Staff may also include ancillary personnel supervised by professional staff
  - RN – LPN – Lab techs – Etc.
  - Must hold current State license when required
  - Must be supervised at all times
    - By a practitioner on RHC's professional staff
  - Supervisory responsibilities may be shared among practitioners
- Surveyor will ask staff to identify their supervisor

Sufficient Staff 85

- Must have sufficient staff to provide services offered
  - Physician, NP, PA, CNM, Social worker, psychologist
  - Available to provide patient care services at all times the clinic is open
  - Must practice within permitted scope of practice
- Services provided are diagnostic and therapeutic
  - Examples:
    - Physical examinations – Health status assessments – Treatment for various conditions – Specific lab services – 1st Responder-type emergency services
- Supplies similar to those in physician office

Staffing and Services

- Must have sufficient qualified staff to provide services for volume of patients see
- May only be open if practitioner on site and available to furnish services
- Telecommunications for performing duties – must still have practitioner on site

Staffing Changes

- If lose PA/NP – may need to require staffing waiver
  - May need to adjust operating hours
  - Change appointment scheduling
- Clinic must notify state agency of changes in staffing that affect certification status

No Practitioner on Site

- Can allow patient into waiting room/non-patient care area – when no practitioner on site to provide care
  - Handle billing inquiries
  - Get out of the weather
- Not considered to be in operation

No Practitioner → No Services

- No healthcare services may be provided until mid-level practitioner, clinical social worker/psychologist or physician is onsite
- Have reasonable timeframes for administrative functions to be completed outside hours of operation
  - Post hours of administrative (billing) hours vs. clinical hours
  - Follow State law if it prohibits access when clinic not in operation

Survey Procedures

- Will determine a practitioner is onsite at all times when open
- Will review staff schedules and clinic's hours
- Will ask staff if clinic ever open and providing service without a practitioner present
- Will verify posted hours – to confirm appropriate staffing within hours of operation

Services 50% of Time 86

- NP, PA or CNM must be available to furnish patient care services
  - At least 50% of the operating hours services are offered
    - Even if physician also present
- If in clinic but not providing care can be counted towards the 50%
  - Services provided to patients outside the clinic – patient's home – still counts
  - However – the physician must be available on-site
  - Interpretive guidelines gives several examples to meet the 50%

Waiver for 50% Requirement

- May request a waiver of requirement for mid-level provider availability 50% of time of operations
- For Medicare-participating RHCs only
- Initial applications not eligible
- Steps:
  - RHC submits written request to SA
  - Demonstrates have been unable despite reasonable efforts to have mid-level on duty 50% in previous 90 days
  - Request submitted at least 6 months after expiration of previous waiver

Physician Responsibilities 100

- Physician/Medical Director (only one)
  - Overall medical direction of clinic
    - Responsible for quality of care in the clinic
  - Health care activities
  - Consultation
  - Medical supervision of staff
    - Including other physicians
    - Does not limit mid-levels scope of practice
  - Provides orders
  - Care services to patients

Physician's Options

- Not required to be on-site to perform all duties
  - Unless no other practitioners on site
- Can use variety of ways and timeframes to complete duties
  - Medical direction >Consultation
  - Supervision >Record review
  - Being on-site to provide services
- State or clinic can establish requirements for on-site presence

PA and NP Responsibilities 101

- Physician must periodically review patient records
- PA and NP must participate with physician in periodic review of medical records
- If State requires collaborating physician
  - Review, co-sign or both for outpatients
  - Must be done
- If co-signature not required – still must do periodic review of mid-level's records

Record Reviews Other Requirements

- If more than one physician
  - Other physicians may conduct the periodic review of records
  - Policies and procedures must specify who authorized to review and sign off if required
- “Periodic” timeframes – not specified in regulation
  - RHC must specify
  - Take into account volume and types of services offered
- Review need not be done on-site

PA/NP Functions 102

- Provide service per clinic policies
  - Must also operate per State scope of practice
- Arrange for/refers patient out
  - When needed service that cannot be provided at the clinic
- Ensures adequate medical records are
  - Maintained
  - And transferred as required
  - When patients referred

Condition

Provision of Services

Question

- Our RHC provides the following patient care services: (check all that apply)
  - Routine health services – annual exams, sports exams, etc
  - Prenatal care
  - Basic laboratory services – UA, CBC, rapid strep, etc.
  - Radiology – plain films only
  - Ultrasound – OB and routine
  - Urgent care

Services Offered 120 – 122

- All services offered must be per applicable Federal, State and local laws
- As primarily engaged in providing outpatient services

Direct Services

- Include
  - Diagnostic and therapeutic services and supplies
  - Commonly furnished in physician's office or at entry point into healthcare delivery system
- Are services provided by clinic's staff
  - MD/NP/PA/CNM/Psychologists/Clinical social workers
  - Plus – services and supplies incidental to the services

Services Included

- Common to physician's office or entry point into system
- Include
  - Taking complete medical history
  - Performing complete examination
  - Assessment of health status
  - Routine lab tests
  - Diagnosis and treatment for common acute and chronic health problems and conditions
  - Optional – Visiting Nurse Services

Other Services

- Not prohibited from providing
- May not be primarily engaged in providing specialized services
- “Primarily engaged” – how determined
  - Look at total hours of operation
  - If majority – i.e., over 50% - involve such services
  - Example: Clinic provides RHC services 9 – 4 Monday – Friday
    - Also offers radiology 1 – 4pm Tuesday and Friday
    - Primarily engaged in offering RHC – 85%

Survey Procedures

- Will review RHC's website – what offered
- Interview clinic director – describe type of services offered
  - Are specialty services included?
- If specialty services are included – will review hours available compared see if majority of time is for RHC services
- Will review records of at least 2 previous months
  - Determine majority of specific services actually provided

Physician, PA and NP Responsibilities 123

- Physician:
  - Develop, execute and periodically review
  - Clinic's written policies and services
  - Provided to Federal program patients
  - Done in conjunction with PA/NPs
- PA & NPs – participate in
  - Development, execution and periodic review
  - Written policies governing care provided

Patient Care Policies

- Services are furnished per appropriate written policies
  - Consistent with State laws
- Policies are developed with advice of a group of professional personnel including
  - One or more physician
  - One or more PA or NP
  - At least one member is not a member of the clinic staff

Policy Review Group

- Clinic must identify in writing names of all persons involved in development of policies
- Review group provides advice to the clinic's leadership on appropriate policies
- Policies are reviewed at least every 2 years
  - Part of Transparency/Hospital Improvement Rule

Leadership and Policies

- Leadership not required to accept advice
- If exercises its authority to reject or modify policy advice
  - Must ensure any changes are clinically appropriate and supportable

Survey Procedures

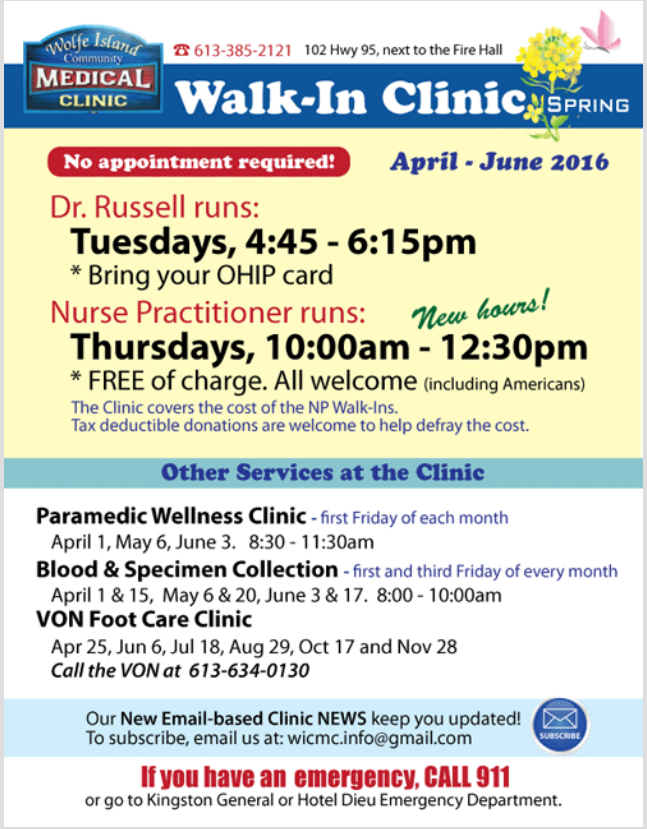
- Will review meeting minutes or documentation
  - Policies reviewed at least every 2 years
  - Were required practitioners actually participated in developing the polices
  - Plus – recommended the policies to leadership
- Will talk to leadership – has it ever rejected the advice
  - If yes – how did it ensure any changes were clinically appropriate
  - Documentation of rationale and any changes made

Patient Care Policies Include 124

- Description of services provided
  - Direct or via contract (agreement/arrangement)
- Guidelines for medical management
  - Conditions requiring consultation or referral
  - Maintenance of medical records
  - Procedures for periodic review and evaluation of services provided

Description of Services

- Must be described in sufficient detail to permit understanding of
  - Scope of all services furnished
  - Scope or type of agreement/arrangement they are furnished through



Examples of Description

- Acceptable description:
  - Taking complete medical histories
  - Performing complete physical examinations
  - Routine lab tests
  - Diagnosis & treatment common acute & chronic health problems & medical conditions
  - Immunization programs
  - Family planning
- Insufficient description:
  - “Complete management of common acute and chronic health problems”

Guidelines – Medical Management

- Written guidelines must include
  - Description of the scope of medical care
  - Furnished by PA, NP or CNM
  - Including extent and nature of required supervision
    - Include State law requirements

Standard Protocols

- Include:
  - Protocols for diagnosis and treatment common conditions or preventive care
  - Guidelines may follow various formats
    - General protocols by symptoms
    - Medical directives by body system
    - Standing orders addressing major categories
      - Health maintenance
      - Chronic health issues
      - Common acute self-limiting problems
      - Medical emergencies

Guidelines Criteria

- Manner to describe criteria for diagnosis and treatment of conditions may vary
- Examples
  - Some will incorporate clinical assessment that includes branching logic – ask questions until find answer
  - Some more narrative with major sections covering specific medical conditions
    - Definition of condition >Etiology
    - Clinical features >Treatment procedures
    - Complications >Consultation and follow up
    - Recommended diagnostic testing – lab, radiology

Guidelines Must Include

- Comprehensive enough to cover most health issues in a primary and preventive care setting
- Describe actions NP, PA or CNM may initiate or implement
  - Consistent with State scope of practice
- Describe circumstances that require consultation with MD/DO
  - Or external referral
- Need to be readily accessible to all practitioners
  - All must be familiar with guidelines

Drugs and Biologicals 125

- Written policies must address how drugs and biologicals are stored, handled and administered within the clinic
- Must
  - Follow accepted professional principles of pharmacy and medication administration
  - Adhere to Federal and State laws
  - Adhere to standards/guidelines for pharmacy and medication administration from nationally recognized organizations*
    - USP, ASHP, ISMP, NCCMERP, INS1

Policies Must Address: Storage of Drugs

- Storage of drugs and biologicals
  - Follow accepted professional principles
  - Must show appropriate storage
  - Show appropriate preparation under proper
    - Sanitation
    - Temperature
    - Light
    - Moisture
    - Ventilation
    - Segregation
    - Security

Policies – Environmental Conditions

- Follow label conditions from manufactures' FDA-approved inserts
  - Temperature – Humidity – Exposure to light – etc.
- Clinic must use caution in administering any drug or biological
  - Not labeled showing proper storage conditions

  -OR-

  - Those that may have been stored under inadequate conditions

Policies – Security of Drugs/Biologicals

- P&P must be consistent with State and Federal laws
  - How stored and secured
  - Who has access to storage area
- Not stored where easily accessible to unauthorized persons
- “Secured”
  - Private office where persons not unsupervised
  - Area restricted to authorized persons only

Drugs and Biologicals – Generally

- Have flexibility in storage of non-controlled
- Areas where staff actively providing care or preparing for patients:
  - Considered secure area
- When area not staffed:
  - Controlled and non-controlled expected to be locked per State/Federal law

Medication Carts

- If use – whenever is in use and unlocked
  - Someone with authorized access
  - Must be within close eyesight of and directly monitoring the cart
  - Person must monitor and be aware of other's activities near the cart
    - They are responsible for security of the drugs and biologicals in the cart

Question

- Our Clinic:
  - Does not maintain any controlled substances on site
  - Has very few controlled substances and limits such to Schedule III – V
  - Has Schedule II through V controlled substances which are maintained in secured locked location with limited access
  - Not sure what our clinic has for controlled substances

Record Keeping – Scheduled Drugs

- Must track receipt and distribution of scheduled drugs
  - Locked storage when not in use
  - Accountability procedures - insure control
  - Tracking movement – entry to departure
    - System to provide documentation in readily retrievable manner
    - Facilitate reconciliation of receipt and disposition
  - Prompt reconciliation of discrepancies in count –
    - Readily identify loss or diversion of controlled substances
    - Minimize time between loss/diversion at detection → determination of extent loss or diversion

Handling Drugs and Biologicals

- “Handling” includes reconstituting or mixing medications
- Compounding – included with “handling”
  - Refers to admixing of sterile intravenous preparations or other drugs
  - On- or off-site
  - Using facility staff or contracted pharmacy service

Compounded Sterile Preparations (CSP)

- Not typical for RHC to furnish compounded sterile preparations
- May be an additional service
- If use CSPs – must ensure compounding performed according to professional principles
- Even if use CSPs – not likely to have own pharmacy that could meet standards of practice for CSP preparation
- More likely – obtain from external source

Outsourcing Facility – 503B

- Drug Quality and Security Act (DQSA) – federal law with oversight of compounding pharmacies
- ***"Outsourcing facility"***
  - One geographic location/address
  - Engaged in compounding of sterile drugs
  - Has elected to register and comply with 503B of FDCA
- Called "503B pharmacies"

To Register as Outsourcing Facility

- Must comply with FDA Current Good Manufacturing Practice (CGMP)
  - Minimum requirements for
    - Methods
    - Facilities
    - Controls used in manufacturing, processing and packaging drugs
- Be inspected by FDA – per risk-based schedule
- Meet other conditions
  - Reporting adverse events
  - Provide FDA with information on products compounded

What RHCs Can Do

- Require compounding pharmacy that supplies drugs to register as outsourcing facility
- Will be
  - Inspected
  - Held to CGMP requirements
  - Required to report adverse event
  - Required to have appropriate labeling
- FDA has list of Registered Human Drug Compounding Outsourcing Facilities

http://www.fda.gov/drugs/guidancecomplianceregulatoryinformiaton/pharamcycompounding.

FDA – Registered Outsourcing Facilities

An official website of the United States government Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

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Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Content current as of: 09/17/2021

Updated as of 9/10/2021

- Information Concerning Outsourcing Facility Registration
- Outsourcing Facility Product Reporting Information

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing	Date of Most Recent Registration as an	End Date of Last FDA Inspection Related to	Was a Form FDA-483	Other Action, if Any, Based on Last Inspection[4,5]	Intends to Compounds Sterile Drugs From Bulk

Compounding *Pharmacies*

- Compounded medication from compounding pharmacy vs. manufacturer or registered outsourcing facility
  - Referred to as “503A pharmacies”
  - Subject to oversight of State pharmacy board only
- Clinic must demonstrate
  - How it assures compounded medications received
  - Have been prepared per accepted professional principles for compounded drugs
  - Plus – applicable State or Federal laws or regulations

Contract Provisions with 503A Pharmacy

- Ensure RHC has access to quality assurance data
  - Verifying the vendor adheres to standards of practice for compounding
  - RHC documents and reviews data obtained
- Require vendor to meet requirements of 503A

Expiration and Beyond Use Dates

- Expiration date – set by manufacturer
  - Based on stability testing – part of FDA approval
  - May be come unusable prior to expiration if subjected to conditions inconsistent with manufacture's labeling
- Beyond use date – may be reached before expiration date
  - Considers specific conditions and potential for deterioration and microbial growth
    - May occur during or after opened
    - During preparation or compounding
  - Based on information from manufacturer

Basic Safe Medication Practices

- Policies must reflect accepted standards of practice
- Information confirmed prior to each medication administration
- “5 Rights”
  - Patient
  - Medication
  - Dose
  - Route
  - Time

Medication Process

- “5 Rights” focus on process of administration
- Medication process has 5 stages
  - Ordering/prescribing
  - Transcribing and verifying
  - Dispensing and delivering
  - Administering
  - Monitoring/reporting
- Clinics encouraged to promote culture of reporting
  - Clarify questions/concerns regarding medications

Survey Procedures

- Will do spot check of drug use and inventory records – all accounted for
- Will look to see if drugs/biologicals stored securely/locked
- Will evaluate system to track movement of all scheduled drugs – entry → departure
  - Does system provide documentation readily to facilitate reconciliation
  - Will look at records for evidence of discrepancies and reconciliation of such
  - Will talk to person responsible for storage

Survey Procedures – continued

- If use CSP and not an FDA registered facility – will ask for evidence the RHC systematically evaluates and monitors the source: adherence to professional principles for compounding
- Will spot-check for expired/unusable medications
- Will ask who can administer medications, including IV medication
  - Are they practicing within permitted scope?
- Will observe medication administration – confirm “5 rights”

Direct Services – Laboratory 135

- RHC provides 6 minimum basic laboratory services for immediate diagnosis and treatment
  - Urine dip
  - Hemoglobin/hematocrit
  - Blood glucose
  - Stool – occult blood
  - Pregnancy tests
  - Primary culture – for transmittal to certified lab

Basic 6 and CLIA

- If cannot provide basic 6 due to State or local law prohibition – laboratory service not required for Medicare certification
- Services must be provided per CLIA requirements
- Operating under current CLIA certification per level of services performed

Additional Lab Services

- Can provide additional lab services
  - On-site or via off-site arrangement
  - Optional services must comply with CLIA requirements
- May have an arrangement with another provider of lab services
- However – arrangement cannot to substitute for requirement of the basic 6 within the RHC but its staff

Emergency Services 136

- RHC provides emergency procedures as first responder
  - To common life-threatening injuries and acute illness
  - Has available drugs and biologicals commonly used in life saving procedure
    - Analgesics
    - Anesthetics (local)
    - Antibiotics
    - Anticonvulsants
    - Antidotes and emetics
    - Serums and toxoids

Sufficient Staff and Drugs

- Must ensure staff is available to handle emergencies
  - At all times clinic operates
- Must maintain type and quantity of drugs commonly used by first responders
- Policies must address which drugs to maintain
  - And in what quantities
- Must maintain enough to handle volume and type of emergency typically encounter

Category of Drugs/Biologicals

- Not all are required to be stored
  - Consider community and medical history of patients
  - Plus – accepted standards of practice
- Should have written policies and procedures
  - Determining what to have on site
  - Who responsible for such a decision
- Be able to provide complete list of all drugs stored and in what quantities

Services Vai Agreement/Arrangement 140

- Clinic has agreements/arrangements with one or more providers/supplier
  - Participating in Medicare/Medicaid
  - To furnish other services
    - Inpatient care
    - Physician services
    - Additional & specialized diagnostic/lab not at clinic
- If not in writing – is evidence patients referred are being accepted and treated

Medical Records

Condition

Patient Health Records

Question

- Our medical records (check all that apply):
  - Are all electronic
  - Interact with a larger system
  - Are paper/hard copy
  - Frequently unavailable – system down
  - Department is managed by one person
  - Sometimes not available when needed

Record System 151

- Clinic maintains a clinical record system per written policies and procedures
- A designated professional staff member
  - Responsible for maintaining records
  - Ensuring records are complete and accurately documents
  - Readily accessible
  - Systematically organized
- Must have a clinical record for each patient
  - Complete, comprehensive and accurate

Responsible Person

- Must have person – could be clinical or administrative “professional person”
  - Responsible for the record system
    - To develop and implement
    - Written policies procedures
    - Approved by leadership and professional staff

Electronic Health Record

- If have EHR – may be part of larger system
  - Or may participate in systematic exchange of patient health information
- Only appropriate staff may have access to RHC records
- Written policies and procedures must reflect it is part of a larger system or exchange
  - Records for all visits must meet requirements of the Condition
  - Readily retrievable and distinguishable from other information in the shared system

HIPAA

- RHC must comply with HIPAA rules when sharing PHI
- CMS will not interpret or assess for compliance with HIPAA
- However – if suspect serious breach will refer to OCR
- Increasing frequency and amount of penalties

2nd OCR Fine

FOR IMMEDIATE RELEASE
December 12, 2019

Contact: HHS Press Office
202-690-6343
media@hhs.gov

OCR Settles Second Case in HIPAA Right of Access Initiative

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services is announcing its second enforcement action and settlement under its HIPAA [1] Right of Access Initiative. OCR announced this initiative earlier this year promising to vigorously enforce the rights of patients to get access to their medical records promptly, without being overcharged, and in the readily producible format of their choice. Korunda Medical, LLC (Korunda) has agreed to take corrective actions and pay $85,000 to settle a potential violation of HIPAA's right of access provision. Korunda is a Florida-based company that provides comprehensive primary care and interventional pain management to approximately 2,000 patients annually.

In March of 2019, OCR received a complaint concerning a Korunda patient alleging that, despite repeatedly asking, Korunda failed to forward a patient's medical records in electronic format to a third party. Not only did Korunda fail to timely provide the records to the third party, but Korunda also failed to provide them in the requested electronic format, and charged more than the reasonably cost-based fees allowed under HIPAA. OCR provided Korunda with technical assistance on how to correct these matters and closed the complaint. Despite OCR's assistance, Korunda continued to fail to provide the requested records, resulting in another complaint to OCR. As a result of OCR's second intervention, the requested records were provided for free in May 2019, and in the format requested.

"For too long, healthcare providers have slow-walked their duty to provide patients their medical records out of a sleepy bureaucratic inertia. We hope our shift to the imposition of corrective actions

9th Settlement 100,000 – Failure to give films

HHS Office for Civil Rights in Action

October 9, 2020
OCR Settles Ninth Investigation in HIPAA Right of Access Initiative

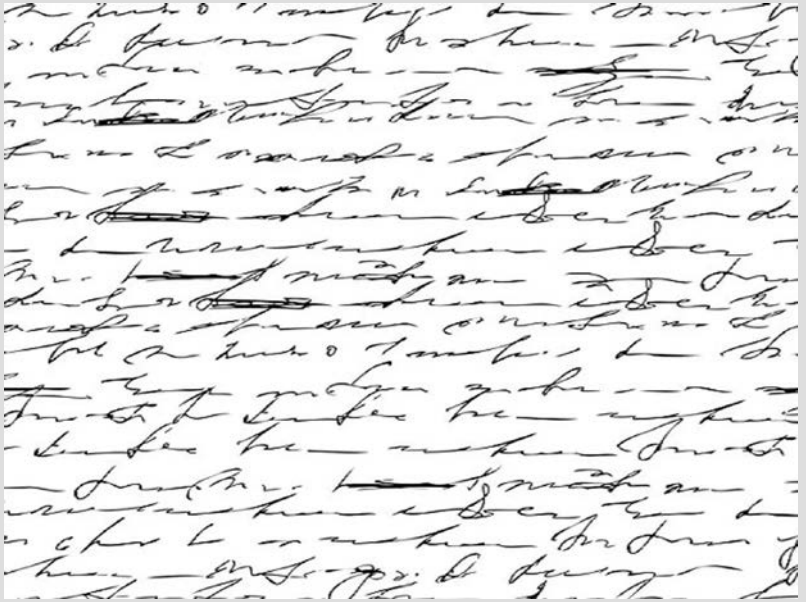
The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) announces that it has settled its ninth enforcement action in its HIPAA Right of Access Initiative. OCR announced this initiative as an enforcement priority in 2019 to support individuals' right to timely access to their health records at a reasonable cost under the HIPAA Privacy Rule.

NY Spine Medicine (NY Spine) has agreed to take corrective actions and pay $100,000 to settle a potential violation of the HIPAA Privacy Rule's right of access standard. NY Spine is a private medical practice specializing in neurology and pain management with offices in New York, NY, and Miami Beach, FL.

In July 2019, OCR received a complaint from an individual alleging that beginning in June 2019, she made multiple requests to NY Spine for a copy of her medical records. NY Spine provided some of the records, but did not provide the diagnostic films that the individual specifically requested. OCR initiated an investigation and determined that NY Spine's failure to provide timely access to all of the requested medical records was a potential violation of the right of access standard. As a result of OCR's investigation, the complainant received all of the requested medical records in October 2020.

Complete and Accurate

- All entries must be legible – read clearly and unambiguously
- Must be complete – all entries of required information are made promptly
  - Available to subsequent caregivers



Accurately Written

- Records must be accurately written
  - Correct information on correct patient
  - Patient identity clear via identifiers
  - Must have a system that assigns a unique patient identifier – MR number
- Policies and procedures must how unique identifiers are generated and assigned

Record Entries

- Entries may only be made by individual authorized by RHC
  - Per written policies and procedures
- Must be dated, timed and authenticated by person making the entry
- If entry made on behalf of practitioner
  - Person must be authorized
  - Then promptly dated, timed and authenticated by practitioner

Author Identification

- Must have a method to identify author of each entry
- Method must ensure entries are not made by someone using another's identity
  - Passwords, card keys to access system
    - Never share passwords or card keys
- Paper system and rubber stamps – must **not** allow others to use stamp

Readily Accessible & Organized

- System must allow clinical staff timely access when needed to open records
- Policies and procedures must address how long closed records will be readily accessible
  - Different from the 6-year retention timeframe
- Record system must be systematically organized
  - Facilitate completion, storage and retrieval of records
  - In a manner that supports timely provision of services

Survey Procedures

(Long Survey procedure)

- Verify written medical records policies and procedures
- Will review only if observations, interview or record reviews indicate non-compliance
- Verify professional staff member designated as responsible for record system
- Will ask the person – any changes to the system and if P&P were updated

Survey Procedure – continued

- If RHC has an EHR – immediately after entrance conference will interview person responsible for an overview
  - System fully integrated or a hybrid
  - Arrangements if system fails – to ensure accessibility
  - Will observe staff using system – can they access information when needed
  - If shared system – is their portion distinguishable
  - If paper – are they legible

Survey Procedures – continued

- Record review – are records inaccurate or incomplete
  - Each entry dated, time and authenticated
  - Practitioner promptly authenticates entries made by others who are authorized to do so
  - Each record is systematically organized
- Record are organized in systematic manner for easy retrieval

Each Record Must Include 152

- Identification & social data
- Evidence of consent forms
- Pertinent medical history
- Assessment of health status and care needs
- Brief summary of episode
- Disposition
- Instructions
- Reports of physical examinations, diagnostic and lab results
- Orders, reports of treatments and medications, other information necessary to monitor progress
- Signatures

Identification and Social Data

- Information to clearly identify the patient
  - Through use of identifiers – name, DOB
- Social data
  - Address
  - Work information
  - Insurance information
  - Names of family members
  - Designated representative, etc.

Question

- Our clinic utilizes a standard “consent to treat”:
  - Only for routine care
  - For all care – including any invasive procedure
  - Only for invasive procedures
  - Only if the provider/physician thinks a separate consent form is necessary

Informed Consent

- Must have written policies that address situations when informed consent is required
  - Plus – under what emergency circumstances informed consent requirement may be waived
- Record must include a record of informed consent for cases where:
  - Policy
  - State
  - Federal law require informed consent

Evidence of Informed Consent

- Record must provide evidence of properly executed informed consent
  - Should reflect the consent process
- Exception: an emergency as specified in the policies – all records must have a properly executed informed consent form ***prior*** to and procedure or treatment requiring one
- Properly executed – must be consistent with
  - Clinic policies
  - Federal and State law or regulation

Minimum Elements of Proper Consent Form

- Name of specific procedure or treatment
- Name of responsible practitioner – performing the procedure or administering medical treatment
- Statement the procedure or treatment was explained to the patient/representative
  - Including:
    - Anticipated benefits
    - Material risks – low severity & high likelihood; high severity & low likelihood
    - Alternative therapies

Minimum Elements – continued

- Signature of patient or representative
- Date and time consent signed by patient or representative
  - If electronic signature – must be documentation how electronic signature verified and alteration prevented
  - Must be documentation that makes clear patient or representative consented to and how alteration prevented

Pertinent Medical History

- Purpose – determine if there is anything in patient's overall condition that would affect the diagnosis or course of treatment
  - Prior occurrence of similar symptoms
  - Medication allergy
  - New or existing co-morbid condition that requires additional intervention to reduce adverse risks

Who May Enter History

- Only qualified personnel by policy may enter the medical history into the record
- In all cases – must be reviewed and authenticated promptly by a practitioner
- Must have written policies and procedures
  - Specifying when new or update history required

Assessment and Summary

- Record must include assessment by practitioner
  - Current health status and needs of patient
  - At time of each visit
- Must be a brief summary or reason for visit
  - Patient's disposition
  - Follow-up instructions
- Only qualified personnel per policy may enter summary
  - Must be authenticated promptly by practitioner

Reports, Test Results and Consults

- Physical examinations must be completed by practitioner, documented and authenticated
  - As per clinic policy and State law
- All diagnostic and laboratory test results must be in the record
  - Interpretations must be authenticated by the practitioner
- Consultant findings and who reports findings must be in the record

Other Required Content

- Orders – dated, timed and signed
- Nursing notes – properly authenticated
- Documentation of treatments provided
- Documentation all medications administered
  - Including adverse reactions
- Documentation of patient's response to all treatments provided
- Other pertinent information required to monitor patient's progress – vital signs

Protection of Information 153

- Clinic maintains confidentiality of information
- Provides safeguard against loss, destruction or unauthorized use
- Written policies and procedures govern use and removal form the clinic and conditions for release of information
- Patient's written consent is required for release of information NOT authorized to be released without consent

Safeguards

- Must have sufficient safeguards to ensure limited access to authorized individual only
- Records must be protected from loss or unintended destruction
- Must be protected from unauthorized access or use
- Nature of safeguards depend on how records created and stored
  - Paper – locked and protected form fire, flood, etc
  - Electronic – passwords, back-up to remote server

$5.1 Million Due to Hacking

HHS Office for Civil Rights in Action

January 15, 2021

Health Insurer Pays $5.1 Million to Settle Data Breach Affecting Over 9.3 Million People

Excellus Health Plan, Inc. has agreed to pay $5.1 million to the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) and to implement a corrective action plan to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules related to a breach affecting over 9.3 million people. Excellus Health Plan is a New York health services corporation that provides health insurance coverage to over 1.5 million people in Upstate and Western New York.

On September 9, 2015, Excellus Health Plan filed a breach report stating that cyber-attackers had gained unauthorized access to its information technology systems. Excellus Health Plan reported that the breach began on or before December 23, 2013, and ended on May 11, 2015. The hackers installed malware and conducted reconnaissance activities that ultimately resulted in the impermissible disclosure of the protected health information of more than 9.3 million individuals, including their names, addresses, dates of birth, email addresses, Social Security numbers, bank account information, health plan claims, and clinical treatment information.

OCR's investigation found potential violations of the HIPAA Rules including failure to conduct an enterprise-wide risk analysis, and failures to implement risk management, information system activity review, and access controls.

"Hacking continues to be the greatest threat to the privacy and security of individuals' health information. In this case, a health plan did not stop hackers from roaming inside its health record system undetected for over a year which endangered the privacy of millions of its beneficiaries," said OCR Director Roger Severino. "We know that the most dangerous hackers are sophisticated, patient, and persistent. Health care entities need to step up their game to protect the privacy of people's health information from this growing threat."

In addition to the monetary settlement, Excellus Health Plan will undertake a corrective action plan that includes two years of monitoring. A copy of the resolution agreement and corrective action plan may be found at https://www.hhs.gov/sites/default/files/excellus-ra-cap.pdf.

Policies and Procedures

- Policies and procedures must address
  - Who may use record
  - How they may use records
  - Who may remove record
  - Under what conditions information may be released
  - To whom information may be released

Release of Information

- Must obtain patient's written consent prior to release
  - Unless – release require by law
- Uses and disclosures of PHI may be made without patient's prior authorization
- CMS cannot assess compliance
  - However – will refer to OCR if have concerns about disclosures made without written consent

Record Retention 154

- Records are retained for at least 6 years from date last entry
  - Longer if required by State statute
  - Montana – hospital is 10 years
    - Minors – to age 21
- Retained in original form or legally reproduced form
  - Hard copy
  - Microfilm
  - Computer memory
- Promptly retrieved and within the RHC

Condition

Program Evaluation

Question

- Our clinic performs regular reviews of the services we provide.
  - Yes
  - No
  - Prefer not to answer

Biennial Evaluation of Program 161

- Clinic carries out or arranges for evaluation of program at least every 2 years
  - New with Hospital Improvement Rule
- Includes review of
  - Utilization of clinic services
    - Including number of patients served
    - Volume of services
  - Representative sample of both active and closed records
  - Health care policies

Purpose

- Purpose of the review to determine:
  - Was utilization of services appropriate
  - Were established policies followed
  - If any changes are needed
- May be done by staff or via an arrangement
- Must have documentation of who conducted the review and their qualifications

Minimum Requirements of Evaluation

- Number of patients served
- Volume of services provided
- Should determine is RHC provides appropriate types and volume of services
  - Based on needs of patient population
- Evaluate if policies were followed
- Whether or not changes to policies or procedures are warranted

Written Plan

- Must have a written plan that specifies
  - Who is to do the evaluation
  - When and how to be done
  - What to be covered within evaluation
- Must include review of active and closed records
- Include at least 5% of current patient or 50 records
  - Which ever is less
- Purpose – determine if utilization of RHC's services was appropriate

What Must Be Evaluated

- Review must also evaluate
  - If all personnel providing direct care adhered to RHC's care policies
- Evaluation of practitioners – by MD/DO
  - If only one – expected will arrange for outside review
- Review of care policies maybe done
  - MD/DO
  - Midlevel
  - RN
  - Other person meeting qualification criteria

Evaluation Findings

- Evaluation finding must be documented in summary report
- Must include recommendations for corrective actions
- Address problems identified in evaluation
- If RHC has developed a QAPI program which meets or exceeds regulatory requirements for this Evaluation – QAPI program is acceptable

Corrective Action 162

- Clinic staff considers the findings of the evaluation
- Takes corrective action – if necessary
- Leadership must consider the findings and any recommendations for change
- Must take corrective actions
  - Change in policies
  - Additional personnel training
  - Changes in supervision
  - Limiting/terminating privileges

Leadership and Actions

- Must document where and when findings and recommendations considered
  - And by whom
- Must document what corrective actions were taken
  - And by whom recommended
- Must document rationale for any decision
  - If does not take corrective actions recommended

  -OR-

  - If takes corrective actions different from those recommended

Emergency Preparedness

Are You Ready?

Emergency Preparedness

- Not a part of Appendix G
- Requirements, final interpretive guidelines and survey procedures in Appendix Z
  - Questions: SCGEmergencyPrep@cms.hhs.gov
  - Includes multiple definitions
- Hospital Improvement Rule
  - Changed everything from yearly to every two years
  - EXCEPT - drills still 2/year

2021 Changes

- Added updates and clarifications to testing and training
- Included Public Health Emergency and requirements
  - EX – Emerging Infectious Diseases

Emergency Preparedness

- Standard: Must comply with all federal, state, and local emergency preparedness (EP) requirements
  - Have and maintain a comprehensive EP program
  - Utilize all-hazards approach – including emerging infections
- Program must include:
  - Plan >Policies & procedures
  - Communication plan >Training & testing
  - Emergency & standby power

Emergency Plan

- Reviewed and updated every 2 years
  - Based on and include documented facility & community-based risk assessment
    - Using all-hazard approach
  - Include strategies for addressing emergency events identified by the risk assessment
  - Address patient populations, persons at-risk, types of services that can be provided and succession plans
  - Include process for cooperation and collaboration with EP officials

Policies & Procedures

- Based on the plan, risk assessment and communication plan
  - Reviewed and updated every 2 years
- Address:
  - Means to shelter in place
  - System of documentation – preserves confidentiality
  - Use of volunteers/other staffing strategies

Communication Plan

- Plan that complies with all laws
  - Reviewed and updated every 2 years
- Must include
  - Names/contact information – patients/staff/physicians
  - Contact information – emergency preparedness staff
  - Primary and alternate means communication
    - Staff
    - Emergency management agencies

Communication Plan

- Must include (cont'd)
  - Method for sharing information/documentation for patients
  - In an evacuation – means to release patient information as permitted
  - Method to provide information about condition/location of patients
  - Method to provide information about occupancy, needs and ability to provide assistance

Training and Testing

- Must develop and maintain training and testing program
  - Based on emergency plan
  - Risk Assessment
  - P&P
  - Communication plan
  - Reviewed and updated every 2 years

Training

- Initial training: to all new and existing staff
  - Those providing service under contract
  - Volunteers
  - Consistent with expected roles
- Done every 2 years
- Maintain documentation of training
- Staff must demonstrate knowledge of procedures
- If P&P updated – must do training

Testing

- Conduct exercises twice a year
  - Participate in full-scale exercise community or facility based every other year
  - If actual disaster – exempt from next full-scale exercise
  - Opposite years – conduct exercise of choice
    - Full-scale, mock, workshop or table-top
  - Analyze and document all drills – revise as necessary

Integrated Healthcare Systems

- If part of integrated healthcare system
  - Demonstrate each separately certified facility participates
  - Include a unified and integrated plan – based on risk assessment
  - Include integrated P&P

Final Discussion

Prairie Valley is a RHC in a remote part of the state where fast-moving and dangerous weather patterns are common.

Patient population varies from newborn to elderly. Services provided are consistent with a rural health clinic, including prenatal care. Pregnancies are referred to a regional hospital 35 miles away.

In December, MV is 38-weeks, Gravid 3 Para 2; history of eclampsia with her last pregnancy. Her CNM has referred her to a perinatologist at the hospital for further care.

Discussion

- During her 39-week visit in January, MV reports spotting, cramping, headache and pedal edema. The CNM wants to send her to the regional hospital for admission. The patient consents but wants to drive rather than go via EMS as recommended by the CNM – financial concern.
- Prairie Valley's policies do not address this situation; rather the decision is left to the provider after discussion with the patient.

Discussion and Guidance

- What would you recommend or suggest to Prairie Valley
  - To address this situation?
  - To address future possible similar events?

Thank You

The End Questions???

- Laura A. Dixon RN,
- BS, JD, RN, CPHRM
- President, Healthcare Risk Education and Consulting, LLC
- Denver, Colorado
- 303-955-8104
- laura@healthcareriskeducationandconsulting.com

APPENDIX

- Resources
- Internet Links

Weblinks – Organizations: Medications

- www.usp.org – US Pharmacopeia
- www.ashp.org – American Society of Health-System Pharmacists
- www.ismp.org/default.asp - Institute for Safe Medication Practices
- www.nccmerp.org – National Coordinating Council for Medication Error Reporting and Prevention
- www.ihi.org/ihi - Institute for Healthcare Improvement
- www.ins1.org – Infusion Nurses Society

Legionnaires' Disease

Use water management programs in buildings to help prevent outbreaks

www.cdc.gov/vitalsigns/legionnaires/index.html

Language: English

Overview

CDC investigated the first outbreak of Legionnaires' disease, a serious lung infection (pneumonia), in 1976. An increasing number of people in the US are getting this disease, which is caused by breathing in small water droplets contaminated with *Legionella germs*. About 5,000 people are diagnosed with Legionnaires' disease and there are at least 20 outbreaks reported each year. Most identified outbreaks are in buildings with large water systems, such as hotels, long-term care facilities, and hospitals. *Legionella* grows best in building water systems that are not well maintained. Building owners and managers should adopt newly published standards that promote *Legionella* water management programs, which are ways to reduce the risk of this germ in building water systems.

Building owners and managers can:

- Learn about and follow newly published standards for *Legionella* water management programs. http://bit.ly/1Ph3wQP
- Determine if the water systems in their buildings are at increased risk of growing and spreading *Legionella*.
- Develop and use a *Legionella* water management program as needed. www.cdc.gov/legionella/WMPtoolkit
- Monitor and respond to changes in water quality.

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CDC Resource Slides

Centers for Disease Control and Prevention

www.cdc.gov/stltpublichealth/townhall/2017/downloads/06-jun-presentation.pdf

Welcome

Office for State, Tribal, Local and Territorial Support

presents

CDC *Vital Signs* Town Hall

Health Care-Associated Legionnaires' Disease: Protect Patients with Prevention and Early Recognition

June 13, 2017

2:00–3:00 PM (ET)

Complaint Manual Update

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 /Survey & Certification Group

Ref: S&C: 13-27-Deemed Providers/Suppliers & Hospitals

DATE: **April 19, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Update of State Operations Manual (SOM) Chapter 5, Complaint Investigation

Memorandum Summary

Post-Complaint Survey Procedure - Deemed Providers/Suppliers:

- A full survey of a deemed provider/supplier after a complaint survey with condition-level findings will be made on a selective rather than an automatic basis.
- All survey reports and related correspondence must be shared promptly with a deemed provider/supplier's accrediting organization (AO).

Hospital Restraint/Seclusion Death Reporting: This section is being moved, to reflect the fact that the procedures therein apply to all hospitals, not just deemed hospitals. We are also streamlining the procedure for making disclosures to State Protection and Advocacy (P&A) agencies, to reduce burden.

A. Full Survey After Complaint for Deemed Providers/Suppliers

Infection Control Breaches

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/Survey & Certification Group

Ref: S&C: 14-36-All

DATE: **May 30, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

Memorandum Summary

- ***Infection Control Breaches Warranting Referral to Public Health Authorities:*** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.

- ***Identification of Public Health Contact:*** SAs should consult with their State's Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer with State public health officials to set up referral processes, but are expected to refer identified breaches to the appropriate State public health contact identified at: http://www.cdc.gov/HAI/state-based/index.html

Insulin Pens

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

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

DATE: **May 18, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Use of Insulin Pens in Health Care Facilities

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

Memorandum Summary

Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. **Insulin pens are meant for use by a single patient only.** Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

Background
Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more

BE AWARE
DON'T SHARE

Insulin pens that contain more than one dose of insulin are only meant for one person.

They ***should never be used for more than one person***, even when the needle is changed.

ONE INSULIN PEN, ONLY ONE PERSON

The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices.

For more information, please visit:
www.ONEandONLYcampaign.org

Insulin Pen Brochure

DON'T DO IT

Sharing Insulin Pens and Other Injection Equipment Jeopardizes Patients

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single person only and are not to be shared. Unfortunately, there have been continuing reports of persons placed at risk of bloodborne and bacterial pathogen transmission through sharing of insulin pens.

A SIMPLE RULE

Injection equipment (e.g., insulin pens, needles and syringes) should **never** be used for more than one person.

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

About the Safe Injection Practices Coalition

The Safe Injection Practices Coalition (SIPC) is a partnership of healthcare-related organizations led by the Centers for Disease Control and Prevention that was formed to promote safe injection practices in all U.S. healthcare settings. The SIPC has developed the One & Only Campaign – a public health education and awareness campaign – aimed at both healthcare providers and patients to advance and promote safe injection practices.

For more information, please visit:
www.ONEandONLYcampaign.org

BE AWARE
DON'T SHARE

ONE INSULIN PEN, ONLY ONE PERSON

What Every Healthcare Professional Needs To Know

ISMP Medication Guidelines

ISMP Subq Insulin

- Insulin is a high alert medication
- Associated with more medication errors than any other drug
  - 16% of all medication errors
  - Leading cause of harmful errors (24%)
  - Results from reliance on only sliding scale to control
    - Failure to increase to control blood sugar
    - Dosing errors
    - Omissions

ISMP's 2020 – 2021 Best Practices *

- #5 Purchase oral liquid dosing devices (oral syringes/cups/droppers) in metric scale such as ml
- #15 Verify and document patient's opioid status and type of pain before prescribing

* Information available at www.drugtopics.com/latest/ismp-unveils-2020-2021-best-safety-practice-updates-ashp-midyear

ONE INSULIN PEN, ONLY ONE PERSON

Recommendations for Safe Insulin Pen Use

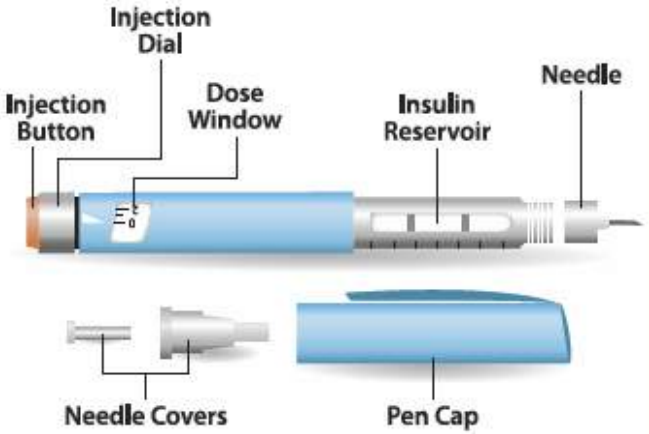
Protection from infection is a basic expectation anywhere healthcare is delivered. Use of insulin pens and other injection equipment for more than one person poses unacceptable risks and should be considered a "never" event.

- Insulin pens and other injection equipment containing multiple doses of medication are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens and other injection equipment should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

These recommendations apply to any setting where insulin pens and other injection equipment are used, including assisted living or residential care facilities, skilled nursing facilities, clinics, health fairs, shelters, detention facilities, senior centers, schools, and camps as well as licensed healthcare facilities.

Insulin Administration

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection. They are intended for single-person use.



In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used for a single person multiple times, using a new needle for each injection.

Back flow of blood into the insulin reservoir can occur during an injection. This creates a risk of bloodborne and bacterial pathogen transmission if the pen is used for more than one person, even when the needle is changed.

The Safe Injection Practices Coalition created an easy to use check list for facilities. Similar to a risk assessment, the list contains the necessary components of injection safety for facilities to quickly assess their practices.

A copy of the checklist can be found at: www.cdc.gov/injectionsafety/Checklist

Single Dose Memo

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

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-35-ALL

DATE: **June 15, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

Memorandum Summary

- *Under certain conditions, it is permissible to repackage single-dose vials or single use vials (collectively referred to in this memorandum as "SDVs") into smaller doses, each intended for a single patient:* The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, *Pharmaceutical Compounding - Sterile Preparations* ("USP <797>"). Under USP <797>, healthcare facilities may repackage SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.
- *Administering drugs from one SDV to multiple patients without adhering to USP <797>*

DO YOU PROVIDE TREATMENT FOR PATIENTS WITH CANCER?

PROTECT YOUR PATIENTS, YOURSELF, AND YOUR BUSINESS

Since 2002, at least nine serious infectious disease outbreaks have occurred in cancer clinics. These outbreaks involved unsafe injection practices, including the reuse of syringes. As a result, hundreds of patients became infected and thousands more required notification and testing for bloodborne pathogens.

REMEMBER! WHEN PREPARING MEDICATIONS AND INJECTIONS...

NEVER reuse these items:

Needles or syringes that have been used for any purpose

Vials with "single-dose vial" printed on the label

Saline bags

Intravenous tubing

ALWAYS follow aseptic technique* when:

Preparing any medication

Disinfecting a vial's septum

Accessing a central line

Injecting any medications

*Aseptic technique is used by health care workers to prevent the contamination of clean areas, equipment, and sterile medications. This will help prevent the spread of infection. Please refer to CDC's Basic Infection Control and Prevention Plan for Outpatient Oncology Settings for more information.

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

LEARN MORE ABOUT WAYS YOU CAN KEEP YOUR PATIENTS

ASHP Foundation
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Advancing Practice

- Optimizing Antithrombotic Management: An Assessment Tool
- Bar Code Guide
- My Medicine List™
- Outsourcing Sterile Products Preparation: Contractor Assessment Tool
- Pharmacy Practice Model Initiative

Outsourcing Sterile Products Preparation: Contractor Assessment Tool

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www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx

2017 ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults

www.ismp.org/Tools/guidelines/Insulin-Guideline.pdf

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit-2020.pdf

Vaccine Storage and Handling Toolkit

The toolkit has been updated for 2020 to clarify language including:

- Beyond use date (BUD)
- Routine maintenance for vaccine storage units
- New definition added to the glossary

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

January 2020

AT-A-GLANCE RESOURCE GUIDE

VACCINE ADMINISTRATION AND STORAGE AND HANDLING

IMMUNIZATION AND VACCINES (GENERAL)

General Recommendations on Immunization – Recommendations of the Advisory Committee on Immunization Practices (ACIP)
Guidance about vaccination and vaccines for health care providers.
www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book), 13th Edition: Course Textbook (2015)
Comprehensive information on routinely used vaccines and the diseases they prevent.
www.cdc.gov/vaccines/pubs/pinkbook/index.html

The Pink Book Webinar Series
One-hour webinars with CDC experts exploring chapters of the Pink Book.
www.cdc.gov/vaccines/ed/webinar-epv/index.html

"You Call the Shots" Online Training Modules

VACCINE STORAGE AND HANDLING

- **Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book): Storage and Handling Chapter**
  www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html

- **Vaccine Storage and Handling Guidelines and Recommendations**
  Resources on vaccine storage and handling recommendations and guidelines.
  www.cdc.gov/vaccines/recs/storage/default.htm

- **Vaccine Storage and Handling Toolkit**
  Comprehensive guidance for health care providers on vaccine storage and handling recommendations and best practices.
  www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

- **"Keys to Storing and Handling Your Vaccine Supply" Training Video**
  This training outlines vaccine storage and handling best practices, and provides helpful tips for preventing errors and preserving vaccine supply and integrity.
  www2.cdc.gov/vaccines/ed/shvideo/

VACCINE ADMINISTRATION

- **Skills Checklist for Immunization**
  A self-assessment tool from the Immunization Action Coalition for health care staff who administer vaccines.
  www.immunize.org/catg.d/p7010.pdf

- **Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book): Vaccine Administration Chapter**

OCR Issues

Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524

Newly Released FAQs on Access Guidance

New Clarification – $6.50 Flat Rate Option is Not a Cap on Fees for Copies of PHI

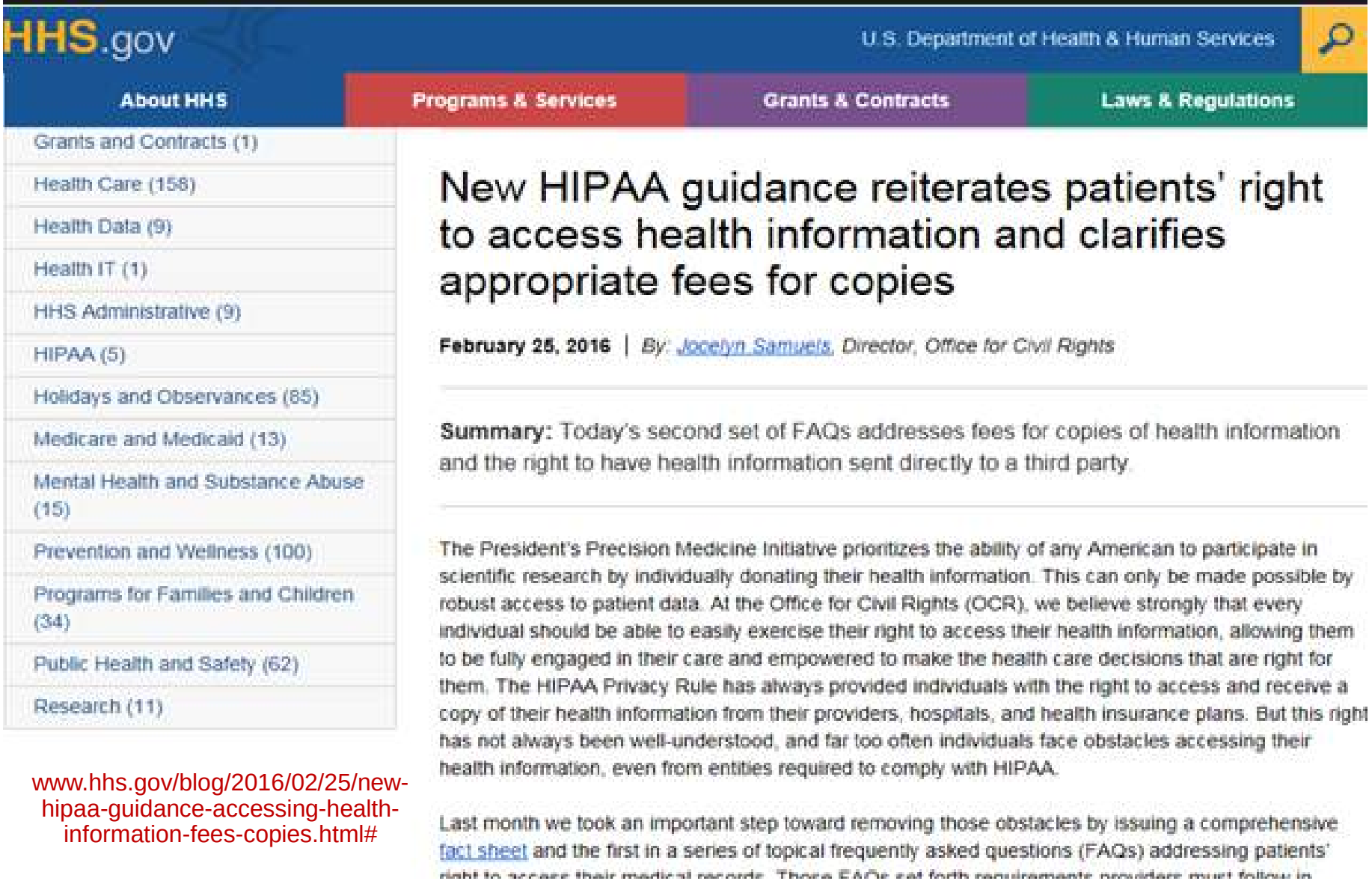
www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html#newlyreleasedfaqs

Introduction

Providing individuals with easy access to their health information empowers them to be more in control of decisions regarding their health and well-being. For example, individuals with access to their health information are better able to monitor chronic conditions, adhere to treatment plans, find and fix errors in their health records, track progress in wellness or disease management programs, and directly contribute their information to research. With the increasing use of and continued advances in health information technology, individuals have ever expanding and innovative opportunities to access their health information electronically, more quickly and easily, in real time and on demand. Putting individuals "in the driver's seat" with respect to their health also is a key component of health reform and the movement to a more patient-centered health care system.

The regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which protect the privacy and security of individuals' identifiable health information and establish an array of individual rights with respect to health information, have always recognized the importance of providing individuals with the ability to access and obtain a copy of their health information. With limited exceptions, the HIPAA Privacy Rule (the Privacy Rule) provides individuals with a legal, enforceable right to see and receive copies upon request of the information in their medical and other health records maintained by their health care providers and health plans.

Second FAQ Feb 2016 and Updated 2017



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New HIPAA guidance reiterates patients' right to access health information and clarifies appropriate fees for copies

February 25, 2016 | *By: Jocelyn Samuels, Director, Office for Civil Rights*

Summary: Today's second set of FAQs addresses fees for copies of health information and the right to have health information sent directly to a third party.

The President's Precision Medicine Initiative prioritizes the ability of any American to participate in scientific research by individually donating their health information. This can only be made possible by robust access to patient data. At the Office for Civil Rights (OCR), we believe strongly that every individual should be able to easily exercise their right to access their health information, allowing them to be fully engaged in their care and empowered to make the health care decisions that are right for them. The HIPAA Privacy Rule has always provided individuals with the right to access and receive a copy of their health information from their providers, hospitals, and health insurance plans. But this right has not always been well-understood, and far too often individuals face obstacles accessing their health information, even from entities required to comply with HIPAA.

Last month we took an important step toward removing those obstacles by issuing a comprehensive fact sheet and the first in a series of topical frequently asked questions (FAQs) addressing patients'

www.hhs.gov/blog/2016/02/25/new-hipaa-guidance-accessing-health-information-fees-copies.html#

Appendix Z Emergency Preparedness

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-29-ALL

DATE: **June 02, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy- Appendix Z, Emergency Preparedness Final Rule Interpretive Guidelines and Survey Procedures

www.cms.gov/files/document/appendices-table-content.pdf

Memorandum Summary

- **Advanced Copy of Interpretive Guidelines:** The Centers for Medicare & Medicaid Services (CMS) is releasing a new Appendix Z of the State Operations Manual (SOM) which contains the interpretive guidelines and survey procedures for the Emergency Preparedness Final Rule.
- **Affects all 17 providers and suppliers:** Appendix Z applies to all 17 providers and suppliers included in the Final Rule.

Background

On September 16, 2016, the final rule on Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers was published (Federal Register Vol. 81, No. 180). This rule affects all 17 provider and supplier types eligible for participation in Medicare. The rule became effective on November 15, 2016 and will be implemented on November 15, 2017.

Updates to Emergency Preparedness

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

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO19-06-ALL

DATE: **February 1, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Emergency Preparedness- Updates to Appendix Z of the State Operations Manual (SOM)

www.cms.gov/files/document/appendices-table-content.pdf

Memorandum Summary

- **Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers:** On September 16, 2016, the *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers* (Emergency Preparedness Rule) final rule was published in the Federal Register.
- Health care providers and suppliers affected by the rule were required comply and implement all regulations by November 15, 2017.
- We are updating Appendix Z of the SOM to reflect changes to add emerging infectious diseases to the definition of all-hazards approach, new Home Health Agency (HHA) citations and clarifications under alternate source power and emergency standby systems.

Background