JOHN D. ARCHBOLD MEMORIAL HOSPITAL
ADVANCED PRACTICE PROVIDER
ANNUAL EDUCATION PACKET
February 2024

1. Patient's Rights and Responsibilities: Administrative Policy 101.05
2. Use of Communication Devices for Patients with Communication Barriers: Nursing Policy 120.03
3. Potential Disruptive Behavior Reports: Medical Staff Policy 13
4. Behaviors that Undermine/Impact a Culture of Safety: Administrative Policy 110.62
5. Workplace Violence Prevention Plan: Administrative Policy 104.11
6. Medical Record/Chart Communication: Medical Staff Rules & Regulations Section II
7. Informed Consent: Administrative Policy 101.18
8. Restraint and Seclusion: Administrative Policy 101.21
9. Suicide Screening and Precautions: Administrative Policy 101.55
10. Provider's Role in Preventing and Controlling Infections
11. Antimicrobial Stewardship: Pharmacy Policy 210
12. Pain Management: Administrative Policy 101.20
13. Opioid Overdose Prevention Toolkit & Checklist for Prescribing Opioids for Chronic Pain
14. Disclosing Unanticipated Adverse Events to Patients and Families: Administrative Policy 101.27
15. Physician Notification of Change in Patient Status: Nursing Policy 59.0
16. Critical Assessment Team (CAT): Nursing Policy 139.0
17. Falls Precaution Program: Administrative Policy 101.38
18. Emergency Response Roles: Medical Staff Rules and Regulations Section XII
19. Fire Response: Emergency Operations Plan
20. Emergency Codes: Administrative Policy 110.61
21. Corporate Compliance:
    - A Prescriber's Guide to Medicare Prescription Drug (Part D) Opioid Policies
    - Medicare Fraud & Abuse: Prevent, Detect, Report
    - Avoiding Medicaid & Medicare Fraud & Abuse
    - Strategy to Fight the Opioid Crisis
    - OIG: Special Fraud Alert: Speaker Programs
    - OIG: Special Fraud Alert: Entering into Arrangements with Purported Telemedicine Companies
    - OIG: Fraud Alert: Physician Compensation Arrangements may result in Significant Liability

Additional Information

- The Joint Commission Public Notice www.archbold.org
- Physician's Portal – Communication Tool
- Archbold Intranet:
    - Policies & Procedures
    - Regulatory guidance included from Joint Commission, GHA, and CMS

Policies address: Patient Rights; Advance Directives; Education of Patient's Families; Ethical Issues; Handoff Communication Tool; Time Out and Procedure Site Verification; Risk Management; Use of Abbreviations in Medical Records and more.

Please sign and date the statement below and return it to the Medical Staff Office.

I have received and take responsibility for the APP Education Packet related to the topics listed below. I am aware that I may contact the Medical Staff Office or the Chief of Staff for any further information or assistance.

Name	Signature	Date

TOPICS ADDRESSED:

1. Patient's Rights and Responsibilities: Administrative Policy 101.05
2. Use of Communication Devices for Patients with Communication Barriers: Nursing Policy 120.03
3. Potential Disruptive Behavior Reports: Medical Staff Policy 13
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ARCHBOLD MEDICAL CENTER
ADMINISTRATIVE POLICY MANUAL

POLICY NUMBER: 101.05

EFFECTIVE: February 1995

SUBJECT: Patients' Rights and Responsibilities

EXPIRES: When Superseded

APPROVED: _____
President

REVIEWED: January 2022

REVISED: January 2022

I. POLICY

It is the policy of Archbold Medical Center to recognize and give careful attention to the basic rights of human beings to be treated with courtesy, consideration and concern. It is also the right of the hospital to expect that behavior on the part of the patient is reasonable and responsible. Archbold provides healthcare services irrespective of age, race, color, creed, ethnicity, religion, national origin, marital status, sex, sexual orientation, gender identity or expression, disability, association, veteran or military status, or any other basis prohibited by federal, state, or local law. Equal access includes physical accommodations for disabled persons, nondiscriminatory delivery of benefits, and reasonable aid in accessing electronic health programs.

II. PURPOSE

To assure the hospital patient of independence of expression, decision, and action and to formally state the concern felt by the hospital for the personal dignity of the patient in a situation where human relationships are of vital concern and to let each patient know that he or she bears a part of the responsibility for his or her own care in the hospital.

III. SPECIAL INSTRUCTIONS

A. The following patient rights are affirmed by the Board of Trustees as being applicable to any and all patients in a manner free from discrimination in Archbold Medical Center. The patient rights are listed below:

1. The patient has the right to reasonable access to care.

2. The patient has the right to respectful and considerate care that is considerate of his or her personal values and beliefs.

3. The patient has the right to religious and spiritual services. Volunteer Chaplains are available to assist patients and families upon request or the patient's own clergy may be contacted. Patient Advocates are also available to assist with any religious or spiritual needs.

4. The patient has the right to respectfully obtain from his or her physician current information concerning his or her diagnosis, treatment, prognosis, and outcomes of care, including unanticipated outcomes, in terms the patient can be reasonably expected to understand.

5. The patient has the right to formally designate a surrogate decision maker of his or her choice.

6. The patient has the right to have someone remain with them for emotional support during their hospital stay unless the visitor's presence compromises the patient's or other's rights, safety or health. The patient has the right to deny visitation at any time.

7. The patient has the right to receive from his or her physician information necessary to give informed consent prior to the start of any treatment or procedure. Patient's family or healthcare surrogate decision maker will be involved to facilitate proper care when appropriate.

8 The patient has a right to be informed and participate in decisions regarding his or her care.

9 The patient has the right to expect reasonable and appropriate pain management and to be involved in care decisions involving managing pain effectively.

10. The patient has the right to refuse treatment to the extent permitted by law and to be informed of the medical consequences of his or her action.

11. The patient has the right to every consideration of his or her privacy concerning his/her own medical care. Case discussion, consultation, examination and treatment are confidential and should be conducted discreetly.

12. The patient has the right to security and personal privacy.

13. The patient has the right to expect that all communications and records pertaining to his or her care should be treated as confidential, and information related to his or her care will only be released in accordance with hospital policy as stated in AMC Administrative Policy 105.06, "Release of Information". Additionally, the patient has specific privacy rights as established by the Health Insurance Portability and Accountability Act, which are explained in detail in the Medical Center's Notice of Privacy Practices.

14. The patient has the right to expect that within its capability, and in accordance with the mission and applicable law, a hospital must make a reasonable response to the request of a patient for services. The patient has the right to expect that prompt and safe transfer will occur when the hospital cannot meet the patient's request or need for treatment or service.

15. The patient has the right to examine and receive an explanation of his or her bill regardless of the source of payment.

16. The patient has the right to know what hospital rules and regulations apply to his or her conduct.

17. The patient has the right of access to people outside the hospital by means of visitors and by verbal and written communication.

18. The patient has the right to formulate advance directives as described in the AMC Administrative Policy 101.20, "Advance Directives".

19. The patient has the right to participate in the consideration of ethical issues that may arise during the course of his or her care. Any such ethical issues may be addressed through the Ethics Committee of the medical staff (see AMC Administrative Policy 101.13).

20. The patient has the right to be informed of any human experimentation or other research/educational projects that affect his or her care.

21. The patient has the right to access protective services through community resources.

22. The patient has the right to participate in the development and implementation of his or her own plan of care.

23. The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

B. The following patient responsibilities are also applicable to any and all patients. These patient responsibilities are listed below:

1. The patient and family are responsible for providing to the best of his or her knowledge, accurate and complete information about his or her present complaints, past illnesses, hospitalizations, medications, and other matters relating to his or her health and making it known whether he or she clearly comprehends a contemplated course of action and what is expected.

2. The patient and family are responsible for reporting perceived risks in his or her care and unexpected changes in the patient's condition.

3. The patient and family are responsible for asking questions when they do not understand what they have been told about the patient's care or what they are expected to do.

4. The patient and family are responsible for following the treatment plan recommended by medical and hospital personnel responsible for his or her care.

5. If the patient or family refuses treatment or fails to follow the practitioner's instructions, they are responsible for the outcomes.

6. The patient and family are responsible for assuring that the financial obligations

of his or her health care are fulfilled promptly.

7. The patient and family are responsible for following hospital rules and regulations affecting patient care and conduct including safe keeping of personal items (see Patient Safety and Security brochure).

8. The patient is responsible for being considerate of the rights of other patients and hospital personnel, and for assisting in the control of noise, the number of visitors, and complying with the policy on smoking and the use of tobacco products (see AMC Administrative Policy 100.03).

9. The patient and family are responsible for being respectful of the property of other persons and of the hospital.

C. It shall be the responsibility of all hospital personnel, individually and collectively, to ensure that the rights of each patient are preserved.

D. The patient will be informed of his or her rights and responsibilities in the information booklet presented to each patient on admission. In the outpatient registration areas, patient's rights and responsibilities will be posted and will be available as a patient handout.

E. Patients wishing to express and resolve a concern regarding the quality of patient care may do so through "Hot Line numbers" described and available in each patient's room. Federal, State and In-House information on how to resolve an unmet need is posted at Registration areas throughout the hospital.

F. The care of all patients must include consideration of the psychosocial, spiritual, and cultural variables that influence the perception of illness and responses to care.

G. Every effort is made to provide for the auditory and visual privacy of patient. Conference rooms are available for use by physicians, nursing staff, ancillary staff, patients and/or families. Provisions for non-ambulatory patients are arranged on an individual basis.

H. Special consideration is made for the dying patient to provide comfort and dignity acknowledging the psychosocial, spiritual, and physical needs of the patient and/or family during this highly personal time.

IV. JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A BROOKS COUNTY HOSPITAL, GRADY GENERAL HOSPITAL, MITCHELL COUNTY HOSPITAL, GLENN-MOR NURSING HOME, MITCHELL CONVALESCENT CENTER, PELHAM PARKWAY NURSING HOME)/ARCHBOLD FOUNDATION, INC./ARCHBOLD HEALTH SERVICES, INC./ARCHBOLD MEDICAL ENTERPRISES, INC./ARCHBOLD MEDICAL GROUP, INC.

A. As applicable.

☐AMH ☐BCH ☐GGH ☐MCH ☐GMNH ☐MCC ☐PPNH

ARCHBOLD MEDICAL CENTER
NURSING POLICY/PROCEDURE MANUAL

POLICY/PROCEDURE NO: 120.03

SUBJECT: Use of Communication Devices for Patients with Communication Barriers

EFFECTIVE: 8/1994

EXPIRES: WHEN SUPERSEDED

APPROVED: _____
Amy Griffin, RN
VP of Patient Care Services

REVIEWED: 10/201

REVISED: 10/2021

I. PURPOSE

The purpose of this policy is to provide guidelines for alternate methods of communication in order to provide quality patient care and to assist the patient with communication barriers in communicating with their healthcare team or family through special assistive devices.

II. POLICY

It is the policy of Archbold Medical Center to provide methods of communication for patients and families who have barriers to communication or limited English proficiency (LEP). LEP is defined as a person who is not able to speak, read, write, hear, or understand the English language at a level that allows the patient to understand their healthcare information. These barriers include patients who are unable to communicate verbally, patients with language barriers, and patients with hearing or vision impairments.

III. PROCEDURE/PROCESS

A. Assessment and Reassessment of Communication Barriers:
   i. Communication limitations that may pose a barrier to care are assessed and documented on admission
   ii. The patient's communication needs are reassessed on a regular basis

B. Provision of Communication Methods
   i. Nursing and ancillary staff are made aware of the patient's disability
   ii. Instructions are given to patients to ensure understanding of communication devices
   iii. Healthcare providers and families should continue to verbally interact with unconscious patients and refrain from inappropriate dialogue in the presence of unconscious patients

iv. Patients who are visually impaired will be provided information in a verbal form
v. Patients who are hearing impaired will be provided information or a device to enhance communication
vi. Patients who have impaired comprehension will have information presented on an appropriate level for understanding and reinforced by the staff
vii. Each patient room has closed captioned television for the hearing impaired
viii. Each patient room has amplified telephones for the hearing impaired
ix. At John D. Archbold Memorial Hospital all communication devices listed below are located in the Nursing Supervisor's office; the Nursing Supervisor's office will utilize a device tracking log to track equipment; staff at affiliate facilities are to contact their department manager for communication devices
    1. Language Services Associates (LSA) for Non-English Speaking
        a. Patients and families who are unable to understand English are provided use of an interpreter for language interpretation; no special phone is required
        b. If the language interpreters are contacted and are unable to provide the specific dialect (in a particular language) a time shall be given for an interpreter to be available to speak (interpret) to the patient
        c. For non-English speaking patients, a select list of translated forms will be available
            i. If a specific form or document is not available in a needed language, an interpreter may be utilized to interpret specific needed documents
    2. LSA-Interpretac System for American Sign Language (ASL)
        a. Patients and families who are deaf are provided use of an interpreter specializing in ASL
    3. Communication Toolkits
        a. Patients who require additional resources for communication are provided communication toolkits; these toolkits contain resources for communication including instructions for LSA systems
        b. Patients who are unable to speak are provided with means of expressing their needs (white boards, writing implements, picture boards, body gestures)
    4. Breath Call Nurse Control Unit
        a. Patients who are paralyzed and unable to use the nurse call system are provided with an alternate method of communication such as the Breath Call Nurse Control Unit
    5. Telecommunication Teletype Device (TTY)

a. A TTY service is available either by the TTY device or by calling 711 for the Telecommunications Relay Service
    i. Internal calls should dial 9 first, then 711
b. This TTY service coverts text to voice or vice versa as needed

C. Restrictions
    i. All healthcare staff are prohibited from using family, friends, or significant others as a medical interpreter
        1. The only acceptable time is in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter available
        2. Adult family members and friends may be used as medical interpreters where the LEP person specifically requests that the accompanying adult interpret or facilitate communication and the accompanying adult agrees to provide such assistance
            a. In these instances, Form NS 737, *Refusal To Use Certified Translator and Release of Liability* will be used for the patient to refuse Archbold's available language service; the certified language service provider will be called to interpret the form to ensure that the patient understands what they are signing
    ii. All healthcare staff are prohibited from relying on a minor child as an interpreter or as a facilitate communicator with LEP
    iii. All healthcare staff will only use the designated assistive devices; any other type of internet translation in prohibited
    iv. Bilingual or multilingual staff are restricted from interpreting without formal training in medical interpreting

D. Documentation
    i. Document the use of communication devices in the patient's medical record
    ii. If a service/interpreter is used for communication, document the date/time, situation, education, interpreter's identification number, the information being translated, and the patient's understanding

IV. SPECIAL INSTRUCTIONS

A. Refer to Language Access Plan – Administrative Policy 101.64

Archbold Medical Center

CALL 866.560.7907

To Access a Qualified Interpreter

- When prompted, please enter your Access Code: **200329**
- Press 1 for Spanish, 2 for Mandarin, 3 for Cantonese, 4 for Arabic, 5 for Vietnamese, 6 for Haitian Creole, 7 for Russian, 8 for French, or 9 for all other languages.
- For prompts 1 through 8 you will be connected directly to an Interpreter and the session may now begin.
- For all other languages, when greeted by a coordinator, request the language needed or ask for assistance in identifying the language.
- Please provide the following information:
  - **3-Digit Location Code**
  - **Department or Unit**
  - **Caller's Last Name, First Name**
  - **Medical Record Number**

Reminder
The interpreter's ID number must be documented in the patient's medical record!

- You will be provided with the Interpreter six-digit ID number, take note of this number.
- Explain the objective of the call to the interpreter. Then proceed by speaking directly to the Limited English Proficient speaker in the first person. Example: "What is your name?" NOT "Interpreter, can you please ask her name?"
- Upon completion of the call please let the interpreter know the session is ending and simply hang up.

Language Services associates

www.LSAweb.com

Client Experience
866.221.1301

Archbold Medical Center

IRIS

How to Access a Qualified Interpreter

- Click  icon on the screen
- Prior to entering the patient room press the icon  or  next to the desired language to connect to an Interpreter.
- Please notate the Interpreter 6-digit ID Number.
- Please provide the following information:
  - **3-Digit Location Code**
  - **Department or Unit**
  - **Caller's Last Name, First Name**
  - **Medical Record Number**

Reminder

The interpreter's ID number must be documented in the patient's medical record!

- Explain the objective of the call to the interpreter. Proceed by speaking directly to the Limited English Proficient speaker in the first person.
- Example: "What is your name?" NOT "Interpreter, can you please ask her name?"
- If using video, please stand to the side or behind the device.
- Upon completion of the interpretation let the interpreter know the session is ending and press the  to disconnect.

Language Services associates

www.LSAweb.com

Technical Support

877.702.4747

Archbold Medical Center
Scheduling a Face-to-Face Interpreter or Virtual Face to Face Session

Online Requests: When you want to schedule a Face to Face or Virtual Face to Face Interpreter please visit https://interpretrac.LSAweb.com and log in using your personalized username and password which was provided to you.

**You will need an INTERPRETRAC login to access this. If you need assistance in setting this up, contact your manager or reach out to LSA by emailing Clientexperience@LSAweb.com*

- Complete all requested information
  - For a Virtual Request click the '**Virtual**' box in the '**Interpretation type**' section
  - Include the Video Conference Link in the '**Meeting Invite URL**' box.

Reminder
The interpreter's ID number must be documented in the patient's medical record!

Telephone Requests: If you prefer to schedule by phone or it is less than **48** hours' notice, please dial: **866.827.7028**

- **ACCOUNT CODE**: **4714**
- When greeted by a Face-to-Face interpreting Project Coordinator, please provide all requested intake.

Language Services associates
www.LSAweb.com

Client Experience
866.221.1301

LSA INTERPRETRAC System Responsibilities
Nurse=BLUE
Nursing Supervisor=GREEN

LSA INTERPRETRAC System

*****LSA INTERPRETRAC available 24 hours a day/7 days a week*****

LSA INTERPRETRAC System Customer Support
1-800-305-9673

1. The Primary Nurse identifies that the hearing impaired patient requires communication assistance and notifies the Nursing Supervisor to bring the LSA INTERPRETRAC System to requesting unit

2. Nursing Supervisor brings LSA INTERPRETRAC System to requesting unit

3. Nursing Supervisor should record the use of the INTERPRETAC System in the folder located inside of the computer case. The following should be documented: Date, Department/Unit, Patient Name and Medical Record Number

4. Primary Nurse:

- Turn LSA INTERPRETRAC System computer on by pressing the "ON" button in top right corner
- Ensure that the speaker is plugged into the computer via the USB port on the left side
  - ***Please do not detach the speaker from the computer after use***
  - A blue light on the speaker indicates the microphone is ready for use
  - A red light on the speaker indicates the microphone is muted
- Kaspersky Login:
  - Username: Pretalk1 (capital "P")
  - Password: pretalk1 (all lower case)
  - Click "Continue"
- CTRL + ALT + DELETE to log on
- Select "LSA INTERPRETRAC" icon in top left corner
- Select "archbold" on right side of screen
- Enter Password: archbold (all lower case)
- Select the "Instant Remote Interpretation Services" tab
- Select the "ASL" (American Sign Language) tab
- The interpreter will appear on the screen and communicate with the patient and nurse via audio and video
  - Once the interpreter is present they will provide an interpreter ID number which is located in the top right corner of the screen
- Click the red "END" button once the session is complete

*****Document the use of the LSA INTERPRETAC System, the interpreter ID number and the interpreter's name in a clinical note in the electronic medical record*****

711 for Telecommunications Relay Service

Telecommunications Relay Services permit persons with a hearing or speech disability to use the telephone system via a text telephone (TTY) or other device to call persons with or without such disabilities.

To make using TRS as simple as possible, you can dial 711 to be automatically connected to a TRS operator. It's fast, functional and free. Dialing 711, both voice and TRS users can initiate a call from any telephone, anywhere in the United States, without having to remember and dial a ten-digit access number.

Dial 711 using private branch exchanges and VoIP

FCC rules require all telephone companies that operate private branch exchanges (PBXs) - a private telephone system within an organization - to implement three-digit 711 dialing for access to TRS. This includes wireline, wireless and payphone providers. PBX operators are required to modify their equipment to enable 711 dialing to ensure everyone has easy access to TRS.

Callers from locations served by PBXs may be required to dial 9 or another prefix before entering the 711 code or placing an outside call.

Providers of interconnected Voice over Internet Protocol (VoIP) service also must offer 711 dialing service.

911 calls

The Americans with Disabilities Act requires that people with disabilities who use TTYs or other devices have direct, equal access to emergency response services. In the event of an emergency, TTY users should call 911 directly and not make a TRS call via 711.

Video and Internet-based relay services

711 dialing access does not work for Video Relay Service (VRS), Internet Protocol Relay (IP Relay) or IP Captioned Telephone Service (IP CTS) calls, because such calls are initiated through the Internet. Hearing persons initiating a VRS, IP Relay, or IP CTS call should call their party directly, and a communications assistant will be automatically connected to the call.

More information on TRS

For more information about the various types of TRS, see the FCC's consumer guide (fcc.gov/guides/telecommunications-relay-service-trs) or visit the website of our Disability Rights Office (fcc.gov/accessibility).

Filing a complaint

You have multiple options for filing a complaint with the FCC:

Federal Communications Commission · Consumer and Governmental Affairs Bureau · 45 L Street NE, Washington, DC 20554
1-888-CALL-FCC (1-888-225-5322) · TTY: 1-888-TELL-FCC (1-888-835-5322) · www.fcc.gov/consumer-governmental-affairs-bureau

- File a complaint online at https://consumercomplaints.fcc.gov
- By phone: 1-888-CALL-FCC (1-888-225-5322); TTY: 1-888-TELL-FCC (1-888-835-5322); ASL: 1-844-432-2275
- By mail (please include your name, address, contact information and as much detail about your complaint as possible):

  Federal Communications Commission
  Consumer and Governmental Affairs Bureau
  Consumer Inquiries and Complaints Division
  45 L Street NE
  Washington, DC 20554

Alternate formats

To request this article in an alternate format - braille, large print, Word or text document or audio - write or call us at the address or phone number at the bottom of the page, or send an email to fcc504@fcc.gov.

Last Reviewed: 01/10/20

Code	Location
101	Advanced Therapy and Sports Medicine
102	Ambulatory Care Center/Women's Imaging
103	Archbold Memorial Hospital
104	Archbold Primary Care
105	Bainbridge Specialty Clinic
106	Brooks County Hospital
107	Brooks County Specialty Clinic
108	Brooks Medical Associates
109	Cairo Internal Medicine
110	Camilla Pediatrics
111	Cardiology/Interventional Cardiology Consultants
112	Ear, Nose, Throat, and Allergy Center
113	Employee Assistance Program
114	Gastroenterology Group/Digestive Disease Center
115	Glenn-Mor Nursing Home
116	Grady County Dialysis
117	Grady General Hospital
118	Grady Specialty Clinic
119	Home Health
120	Hospice
121	Medical Group of Mitchell County
122	Mitchell Convalescent Center
123	Mitchell County Hospital
124	Mitchell County Specialty
125	Nephrology Associates
126	Neurology Associates
127	Neurosurgery Services
128	Northside
129	Oncology/Infusion Center
130	Patient Financial Services
131	Pelham Parkway Nursing Home
132	Pelham Primary Care Clinic
133	Pelham Primary Care
134	Pulmonary Medicine
135	South Georgia Surgical Associates
136	Thomasville Orthopedic
137	Urgent Care Center
138	Urology Associates

Communication Device Log

Patient Name	MRN	Type of Device	Date Received	Date Returned	Nursing Supervisor Signature

John D. Archbold Memorial Hospital
Medical Staff Policy: Potential Disruptive Behavior Reports

The John D. Archbold Memorial Hospital Archbold Division Medical Staff Bylaws Article V addresses identification and potential actions that can be taken for questions of marginal disruptive behavior, disregard for rules, physical or mental impairment, or unethical behavior.

This Medical Staff Policy provides a procedure for processing complaints of potential disruptive behavior in order to facilitate the aims of Article V (Exhibit A). All activities utilized in this policy and procedure are part of Archbold Memorial Hospital's confidential performance improvement and peer review activities. Issues related to professional competence and quality of care shall continue to be addressed through existing departmental QA subcommittees.

1. Reports shall be submitted in writing using the attached form. (Exhibit B)

    a. The form shall be signed by the individual making the report.

    b. Anonymous reports are allowed, but should be completed by a supervisor or Medical Staff department chair who shall sign the report form.

    c. All who report shall be assured that intimidation or retaliation as a result of filing a report is not acceptable and shall be reported to the MEC for action as allowed in the medical staff bylaws.

    d. Reports shall be filed with the Chief Medical Officer (CMO)

    e. The CMO shall inform in writing the individual filing the report that the matter will be handled according to confidential Medical Staff Quality and Peer review standards. (see template letter Exhibit C)

2. The CMO shall review the report for completeness.

3. The CMO shall forward the report to the appropriate Medical Staff Department chair attached to the Department Chair Action form (Exhibit D) and assist the chair with the evaluation as needed.

4. The Department Chair shall choose one or more of the following actions and indicate the decision on the Department Chair Action form and sign the reporting form.

    a. The situation does not rise to the level of behavior described in Article V of the Medical Staff Bylaws nor does it rise to the level of behavior described in Archbold Administrative Policy 110.62 (Exhibit E).

b. The situation potentially may rise to the level of behavior described in Article V of the Medical Staff Bylaws and / or Archbold Administrative Policy 110.62, however, documentation is inadequate and the situation cannot be substantiated.

c. The situation may rise to the level of behavior described in Article V of the Medical Staff Bylaws and / or Archbold Administrative Policy 110.62 and a collegial discussion for additional information was conducted.

d. The situation may rise to the level of behavior described in Article V of the Medical Staff Bylaws and / or Archbold Administrative Policy 110.62 and a collegial discussion for additional information was accompanied by collegial intervention. (Collegial interventions should be witnessed by the CMO and / or the Chief of the Medical Staff)

e. The situation may rise to the level of behavior described in Article V of the Medical Staff Bylaws and / or Archbold Administrative Policy 110.62 and after a collegial discussion for additional information the matter is referred to the Medical Executive Committee (MEC).

f. The report form is filed in the confidential CMO files for information.

g. The report form is filed in the confidential credentials QA file.

It should be noted that none of the actions available to the Department Chair described here constitute an investigation as described in the Medical Staff Bylaws. Referrals to the MEC shall be handled in accordance with the Medical Staff Bylaws.

5. The CMO shall sign the Department Action form to indicate completion of the process and filing of the forms. A copy shall be provided to the subject of the report by the CMO or Department Chair.

6. A Medical Staff member may have access to his / her confidential files for review and shall sign a confidentiality agreement and statement agreeing to refrain from intimidation or retaliation to individuals filing reports. (Exhibit F) Medical Staff members may submit a written response that will be maintained in the credentialing confidential QA file.

John D. Archbold Memorial Hospital
Medical Staff Policy: Potential Disruptive Behavior Reports

Exhibit A

ARTICLE V

QUESTION OF MARGINAL PRACTICE, BEHAVIOR THAT UNDERMINES A CULTURE OF SAFETY, DISREGARD FOR RULES, PHYSICAL OR MENTAL IMPAIRMENT, OR UNETHICAL CONDUCT

V.A. Problem Identification

(1) Questions related to a Medical Staff member's clinical judgment or skills, compliance with Hospital and Medical Staff rules, physical or mental status, or ethical conduct that adversely affect, or could adversely affect, patients, the Medical Staff, the Hospital or its employees, are addressed by the Medical Executive Committee and the Board in a timely manner.

(2) Concerns that arise through a complaint/referral from a Medical Staff member, patient, or Hospital employees (if related to behavior that undermines a culture of safety) will be will be communicated to the CMO or the Chief of Staff who will work in conjunction with the appropriate Hospital or Medical Staff to review the matter. A report pertaining to the issue may be presented by the CMO or Chief of Staff to the Medical Staff Leadership for careful consideration and disposition.

V.B. Collegial Intervention

(1) AMH encourages collegial and educational efforts by the Medical Staff leaders and Hospital management to address questions relating to an individual's clinical practice or professional conduct. The goal of these efforts is to arrive at voluntary, responsive action by the individual to resolve questions that have been raised.

(2) These efforts may include, but are not limited to, counseling, sharing of comparative data, monitoring, and additional training or education.

(3) All collegial intervention efforts by the Medical Staff leaders and Hospital management in this regard are part of AMH's confidential performance improvement and peer review activities.

(4) Medical Staff leaders may also handle these matters using other applicable policies of AMH and its Medical Staff.

V.C. Referral to Medical Executive Committee

Whenever a trend has been identified, or a serious question has been raised, or where collegial efforts have not resolved an issue, regarding:

the clinical competence or clinical practice of any member of the AMH Medical Staff, including the care, treatment or management of a patient or patients;

(2) the known or suspected violation by any member of the AMH Medical Staff of applicable ethical standards or the bylaws, policies, rules or regulations of AMH or its Medical Staff; or

(3) conduct by any member of the AMH Medical Staff that is considered lower than the standards of AMH or disruptive to the orderly operation of AMH or its Medical Staff, including the inability of the member to work harmoniously with others,

the matter may be referred to the Medical Executive Committee through the Chief Medical Officer or the Chief of Staff.

ARCHBOLD
ADMINISTRATIVE POLICY MANUAL

POLICY NUMBER: 110.62

EFFECTIVE: February 2009

SUBJECT: Behaviors that Undermine/Impact a Culture of Safety

EXPIRES: When Superseded

APPROVED: _____
President

REVIEWED: December 2023

REVISED: December 2023

I. POLICY

Archbold Medical Center desires to maintain a workplace/clinical environment that is free from inappropriate, intimidating, and/or any other behavior that undermines a culture of safety. It is the policy of the Center to respond to such behavior in a timely manner in order to maintain a safe and professional patient care and work environment allowing us to meet the needs of our patients, employees and visitors. Professional judgment and Archbold Medical Center policies will be used to dictate the individual approach to each instance of such behavior. This will allow us to limit the impact such behavior may have on the environment of care. The goal of the policy is to allow for prevention and early intervention of any behavior undermines/impacts a culture of safety.

Also reference Administrative Policy 104.11 – Workplace Violence Prevention Plan

II. EMPLOYEE, PHYSICIAN AND CONTRACT PERSONNEL

A. DEFINITION

Behaviors that undermine/impact a culture of safety are behaviors that intimidate staff, causes disorder or confusion; interrupts, hinders, or impedes the usual course of operations. Such behavior affects morale, staff turnover and can harm patient care. Intimidating behaviors include overt actions such as verbal outbursts and physical threats, as well as passive activities such as refusing to perform assigned tasks or quietly exhibiting uncooperative attitudes during routine activities. Such behaviors include reluctance or refusal to answer questions, return phone calls or pages; condescending language or sarcasm; and impatience with questions. Overt and passive behaviors undermine team effectiveness and can compromise the safety of patients. All intimidating and disruptive behaviors are unprofessional and will not be tolerated.

B. PURPOSE

The purpose of addressing employee, physician and contract personnel disruptive behavior is not to punish an employee or physician, but is an attempt to work with them to stop improper conduct that impacts an environment of safety so that the care of the patient is not compromised. Safety and quality of patient care is dependent upon teamwork, communication, and a collaborative work environment. To assure quality and to promote a culture of safety, health care organizations must address the problem of behaviors that threaten the performance of the health care team.

C. PROCEDURE

1. Every employee is responsible for reporting such behavior to his or her immediate supervisor. If the immediate supervisor is not available or is the one being disruptive, then the employee should report to his or her next level supervisor, the Human Resources Department, or Administration. Those who report will not be retaliated against.

2. Reports of disruptive or improper conduct will be investigated by the appropriate party. The Human Resources Department will assist in the investigation of employee incidents and the Medical Staff Office will assist in the investigation of physician incidents. Administration will assist any investigation into board member conduct and/or any other person as deemed appropriate.

3. After the conclusion of the investigation, any or all of the following actions may occur:

   a. Determine that no action is justified;

   b. Issue a letter of guidance, counsel, warning, or reprimand for physicians or board members and Verbal, Written, or Final Corrective Interviews for employees;

   c. Impose terms of probation or monitoring;

   d. Impose conditions for continued appointment or employment;

   e. Impose a requirement of consultation;

   f. Recommend additional training or education;

   g. Recommend reduction of clinical privileges;

   h. Recommend suspension of clinical privileges or employment;

   i. Recommend revocation of appointment, clinical privileges, or termination of employment;

   j. Other recommendations as deemed appropriate or necessary.

III. PATIENT, PARENT, LEGAL GUARDIAN, FAMILY MEMBER, VISITOR DISRUPTIVE BEHAVIOR

A. DEFINITION

1. Threat is defined as:

a. Any physical assault, threat of physical assault or attempted intimidation.

b. Verbal abuse, including but not limited to offensive language, swearing, threats, whether in person or by telephone calls, faxes or any written communication.

c. Possession of firearms or weapons (refer to Administrative Policy 104.11)

2. Disruptive behavior is defined as:

a. Yelling or screaming at staff or others

b. Any disruption of staff's ability to care for patient(s)

c. A perception by staff of discomfort or interference with the environment of care

B. PURPOSE

The purpose of addressing patient, parent, legal guardian, family member and visitor disruptive behavior is to assure the safety of our patients and staff as well as to promote an environment of health and healing for our patients. Safety and quality of patient care is dependent upon teamwork, communication, and a collaborative work environment. To assure quality and to promote a culture of safety, the Center must address the problem of behaviors that threaten the performance of the health care team.

C. PROCEDURE

1. **Threats** – If, at any time a staff member perceives a threat to themselves or others, security and the staff member's supervisor or other designated reporting officer should be notified. If you are in a facility where security is not available, you should notify your reporting officer and notify local law enforcement if necessary. **Administration should also be notified of situations of threatening or disruptive behavior.**

a. Staff should take appropriate actions to protect their patients, staff and visitors by closing doors to patient's room and, if possible, isolating the threatening individual. Staff should not argue with the individual or risk endangerment to self or others in attempting to secure a weapon or control an individual's behavior.

b. The administrative supervisor and appropriate managers should be notified as soon as possible.

c. If possible to do so safely, Security or other appropriately designated personnel will remove the threatening individual from the area as expeditiously as possible. If it is not possible for Security or other designated personnel to safely remove the threatening individual, Security

will immediately contact local law enforcement and minimize the danger to other patients, staff and visitors to the extent possible.

d. Direct assaults and/or incidents of battery will be brought immediately to the attention of Security and/or Administration and Risk Management. In such cases, criminal charges against the individual will be considered appropriate.

e. Archbold Medical Center reserves the right to ban threatening individuals from specific Archbold facilities and property **unless they need to seek emergency medical treatment**.

f. After being banned from the specified entity/property, any unapproved return by a threatening individual will be considered a case of criminal trespass and shall be immediately brought to the attention of Security and/or the local law enforcement.

g. In the event the banned individual needs to return to the hospital for reasons other than an emergency situation, administration will need to approve the visit. Appropriate personnel will be notified so the visit can be planned with adequate safety measures in place.

h. If the threatening individual is a patient, the attending physician and other appropriate care providers will be notified. Archbold Medical Center reserves the right to ban the patient from facilities and property upon discharge and shall not be allowed to return except as a patient requiring emergency treatment or other pre-approved visit. If necessary, criminal charges against the threatening individual will be considered appropriate.

2. If there is no perceived immediate threat, yet an individual demonstrates disruptive behavior that undermines/impacts a culture of safety (as defined above), the staff should contact Security or other appropriate personnel to discuss with the individual the disruptive and inappropriate behaviors and inform the individual of Archbold Medical Center's expectations with respect to his/her behavior. The disruptive individual must read and sign the Individual Behavior Contract (IBC), Form #ADM 166. The IBC should be presented to and discussed with the subject by either security or a patient representative, whichever is most appropriate for the individual situation. One copy will be given to the individual, one copy of the IBC will be placed in the relevant patient's medical record, and one will be given to Security or the appropriate personnel for tracking purposes.

a. If the individual acts appropriately once confronted and agrees to sign the IBC but it is determined that he/she has unresolved issues or concerns about the care the patient is receiving or any other aspect of the environment of care, he/she should be given the opportunity to speak to the physician and/or unit Department Head.

b. The IBC will become a permanent part of the relevant patient's medical

record and should be easily accessible for all health care providers during the patient's hospitalization/treatment.

c. If the IBC is violated, Security or other appropriate personnel shall be notified and the individual will be escorted off of the premises. Local law enforcement will be notified if necessary. Archbold Medical Center reserves the right to ban disruptive individuals from specific facilities and property **unless they need to seek emergency medical treatment.**

d. If the patient is transferred to another unit or hospital, staff should ensure there is appropriate communication regarding the individual's disruptive behavior. All communication must be factual and should not include unsupported assumptions about intent or motivation underlying the behavior.

e. It is important that staff work together to maintain a consistent approach to disruptive individual(s). The IBC should be initiated at the initial signs of disruptive behavior. Staff should be consistent and unified in their response to handling any issues that may arise.

3. History of Violence EHR Alert: requests are made to Risk Management to add history of violence alert to a patient electronic health record. Risk Management will review occurrence report(s), patient record, and/or consult Security. Risk Management will add and/or delete history of violence alerts from EHR. Risk Management will review alerts annually and as needed to determine if alerts may be removed from patient's record. Security may be consulted.

a. The alert indicates that this patient has a history of violence and has a potential for escalated behavior. Staff should take precautions for their safety, recognize escalating behavior and de-escalate, call code grey, notify Security, and/or Law enforcement if needed.

b. The alert shall not compromise the quality of care, stigmatize or label the patient.

I. IV. JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A ARCHBOLD MEMORIAL, ARCHBOLD BROOKS, ARCHBOLD GRADY, ARCHBOLD MITCHELL, ARCHBOLD LIVING THOMASVILLE, ARCHBOLD LIVING CAMILLA, ARCHBOLD LIVING PELHAM, ARCHBOLD LIVING CAIRO) / ARCHBOLD FOUNDATION, INC./ ARCHBOLD MEDICAL GROUP, INC.

A. As applicable.

ARCHBOLD MEDICAL CENTER
ADMINISTRATIVE POLICY MANUAL

POLICY NUMBER: 104.11

EFFECTIVE: March 2009

SUBJECT: Workplace Violence Prevention Plan

EXPIRES: When Superseded

APPROVED: _____
President

REVIEWED: January 2020

REVISED: January 2020

I. POLICY:

A. Archbold Medical Center is committed to providing a safe and secure environment for our patients, visitors and staff. Therefore, Archbold Medical Center has no tolerance for acts or threats of physical violence, including, but not limited to, coercion, intimidation, stalking or harassment that affects the hospital or occurs on any Archbold owned or operated property. Weapons are strictly prohibited from Medical Center property other than those carried by law enforcement officials.

B. All fire arms and weapons, other than those carried by law enforcement officials, including those whose owners have a Concealed and Carry Weapons License are strictly prohibited from all Archbold property. This includes, but is not limited to, having weapons in purses, desks, lockers or in any vehicle parked on Archbold property. Employees who violate this policy will be disciplined up to and including termination. Non-employees who bring weapons onto Archbold owned or operated property are subject to legal action by local law enforcement authorities as appropriate.

C. This prohibition against threats and acts of violence applies to all Archbold patients, visitors, and employees. Violations of this policy by employees will be interpreted as misconduct and shall lead to disciplinary action up to termination and/or legal action with the appropriate law enforcement authorities. Victims of workplace violence will not be discriminated against.

II. PURPOSE:

To provide guidance and protocols for dealing with and prevention of workplace violence.

III. PROCEDURES:

A. Archbold Medical Center has established a core Critical Event Team (CET) consisting of: Director of Human Resources; Director of Risk Management; Director of Employee Assistance Programs; Security Manager; other individuals/resources will be involved depending on the situation.

B. In incidents where violence is imminent, Local law enforcement shall be contacted first. Acts of violence, or threats or threatening behavior shall immediately be reported to the immediate area supervisor and to Archbold Medical Center Campus Security (229) 228-2000 or directly to (229) 584-7233 (SAFE)/extension; SAFE for immediate implementation of this workplace violence procedure, investigation and

other assistance as deemed appropriate. All information gathered during a threat or incidence of violence is strictly confidential.

C. Acts of workplace violence are many times the continuation of domestic disputes that are brought into the hospital by a friend or relative. Each employee has the responsibility to assist in protecting fellow employees from violent acts. If an employee feels there is a possibility of domestic violence being brought into the facility, he/she shall contact Security, the Directors of Employee Assistance Programs, Risk Management and Human Resources. This information will be kept in strictest confidence while levels of security are increased to deter an event from occurring.

D. No counter-threats of the individual threatening violence will be made.

E. Security shall be provided as needed for the individual threatened, as well as co-workers and the public at the work-site, maintaining confidentiality.

F. If the individual who allegedly made such threats is an employee, he/she shall be placed on administrative leave pending the outcome of the CET investigation.

G. The incident shall be recorded on the on-line occurrence reporting system all information regarding the incident within 24 hours of the event. (Answer the Who, What, When, Where, Why and How)

IV. SPECIAL INSTRUCTION:

A. Managing the Aftermath of an Incident

Employees with psychological consequences of workplace violence will be provided the appropriate supportive services to assist them to deal with the situation. Archbold Medical Center provides support to employees through the employee assistance program (EAP). EAP is available to employees and their families at no charge. Employees can call at 229-228-2210 or 877-327-2724.

B. Responsible Personnel

All hospital personnel are responsible for maintaining a violence-free environment.

1. The Critical Event Team is responsible for the following:

a. Establishing and maintaining policies and procedures to deal with workplace violence.

b. Reviewing Archbold Medical Center's current readiness to respond to issues of workplace violence.

c. Establishing liaison with local law enforcement and other supportive agencies.

d. Development of training and education programs.

e. Hazard control and prevention.

f. Investigation and evaluation of violent incidents.

g. Record keeping.

h. Annual evaluation of this policy with a through review of past incidents.

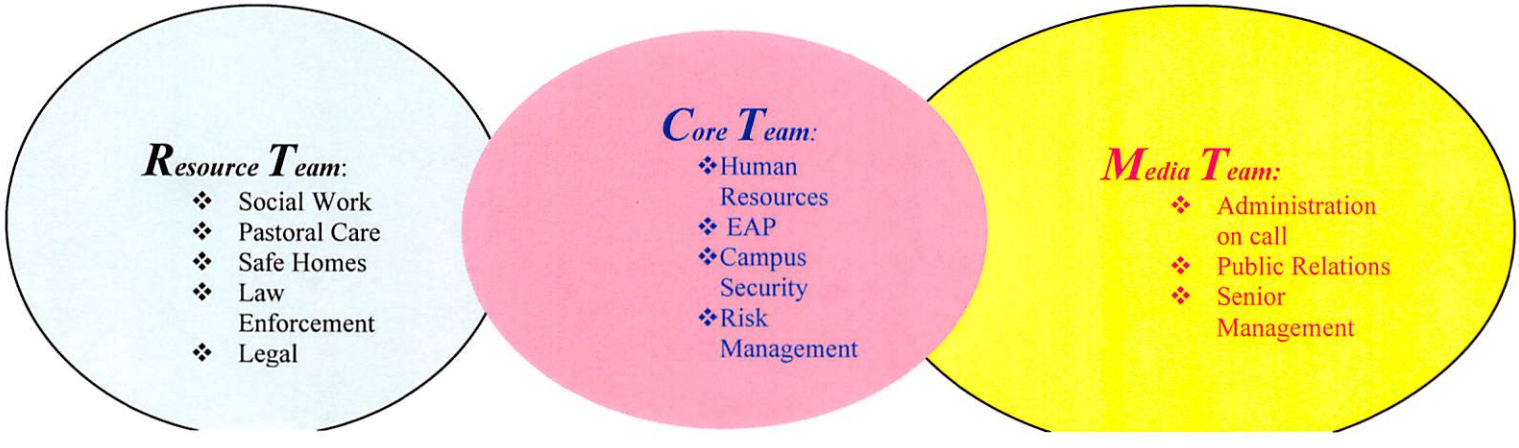
i. Debriefing/Defusing/Critique of process.

2. Directors, Managers and Supervisors are responsible for handling threats or acts of violence within their department. Threats, implied or direct, shall be assessed to determine if violence is possible and what steps should be taken to handle the situation. All steps taken, and relative information, shall be documented in accordance with Archbold Medical Center Occurrence Reporting Process. Once this report is completed, a copy will be forwarded to the Director of Risk Management, Security Manager and other appropriate personnel.

3. Employees are responsible for helping to maintain a safe workplace by neither tolerating nor making threats, implied or direct, nor behaving in an inappropriate manner. Employees must immediately report all violence, threats (perceived or otherwise) to your first line supervisor or to a core CET member. No employee will be disciplined or discharged for reporting any threats or acts of violence. However, employees should recognize that false accusations can have serious effects on an innocent employee. The making of accusations which are known by the accusing person to be false is a form of misconduct and will result in disciplinary action up to and including termination.

V. JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A BROOKS COUNTY HOSPITAL, GRADY GENERAL HOSPITAL, MITCHELL COUNTY HOSPITAL, GLENN-MOR NURSING HOME, MITCHELL CONVALESCENT CENTER, PELHAM PARKWAY NURSING HOME)/ARCHBOLD FOUNDATION, INC./ARCHBOLD HEALTH SERVICES, INC./ARCHBOLD MEDICAL ENTERPRISES, INC./ARCHBOLD MEDICAL GROUP, INC.

A. As applicable.



Please sign and date the statement below and return it to the Medical Staff Office.

I have received and take responsibility for the APP Education Packet related to the topics listed below. I am aware that I may contact the Medical Staff Office or the Chief of Staff for any further information or assistance.

Name	Signature	Date

TOPICS ADDRESSED:

1. Patient's Rights and Responsibilities: Administrative Policy 101.05
2. Use of Communication Devices for Patients with Communication Barriers: Nursing Policy 120.03
3. Potential Disruptive Behavior Reports: Medical Staff Policy 13
4. Behaviors that Undermine/Impact a Culture of Safety: Administrative Policy 110.62
5. Workplace Violence Prevention Plan: Administrative Policy 104.11
6. Medical Record/Chart Communication: Medical Staff Rules & Regulations Section II
7. Informed Consent: Administrative Policy 101.18
8. Restraint and Seclusion: Administrative Policy 101.21
9. Suicide Screening and Precautions: Administrative Policy 101.55
10. Provider's Role in Preventing and Controlling Infections
11. Antimicrobial Stewardship: Pharmacy Policy 210
12. Pain Management: Administrative Policy 101.20
13. Opioid Overdose Prevention Toolkit & Checklist for Prescribing Opioids for Chronic Pain
14. Disclosing Unanticipated Adverse Events to Patients and Families: Administrative Policy 101.27
15. Physician Notification of Change in Patient Status: Nursing Policy 59.0
16. Critical Assessment Team (CAT): Nursing Policy 139.0
17. Falls Precaution Program: Administrative Policy 101.38
18. Emergency Response Roles: Medical Staff Rules and Regulations Section XII
19. Fire Response: Emergency Operations Plan
20. Emergency Codes: Administrative Policy 110.61
21. Corporate Compliance:
    - A Prescriber's Guide to Medicare Prescription Drug (Part D) Opioid Policies
    - Medicare Fraud & Abuse: Prevent, Detect, Report
    - Avoiding Medicaid & Medicare Fraud & Abuse
    - Strategy to Fight the Opioid Crisis
    - OIG: Special Fraud Alert: Speaker Programs
    - OIG: Special Fraud Alert: Entering into Arrangements with Purported Telemedicine Companies
    - OIG: Fraud Alert: Physician Compensation Arrangements may result in Significant Liability

Additional Information

- The Joint Commission Public Notice www.archbold.org
- Physician's Portal – Communication Tool
- Archbold Intranet:
    - Policies & Procedures
    - Regulatory guidance included from Joint Commission, GHA, and CMS

Policies address: Patient Rights; Advance Directives; Education of Patient's Families; Ethical Issues; Handoff Communication Tool; Time Out and Procedure Site Verification; Risk Management; Use of Abbreviations in Medical Records and more.

II. MEDICAL RECORD/CHART COMMUNICATION:

A. All orders will be entered electronically except in an emergency situation or if the electronic system is unavailable. Verbal orders should be used infrequently and limited to situations in which it is impossible or impractical for the prescriber to enter the order electronically. When telephone or verbal orders are reasonably necessary, they shall be dictated directly to qualified Hospital personnel with verification read back by the person receiving the order. The responsible Practitioner will authenticate the order by signature within fourteen (14) days.

Dependent nutrition related orders are placed by a RDN upon receiving a directive by the physician. Dependent orders may include but are not limited to verbal orders, telephone orders, organization approved protocols and standing order sets. The responsible Practitioner will authenticate the order by signature within fourteen (14) days.

B. Pre-printed paper orders are not acceptable. Order sets are a validated tool and are encouraged. They should be evidence based and must be approved by the relevant department(s), the Physician Advisory Committee, and the MEC.

C. All documentation into the medical record must be entered electronically or via dictation that is then entered electronically. This includes history and physicals, progress notes, procedure notes, assessments, and discharge summary. All entries must be timed. The MEC has the authority to define acceptable electronic formats for different categories of documentation.

D. The responsible Practitioner must authenticate behavioral restraint orders within one (1) hour and other restraint orders daily.

E. All medical records are the property of the Hospital and may only be removed from the Hospital in accordance with a valid court order, subpoena or as otherwise legally required by applicable Federal and Georgia laws and regulations.

F. Medical Record Contents

a. The MEC and hospital govern which individuals are allowed to enter information into the medical record. Any professional that is employed, credentialed, or contracted by the organization to perform duties related to patient care is allowed to enter information into the medical record.

b. The history and physical should contain, at a minimum, the following information.

- Chief complaint

- History of the present illness
- Past medical history
- Current medications
- Allergies
- Physical exam
- Assessment and plan of care

c. The discharge summary should, at a minimum, the following information.
    - Admission date
    - Discharge date
    - Admitting diagnosis
    - Discharge diagnosis/diagnoses
    - Procedures done
    - Hospital course
    - Discharge medications
    - Discharge instructions and follow up

d. The written operative note should, at a minimum, include the following information.
    - Primary surgeon
    - Assistants
    - Pre-operative diagnosis
    - Post-operative diagnosis
    - Findings
    - Procedures performed
    - Specimens
    - Estimated blood loss

e. Daily progress notes should contain adequate information to communicate the patient's current status and the physician's assessment and plan of care.

f. Only approved abbreviations may be used in the medical record.

g. The medical record is integral to the patient's care. Proper use of the medical record, including the electronic health record, will be reviewed as part of a practitioner's quality of care.

G. Completion of Medical Records - Procedure

a. Medical Staff Bylaws require that summaries are completed within 48 hours after discharge.
b. Delinquent medical records are available to physicians online at all times within the Electronic Medical Record.
c. Reminder letters are printed weekly (every Tuesday) and are sent to the physician.

d. Vacation: If a physician plans to be on vacation more than three days and wants an exemption from the medical record completion procedure, he/she must notify

the Medical Staff Office in writing stating the date he/she shall leave and return. The physician shall complete all the records in his/her queue before leaving town.

e. It is the preference of the Medical Executive Committee that every physician on the medical staff shall complete all the records in their queue weekly.

H. Completion of Medical Records – Delinquency Process

a. Any one of the following delinquencies will trigger the loss of hospital privileges from the time of notification, until twenty-four (24) hours after verification that the charts have been completed.
    - More than ten (10) records requiring a signature that exceed the (14) day timeframe for completion.
    - More than five (5) history and physicals exceeding the 24-hour timeframe.
    - More than five (5) operative notes that are not initiated immediately post- op or not completed within 24 hours post-op.
    - More than five (5) delinquent discharge summaries exceeding the forty-eight (48) hour timeframe.

b. If a physician is delinquent the Medical Records Department will inform the physician in writing and/or in person.

c. The Chief of Staff has the discretion to defer suspension if it should produce a hardship on an innocent party for emergency coverage.

d. If a physician fails to comply with the delinquency process the Chief Medical Officer will be notified and will communicate with the Chief of Staff**.** They will assist in notifying the physician and the admitting office that no patient including observation status will be admitted to the service of the staff member or seen in consultation, and no patient will be scheduled for short stay surgery except for unassigned patients received through the emergency room.

e. When a physician has lost hospital privileges because of delinquent medical records he/she will be required to accept patients assigned by the emergency room physician in the usual rotating order. If he/she has a private patient who requires admission then it is that physician's responsibility to find another physician to admit the patient. Except for the above, no patient should be admitted or transferred to the care of a physician who does not have admitting privileges.

f. Twenty-four hours <u>after</u> verification of completion a memo of restoration of privileges is generated by the Medical Records Department and signed by the Chief of Staff or Chief Medical Officer. It is then distributed to the parties referenced in section (b) above.

g. The delinquent medical record count will revert to zero if a physician completes delinquencies prior to suspension. Once a physician receives a suspension for delinquent medical records, any single medical record delinquency shall result in loss of admitting privileges, until twenty-four (24) hours after verification that

the deficiency has been completed. The delinquency count will revert to zero at the beginning of the calendar year.

h. The only acceptable reason for not completing records in this time period shall be:
    - Delays in the Medical Records Department. Such delays must be documented in writing to the Chief of Staff.
    - Sickness or vacation. An extension equal to the time of vacation or sickness may be allowed by the Chief of Staff upon written request from the physician requesting the extension.
    - An emergency situation. An extension may be allowed by the Chief of Staff upon written request from the physician requesting the extension.
    - If an extension is allowed the Chief Staff shall notify the Medical Records Department giving the specific limits of the extension in writing.

i. For repeated violations the physician will be referred to the Medical Executive Committee.

j. In addition to suspension, the following will be in effect for patient medical records delinquency:

    Standard reappointment cycles are for a two-year period. In a two-year reappointment cycle, for a physician to fail to complete any (1) of the below:
    - 10 admission history and physical reports in the 24-hour time frame
    - 10 operative notes not completed within 24 hours post-op
    - 10 medical records not completed within the 14-day time frame to include completed discharge summaries, death summaries and required signatures,

    the medical staff shall fine the physician $500 dollars to be paid at time of reappointment.

    If in the consecutive 2-year time, the physician should again have failed to complete any (1) of the below:
    - 10 admission history and physical reports in the 24-hour time frame
    - 10 operative notes not completed within 24 hours post-op
    - 10 medical records not completed within the 14-day time frame to include completed discharge summaries, death summaries, and required signatures,

    the medical staff shall fine the physician $1000 dollars to be paid at time of reappointment.

    Mid-levels will be expected to complete charting in a time period which will allow the physician time to complete the charts within the 14-day time frame.

The other rules and remedies are still in effect and can be used should a physician continue to fail to complete their records in a timely manner these include loss of privileges and/or appearance in front of the Medical executive committee

ARCHBOLD MEDICAL CENTER
ADMINISTRATIVE POLICY MANUAL

POLICY NUMBER: 101.18

EFFECTIVE: November 1991

SUBJECT: Informed Consent

EXPIRES: When Superseded

APPROVED: _____
President

REVIEWED: March 2022

REVISED: March 2022

I. POLICY

A. It is the policy of Archbold Medical Center, Inc. that the Responsible Physician or approved designee (as defined below in sections IV and V) shall obtain the patient's informed consent as required by O.C.G.A. § 31-9-6., Conditions of Participation, Joint Commission Standards, and this Policy. Informed consent will be obtained from any patient who undergoes any surgical procedure under general anesthesia, spinal anesthesia, or major regional anesthesia, invasive procedure or any treatment with more than minimal risk, amniocentesis diagnostic procedure, or a diagnostic procedure which involves the intravenous or intraductal injection of a contrast material. Such person shall be informed in general terms of the following:

1. A diagnosis of the patient's condition requiring such proposed surgical or diagnostic procedure;

2. The nature, purpose, and potential benefits of such proposed surgical or diagnostic procedure;

3. The material risks and side effects generally recognized and accepted by reasonably prudent physicians of infection, allergic reaction, severe loss of blood, loss or loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death involved in such proposed surgical or diagnostic procedure, including any potential problems that might occur during recuperation, which, if disclosed to a reasonably prudent person in the patient's position, could reasonably be expected to cause such prudent person to decline such proposed surgical or diagnostic procedure on the basis of the material risk of injury that could result from such proposed surgical or diagnostic procedure;

4. The likelihood of success of such proposed surgical or diagnostic procedure;

5. The practical alternatives, including benefits, risks, and side effects, to such proposed surgical or diagnostic procedure which are generally recognized and accepted by reasonably prudent physicians; and

6. The prognosis of the patient's condition if such proposed surgical or diagnostic procedure is rejected.

B. Adult patients (aged 18+) who have the ability to consent for themselves (i.e., the adult

patient has sufficient understanding or capacity to make significant responsible decisions) shall be allowed to consent or to refusal medical treatment if they choose, in accordance with this Policy or the law.

II. PURPOSE

A. To provide guidelines for healthcare providers who are involved in the care of the patient regarding the informed consent process and Federal and State law and Joint Commission Standards.

B. To clarify roles of the physician, mid-level providers, and Medical Center staff as they relate to obtaining informed consent from the patient/ legal representative.

III. DEFINITIONS

Responsible Physician: The physician who performs the treatment or procedure or the physician under whose direct orders the treatment or procedure is performed by a non-physician.

IV. RESPONSIBLE PHYSICIAN'S ROLE

A. Prior to the administration of anesthesia and prior to conducting any surgical procedure under general anesthesia, spinal anesthesia, or major regional anesthesia, an invasive procedure or any treatment with more than minimal risk, an amniocentesis diagnostic procedure, or a diagnostic procedure which involves the intravenous or intraductal injection of a contrast material, the Responsible Physician or their designee, should obtain the patient's Informed Consent in writing from the patient or, if patient is unable to consent, from patient's legal representative as required by this policy and state law.

B. Informed consent must be obtained on preapproved Archbold form MS-108, "Informed Consent and Request for Surgically Invasive Procedure, or Diagnostic Procedure, or Treatment", which can also be accessed electronically via a web-based program available to all credentialed medical staff and clinical staff.

C. Informed consent should be signed by a person legally authorized to consent on behalf of a patient. See Section VII – Who May Consent - for a listing of such persons.

D. In order for the consent to be presumed to be valid, the consent must be in writing (signed and dated by the consenting party) and the patient and/or legal representative must be informed by the Responsible Physician or their designee in general terms of the following -

1. A diagnosis of the patient's condition requiring such proposed surgical or diagnostic procedure;

2. The nature, purpose and potential benefits of such proposed surgical or diagnostic procedure;

3. The material risks and side effects generally recognized and accepted by reasonably prudent physicians of infection, allergic reaction, severe loss of

blood, loss or loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death involved in such proposed surgical or diagnostic procedure which, if disclosed to a reasonably prudent person in the patient's position, could reasonably be expected to cause such prudent person to decline such proposed surgical or diagnostic procedure on the basis of the material risk of injury that could result from such proposed surgical or diagnostic procedure;

4. The likelihood of success of such proposed surgical or diagnostic procedure;

5. The practical alternatives, including benefits, risks, and side effects, to such proposed surgical or diagnostic procedure which are generally recognized and accepted by reasonably prudent physicians - including any potential problems that might occur during recuperation.; and

6. The prognosis of the patient's condition if such proposed surgical or diagnostic procedure is rejected.

E. Abbreviations should be avoided.

F. In situations where informed consent to a surgical or diagnostic procedure is required, it shall be the responsibility of the Responsible Physician to ensure that the information required is disclosed and that the consent is obtained. The information provided may be disclosed through the use of video tapes, audio tapes, pamphlets, booklets, or other means of communication or through conversations with nurses, physician assistants, trained counselors, patient educators, or other similar persons known by the Responsible Physician to be knowledgeable and capable of communicating such information. Information provided should be tailored to patient's age, language and ability to understand.

V. MEDICAL CENTER'S ROLE

A. The Medical Center provides a designated, web-based application tool for providers to document required elements of informed consent from patients. Archbold Form MS-108, "Informed Consent and Request for Surgically Invasive Procedure, or Diagnostic Procedure, or Treatment" is also available for use during down-time procedures.

B. The Medical Center may provide language translation and interpretation services and may provide information to assist vision, speech, hearing and cognitively impaired patients to assist Responsible Physician or their designee in informing the patient.

C. A Medical Center staff member or family member who is not consenting on behalf of the patient may witness the patient's or consenting party's signature.

D. Staff may answer patient questions concerning the proposed treatment or procedure with the Responsible Physician being contacted if the patient has questions about the nature of the treatment or procedure, or its benefits or risks indicating the patient may not have sufficient information about the procedure.

E. Radiologic technologists/radiology nurses who have received specific education on informed consent from staff radiologists (who would otherwise be Responsible Physicians) may obtain informed consent for procedures involving the use of IV contrast material or radioisotopes.

VI. DURATION OF INFORMED CONSENT

A. Informed consent may be considered valid for a maximum of 30 days from when the patient or authorized person signs the consent unless circumstances change so as to materially affect the nature of, the risks or benefits of, and/or the alternatives to the procedure which the patient consented.

B. Informed consent is obtained prior to administration of pre-operative medication and before each applicable procedure. However, patients receiving certain therapeutic treatments involving a course of multiple treatments may consent to an entire course of routine therapy prior to the first treatment, and a single consent form may be signed for the entire course of treatment (not to exceed one year) if:

a. The entire course of treatment is disclosed, consented to, and documented in accordance with this policy; and

b. No material change occurs in the risks, benefits, and/or alternatives to the treatment

Examples of these exceptions would be chemotherapy and radiation.

VII. WHO MAY CONSENT[1]

In addition to such other persons as may be authorized and empowered, any one of the following persons is authorized to consent, either orally or otherwise, to any surgical or medical treatment or procedures not prohibited by law which may be suggested, recommended, prescribed, or directed by a duly licensed physician:

A. Any adult, for himself or herself, whether by living will, advance directive for health care, or otherwise;

1. Any person authorized to give such consent for the adult under an advance directive for health care or durable power of attorney for health care;

B. In the absence or unavailability of a person authorized pursuant to paragraph (A) (1), any married person for his or her spouse;

C. In the absence or unavailability of a living spouse, any parent, whether an adult or a minor, for his or her minor child;

D. Any person temporarily standing in loco parentis, whether formally serving or not, for the minor under his or her care; and any guardian, for his or her ward;

E. Any female, regardless of age or marital status, for herself when given in connection with pregnancy, or the prevention thereof, or childbirth;

F. Upon the inability of any adult to consent for himself or herself[1] and in the absence of any person to consent under paragraphs (A) (1) through (E) above, the following persons in the following order of priority:

1. Any adult child for his or her parents;

2. Any parent for his or her adult child;

3. Any adult for his or her brother or sister;

4. Any grandparent for his or her grandchild;

5. Any adult grandchild for his or her grandparent; or

6. Any adult niece, nephew, aunt, or uncle of the patient who is related to the patient in the first degree; or

G. Upon the inability of any adult to consent for himself or herself[2] and in the absence of any person to consent under paragraphs (A) through (F) above, an adult friend of the patient.

For purposes of this paragraph, "adult friend" means an adult who has exhibited special care and concern for the patient, who is generally familiar with the patient's health care views and desires, and who is willing and able to become involved in the patient's health care decisions and to act in the patient's best interest. The adult friend shall sign and date an acknowledgment form provided by the hospital or other health care facility in which the patient is located for placement in the patient's records certifying that he or she meets such criteria.

H. In the absence, after reasonable inquiry, of any person authorized above to consent for the patient, a Medical Center or other health care facility or any interested person may initiate proceedings for expedited judicial intervention to appoint a temporary medical consent guardian pursuant to O.C.G.A. §29-4-18. Contact Risk Management and/or Patient Advocate to initiate guardianship process. Note: In an <u>emergent</u> situation where the patient is unable to consent for themselves, no other individual is available to consent on behalf of the patient, and judicial proceedings for guardianship may involve a harmful delay to the patient’s health or condition, the treating physician, in consultation with another physician, both exercising professional judgment on behalf of the patient, may authorize treatment. See Nursing Policy #35, “Consent for Admission, Treatment, Procedure, and Transfer.”

[1] For purposes of this section, the term "inability of any adult to consent for himself or herself" means there is a determination in the medical record by a licensed physician after the physician has personally examined the adult that the adult "lacks sufficient understanding or capacity to make significant responsible decisions" regarding his or her medical treatment or the ability to communicate by any means such decisions.

[2] For purposes of this section, the term "inability of any adult to consent for himself or herself" means there is a determination in the medical record by a licensed physician after the physician has personally examined the adult that the adult "lacks sufficient understanding or capacity to make significant responsible decisions" regarding his or her medical treatment or the ability to communicate by any means such decisions.

VIII. EXCEPTIONS TO INFORMED CONSENT REQUIREMENT

A. Informed consent shall be obtained prior to any surgical procedure under general anesthesia, spinal anesthesia, or major regional anesthesia, any invasive procedure with more than minimal risk, any amniocentesis diagnostic procedure, or any diagnostic procedure which involves the intravenous or intraductal injection of a contrast material, except when the facts and circumstances clearly justify the following emergency situations:

1. According to competent medical judgment, the proposed surgical or medical treatment or procedures are reasonably necessary and a person authorized to consent (under O.C.G.A. §31-9-2 as noted above in this Policy) is not readily available and any delay in treatment could reasonably be expected to jeopardize the life and health of the person affected or could reasonably result in disfigurement or impaired faculties.

2. In addition to any instances in which consent is excused or implied by the Law, a consent to surgical or medical treatment or procedures suggested, recommended, prescribed or directed by a duly licensed physician will be implied where an emergency exist.

B. This Policy shall not apply to involuntary treatment for mental illness and/or involuntary treatment for alcohol or substance abuse. For this condition, the Responsible Physician or licensed practitioner authorized by state law will complete the State of Georgia's Certificate Authorizing Transport to Emergency Receiving Facility and Report of Transportation (Addictive Diseases), as applicable.

IX. REFUSAL TO CONSENT

Adult patients (age 18+) have the right to refuse to consent to medical treatment. Such patients should be apprised of the risk of refusal to consent and should be asked to sign Form MR 155, "Release from Responsibility of Discharge."

X. JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A BROOKS COUNTY HOSPITAL, GRADY GENERAL HOSPITAL, MITCHELL COUNTY HOSPITAL, GLENN-MOR NURSING HOME, MITCHELL CONVALESCENT CENTER, PELHAM PARKWAY NURSING HOME)/ ARCHBOLD MEDICAL GROUP, INC.

A. As applicable.

XI. ARCHBOLD FOUNDATION, INC./ ARCHBOLD HEALTH SERVICES, INC./ ARCHBOLD MEDICAL ENTERPRISES, INC./

Not applicable.

Regulatory citations: O.C.G.A.§ 31-9-1 et seq.
42 C.F.R. §§ 482.24 and 482.13
Joint Commission: RI.01.03.01 standards (Rights and Responsibilities of the Individual)

ARCHBOLD
ADMINISTRATIVE POLICY MANUAL

POLICY NUMBER: 101.21

EFFECTIVE: February 2001

SUBJECT: Restraint and Seclusion

EXPIRES: When Superseded

APPROVED: _____
President

REVIEWED: July 2023

REVISED: July 2023

I. POLICY

A. Physical restraint is considered only as a temporary means of management when the patient is in immediate danger of harming self or others. The patient's right to be free from restraint is paramount. Restraints **may not** be used for purposes of staff convenience or patient discipline, punishment, coercion or retaliation.

B. In the event that a physical restraint is deemed necessary after careful assessment, it should be utilized in accordance with modifications to the patient's plan of care and only after alternative measures are found ineffective.

C. Restraints may be initiated and terminated by registered nurses (RN), physicians, or other licensed practitioners (LP) who receive training at orientation, before participating in the use of restraint and on a periodic basis thereafter to perform these interventions. Each initiation of a restraint requires an order from the physician or LP that has working knowledge of the hospital's restraint policy. Implementation of restraint is done using safe techniques, identified within this policy. Others including but not limited to, LPNs, security personnel, social workers or unlicensed staff may, after receiving instruction and demonstrating competence, apply and remove restraints in collaboration with a registered nurse and/or LP.

D. In instances of restraint use, ongoing evaluation of the patient's need for restraint must be conducted and restraint use ended at the earliest possible time.

II. PURPOSE

The decision to use restraint is driven not by diagnosis, but by individual assessment that concludes, for this patient, at this time, the use of alternative measures poses a greater risk than the risk of using a restraint for patient safety and/or safety of others. We believe that the patient has the right to be free from any form of restraint. However, if restraint is necessary, the intervention is applied in such a manner to protect the patient's safety, rights, dignity, and well-being. The purpose of this policy is to describe when and how a restraint device may be initiated to manage patient safety when less restrictive alternative means are insufficient to provide effective treatment/care.

III. DEFINITIONS

A. Restraint: Any method (physical or chemical) of restricting a patient's freedom of movement (including seclusion), physical activity or normal access to his or her body that:

1. is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient, or his or her legal representative, has consented;

2. is not indicated to treat the patient's medical condition or symptoms; or

3. does not promote the patient's independent functioning.

B. Physical Restraint: **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.

Generally, if a patient can easily remove a device, the device would not be considered a restraint. The following would **NOT** be considered a restraint:

1. Use of an IV arm board to stabilize an IV line.

2. A mechanical support used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support.

3. A medically necessary positioning or securing device used to maintain the position, limit mobility, or temporarily immobilize the patient during medical, dental, diagnostic, or surgical procedures.

4. A "light" grasp to escort the patient to a desired location.

5. Picking up, redirecting, or holding an infant, toddler, or preschool-aged child to comfort the patient.

6. Recovery from anesthesia that occurs when the patient is in a critical care or post-anesthesia care unit.

- **However,** a restraint order would be necessary if the intervention is maintained when the patient is transferred to another unit, or recovers from the effects of the anesthesia (whichever occurs first).

7. Holding a patient for the purpose of conducting routine physical examinations or tests.

   - **However,** holding a patient in a manner that restricts the patient's movement against the patient's will is considered restraint.

8. Protecting the patient from falling out of bed i.e. seizure precautions or a bed that constantly moves for medical reason.

   - **However,** the use of side rails to restrict the patient's freedom to exit the bed would be considered a restraint i.e. 4 side rails

9. Law Enforcement Devices such as handcuffs or other restrictive devices applied by non-hospital employed or contracted law enforcement officials for custody, detention, and public safety are not governed by this policy. Please refer to Administrative Policy 101.81 – Use of Restraint Devices by Law Enforcement Personnel or Correctional Officers within Hospital Setting.

C. Chemical Restraint: A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

D. Seclusion: The involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

E. Non-Violent or Non-Self-Destructive Restraint Use: Restraint used to manage behaviors which interfere with medical/surgical healing. For example, the patient may be pulling out lines or tubes and less restrictive methods or alternative measures have not worked.

F. Violent or Self-Destructive Restraint Use: Restraint used to manage behaviors which are unanticipated, severely aggressive or destructive; places the patient and/or others in imminent risk of harm; and non-physical intervention has not been effective.

G. Licensed Provider (LP): Any individual that is permitted by both State law and hospital policy to care for patients independently, within the scope of their licensure, and consistent with granted privileges to order restraints.

H. Episode: A restraint episode is initiated when a patient is placed in restraints and ends when a patient is removed from restraints. When a restraint is discontinued for any period of time, this is considered the end of an episode and a new order is required to

reapply. The exception is when the restraint is removed to provide care. i.e., removed for bathing or during a procedure.

IV. ALTERNATIVES TO RESTRAINT OR SECLUSION

A. Unless safety requires an immediate response, restraint or seclusion are used only after other alternative less restrictive methods have proven ineffective. All attempted alternatives must be documented with the patient's response, as well as the behaviors and actions leading to the use of restraint or seclusion. Some Alternatives may include, but not limited to:

1. Verbal intervention.
2. Increased observation or direct continuous observation (l:l care).
3. Reorientation.
4. Participation of family in care process.
5. Decrease sensory stimulation, i.e.: excessive noise, light, etc.
6. Utilization of protective devices (i.e.: bed alarm, gap protectors, chair alarms).
7. Positioning changes/comfort changes.
8. Placements of call light and personal items within the patient's reach.
9. Relaxation aids.
10. Pharmacological review or treatment interventions as ordered by the physician.
11. Diversional activities, such as TV or music.
12. Lap belts that can be released by the patient.
13. Placement of bed in a low position.
14. Place patient close to nursing station.

V. ASSESSMENT/EVALUATION

A. An assessment will be performed by the provider or trained nurse to determine current physical and psychological risk factors as well as special need. Also, to determine that all alternative interventions have been considered or have failed and assess the risks and benefits of restraint use.

B. The assessment will determine clinical justification and will be completed upon initiation of restraint or seclusion and documented in the medical record prior to initiation or shortly thereafter in an emergency situation.

C. Non-Violent/Non-Self-Destructive:

1. Clinical justification criteria:

a. Allow medical treatments to continue without interruption.

b. Prevent pulling out of necessary tubes or drains.

c. Provide safety when the patient is unable to follow direction.

2. Initial Assessment/Evaluation will include:

a. Clinical Justification – behavior requiring restraints.

b. Contributing factors.

c. Less restrictive intervention tried or determined insufficient.

d. Type of restraint.

e. Response to restraint.

f. Restraint applied safely/properly.

g. Patient/family education.

D. Violent/Self-Destructive:

1. Clinical justification criteria:

a. Prevent imminent danger to self or others.

b. To administer stat IM psychotropic medication due to active dangerous behavior to self or others.

c. Chemically restrain a patient.

2. Initial Assessment/Evaluation will include:

a. Clinical justification – behavior requiring restraints.

b. Contributing factors.

c. Less restrictive intervention tried or determined insufficient.

d. Type of restraint.

e. Response to restraint.

f. Restraint applied safely/properly.

g. Patient/family education.

h. A face-to-face evaluation that includes a physical and behavioral assessment must be performed by the physician, LP or specially trained RN, within 1 hour of initiation of behavioral restraint or seclusion.

i. The 1-hour face-to-face evaluation will include:

- Physical and behavioral assessment.
- Reaction to intervention
- Medical and behavioral condition
- The need to continue or terminate restraint or seclusion

ii. If the patient is removed from restraint prior to the evaluation, the 1-hour face-to-face assessment must still be performed.

E. Patient Education

Whenever possible/appropriate, the patient and/or family are included in the decision-making process and will be educated on the rationale for restraints, alternatives attempted, and criteria for removal. Education should be documented.

F. Plan of Care

The use of restraints or seclusion necessitates a written modification of the patient's plan of care upon initiation and revised as needed.

VI. PROVIDER ORDER

A. Non-Violent/Non-Self-Destructive:

1. The provider responsible for the patient's ongoing care must order the use of restraint prior to the application. However, a qualified nurse may apply a restraint in response to an unanticipated event prior to obtaining the order. The provider must be notified and an order obtained as soon as possible (within 1 hour).

2. If the attending physician did not order the restraint, he or she must be contacted as soon as possible (within 1 hour).

3. Orders for the use of restraint to protect the physical safety of the non-violent or non-self-destructive patients must be renewed daily until the restraint is discontinued.

B. Violent/Self-Destructive:

1. The provider responsible for the patient's ongoing care must order the use of restraint or seclusion prior to the application. However, a qualified nurse may apply a restraint in response to an unanticipated event prior to obtaining the order. The provider must be notified and an order obtained immediately (or within a few minutes) following initiation of restraint.

2. If the attending physician did not order the restraint, he or she must be contacted as soon as possible (within 1 hour) of the completion of the face-to-face assessment.

C. PRN orders are NOT allowed. A "trial release" constitutes a PRN use of restraint or seclusion, and, therefore, is not permitted.

- **However**, a temporary, directly-supervised release that occurs for the purpose of caring for a patient's needs (e.g., toileting, feeding, or range of motion exercises) is **not** considered a discontinuation of the restraint or seclusion intervention.

D. If restraint or seclusion is discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating the use of restraint or seclusion.

E. The order for restraint will include:

1. Type of Restraint.

2. Reason for Restraint or Seclusion (clinical justification).

3. Duration of Restraint.

4. Criteria for release

VII. APPLICATION OF RESTRAINT

A. Apply the restraint in a manner that respects the patient's rights, confidentiality, dignity, and privacy. Only trained staff may apply restraints as per manufacturer's guidelines.

1. Assist the patient to a permissible position of comfort and attempt to gain the patient's cooperation.

2. Offer support and reassurance. Communicate and assure the patient that he/she is not alone.

3. Explain the procedure and the necessity for the procedure to the patient, and family or significant other, as well as the behavioral criteria for release, as appropriate.

4. Remove shoes and loosen or remove clothing as necessary. Check pockets for any contraband, as appropriate.

5. Restrain the patient in supine position unless medically contraindicated. For patients in a bed, assure head of bed is elevated to at least 30 degrees.

6. Restraints should be secured to the bedframe, not side rails or any portion of bed that can be adjusted.

7. Seclusion will only be allowed in a designated 'Safe Room' that is continuously monitored.

8. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored face-to-face by a trained staff member;

or

by trained staff using both video and audio equipment and in close proximity to the patient.

VIII. MONITORING

A. Qualified staff will monitor/evaluate the patient on the following, as needed. Each item is not required to be evaluated with each assessment and depends on the patient's condition and circumstances surrounding the patient's care. (ie. if patient is NPO, the patient should not be offered fluids).

B. The nurse may delegate monitoring activities to personnel that have been trained and it is within their scope of practice.

C. All monitoring criteria will be documented in the medical record.

D. Non-Violent/Non-Self-Destructive:

1. Every 2 hours or more frequently, if necessary:

   a. Circulation, skin integrity.

   b. Assess for release.

   c. Restraints applied correctly.

   d. Range of motion/release while awake.

   e. Hydration while awake.

   f. Elimination while awake.

   g. Nutritional needs while awake.

   h. Vital signs – every 4 hour or per physician order.

2. Hygiene needs as needed.

E. Violent/Self-Destructive:

1. Every 30 minutes or more frequently, if necessary:

- Safety Check
- Circulation/skin
- Restraints applied correctly
- Assess for release

2. Every 2 hours or more frequently if necessary:

- Nutrition/hydration
- Elimination
- ROM
- Vital signs

3. Hygiene needs as needed.

IX. REASSESSMENT/REEVALUATION

A. Non-Violent/Non-Self-Destructive:

1. Continued use of restraint requires a qualified RN to examine the patient and determine if the restraint continues to be clinically justified at least once a shift.

2. Reassessment will include:

a. Clinical justification – behavior requiring restraints.

b. Contributing factors.

c. Less restrictive intervention tried or determined insufficient.

d. Type of restraint.

e. Response to restraint.

B. Violent/Self-Destructive:

1. Qualified RN reassesses at least every:

a. 4 hours for ages >18

b. 2 hours for ages 9-17

c. 1 hour for ages <9

2. Reassessment will include:

a. Clinical justification – behavior requiring restraints.

b. Contributing factors.

c. Less restrictive intervention tried or determined insufficient.

d. Type of restraint.

e. Response to restraint.

3. The RN must notify the provider, report the results of the most recent assessment and request the original order be renewed. Whether or not the provider needs to personally assess the patient will be at the discretion of the provider.

4. A physician, or LP, who is primarily responsible for the ongoing care sees and evaluates the patient every 24 hours before writing a new order.

X. RESTRAINT REMOVAL

A. When the physician, LP, or RN determines the patient meets criteria, the restraint/seclusion must be discontinued at the earliest time possible regardless of the length of time identified in the order.

B. Time of removal and behavior that supports removal should be documented in the medical record.

XI. DOCUMENTATION

A. Each episode of restraint or seclusion should contain at least the following documentation in the patient's medical record:

1. All in-person medical and behavioral evaluations of the patient.

2. The patient's condition/symptom(s) that warranted the use of restraint or seclusion.

3. Any alternatives/less restrictive interventions attempted.

4. Intervention used and patient's response.

5. Individual patient assessments and reassessments.

6. Intervals for monitoring.

7. Orders for restraint or seclusion, including device or method used.

8. Revisions to the plan of care.

9. The 1 hour face-to-face evaluation (for violent/self-destructive).

10. Each in-person evaluation of and re-evaluation of the patient.

11. Notification of the attending provider of the initiation of restraint or seclusion.

12. Consultations.

13. Any injuries to patient or death associated with the use of restraint or seclusion.

XII. EDUCATION AND COMPETENCY

A. Archbold Medical Center educates and assesses the competence of staff in minimizing the use of restraint, and before they participate in any use of restraint, in their safe use. This is done during orientation and reviewed annually.

B. Providers authorized to order restraint or seclusion must have a working knowledge of this policy regarding the use of restraint or seclusion.

C. Training should be targeted to the specific needs of the patient populations being served, and to the competency level of staff.

D. As appropriate to scope of practice and job function, staff whom perform assessments, monitor patients, and/or provide care to patients in restraint or seclusion must be trained in the following:

1. Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

2. The use of nonphysical intervention skills.

3. Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, ~~or~~ behavioral status or condition.

4. The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical

and psychological distress (for example, positional asphyxia).

5. Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

6. Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, and vital signs.

7. The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

E. Individuals providing staff training are qualified by education, training, and experience in techniques used to address patients' behaviors. Successful completion of training and demonstration of competency is documented in staff personnel records.

XIII. REPORTING REQUIREMENTS

A. For compliance with CMS mandatory reporting refer to Administrative policy 101.33-Required Reporting of the Georgia Department of Community Health for Certain Patient Incidents.

XIV. PERFORMANCE IMPROVEMENT

A. Through the Quality Assurance Performance Improvement (QAPI) program, the organization will ensure system and processes are in place that support the patients' rights addressed in this policy and that eliminate the inappropriate use of restraint or seclusion. The organization will:

1. Assess and monitor the use of restraint or seclusion.

2. Implement actions to ensure that restraint or seclusion is used only to ensure the physical safety of the patient, staff and others.

3. Comply with the requirements set forth in this standard as well as State law and this policy when the use of restraint or seclusion is necessary.

XV. JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A ARCHBOLD MEMORIAL, ARCHBOLD BROOKS, ARCHBOLD GRADY, ARCHBOLD MITCHELL, ARCHBOLD LIVING THOMASVILLE, ARCHBOLD LIVING CAMILLA, ARCHBOLD LIVING PELHAM, ARCHBOLD LIVING CAIRO); ARCHBOLD FOUNDATION, INC.; AND ARCHBOLD MEDICAL GROUP, INC.

A. As applicable

Appendix A

Non-Violent/Non-Self-Destructive	Violent/Self-Destructive
Clinical Justification Criteria	
1. Allow Medical Treatments to continue without interruption 2. Prevent pulling out of necessary tubes or drains 3. Provide safety when the patient is unable to follow direction	1. Prevent imminent danger to self or others 2. To administer stat IM psychotropic medication due to active dangerous behavior to self or others 3. Chemically restrain a patient
Initial Assessment/Evaluation	
1. Assessment will include: • Clinical Justification -behavior requiring restraints • Contributing factors • Less restrictive intervention tried or determined insufficient • Type of restraint • Response to restraint • Restraint applied safely/properly • Patient/Family education	1. Assessment will include: • Clinical Justification -behavior requiring restraints • Contributing factors • Less restrictive intervention tried or determined insufficient • Type of restraint • Response to restraint • Restraint applied safely/properly • Patient/Family education 2. A face-to-face evaluation that includes a physical and behavioral assessment must be performed by the physician, LP or specially trained RN within 1 hour of initiation of restraint or seclusion. 3. The 1 hour face-to-face evaluation will include: • Physical and Behavioral assessment • Reaction to intervention • Medical and behavioral condition • The need to continue or terminate restraint or seclusion 4. If the patient is removed from restraint prior to the evaluation, the 1hour face-to-face must still be performed.

Non-Violent/Non-Self-Destructive	Violent/Self-Destructive
Time Duration/Limit of Order	
1. A provider responsible for the patient's ongoing care must order the use of restraint prior to the application. 2. However, a qualified nurse may apply a restraint in response to an unanticipated event prior to obtaining an order. The provider must be notified and the order obtained as soon as possible (within 1 hour). 3. If the attending physician did not order the restraint, he or she must be contacted as soon as possible (within 1 hour). 4. Orders for the use of restraint to protect the physical safety of the non-violent or non-self-destructive patients must be renewed daily until the restraint is discontinued.	1. A provider responsible for the patient's ongoing care must order the use of restraint or seclusion prior to the application. 2. However, a qualified nurse may apply a restraint in response to an unanticipated event prior to obtaining an order. The provider must be notified and the order obtained immediately (or within a few minutes). 3. If the attending physician did not order the restraint, he or she must be contacted as soon as possible (within 1 hour) of the completion of the face-to-face assessment. 4. Orders are renewed within the following time-frames up to a total of 24 hours: • 4 hours for ages > 18 • 2 hours for ages 9-17 • 1 hour for ages < 9 5. Time-limited orders do not mean that restraint or seclusion must be applied for the entire length of time for which order is written.
Physician Order	
• Type of Restraint • Reason for Restraint or Seclusion (clinical justification) • Duration of Restraint • Criteria for release	
Monitoring	
1. Every 2 hours or more frequently if necessary • Circulation, skin integrity • Assess for release. • Restraints applied correctly • Range of Motion/Release while awake • Hydration while awake • Elimination while awake • Nutritional needs while awake • Vital signs – every 4 hours or per physician order	1. Every 30 minutes or more frequently if necessary: • Safety Check • Circulation/skin • Restraints applied correctly • Assess for release 2. Every 2 hours or more frequently if necessary: • Nutrition/Hydration • Elimination • ROM • Vital Signs

2. Hygiene needs as needed but not less than daily	3. Hygiene needs as needed but not less than daily.
Non-Violent/Non-Self-Destructive	**Violent/Self-Destructive**
Reevaluation	
1. Continued use of restraint requires a qualified RN to examine the patient and determine if the restraint continues to be clinically justified at least once a shift. 2. Reassessment will include: • Clinical Justification -behavior requiring restraints • Contributing factors • Less restrictive intervention tried or determined insufficient • Type of restraint • Response to restraint	1. Qualified RN reassesses at least every: a. 4 hours for ages > 18 b. 2 hours for ages 9-17 c. 1 hour for ages < 9 2. Reassessment will include: • Clinical Justification -behavior requiring restraints • Contributing factors • Less restrictive intervention tried or determined insufficient • Type of restraint • Response to restraint 3. The RN must notify the provider, report the results of the most recent assessment and request the original order be renewed. Whether or not the provider needs to personally assess the patient will be at the discretion of the provider. 4. A physician, or LP, who is primarily responsible for the ongoing care sees and evaluates the patient every 24 hours before writing a new order.

REFERENCES

- The Joint Commission (2018). TJC Accreditation Program: Hospital; Chapter: Provision of Care, Treatment, and Services.
- Centers for Medicare and Medicaid Services (2018). State Operations Manual. Appendix A-Survey Protocols. Restraints 482.13.

ARCHBOLD
ADMINISTRATIVE POLICY MANUAL

SUBJECT: Suicide Screening and Precautions

POLICY NUMBER: 101.55

EFFECTIVE: November 2012

EXPIRES: When Superseded

REVIEWED: January 2024

REVISED: January 2024

APPROVED: _____
President

I. POLICY

It is the policy of Archbold Medical Center to provide a safe environment for the patient displaying suicidal behavior, ideations, or found to be at risk for suicide. Patients will be screened for risk of suicide as part of the hospital's admission procedures. Patients indicated to be at risk for suicide will further be assessed to determine severity of ideations, and be placed on suicide precautions that prescribe specific steps staff will take to reduce risk and provide treatment for the patient's condition. Additional interventions may be taken to address a particular patient's individual circumstances when authorized by a Licensed Practitioner's (LP) order. Suicide precautions will be discontinued by the LP when clinically indicated.

II. PURPOSE

To describe procedures for identifying individuals at risk for suicide and to provide protection for the patient's emotional and physical health in a safe environment with appropriate interventions.

III. DEFINITIONS

A. **Patient Safety Monitor (PSM):** Any personnel who have completed education in the care of patients requiring continuous supervision with a focus on patient safety. For this policy, it is also someone who has ongoing education related to monitoring a patient at risk for suicide i.e. techs, nurse, security, qualified sitter.

B. **Suicide Precautions:** safety measures put into place by clinical staff when suicide risk is determined. These measures may be put in place pending physician orders for suicide precautions and include measures for monitoring and maintaining a safe environment.

C. **Constant Direct Observation:** the observation of a patient at all times.

D. **One to One Observation:** a competent observer to one patient within line of sight, in close proximity with no physical barriers.

E. **Seclusion**: the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving.

IV. SUICIDE RISK SCREENING, ASSESSMENT, AND REASSESSMENT

A. Suicide screening is a tool utilized to trigger a more in-depth assessment and evaluation by the qualified provider if indicated. The approach to the care of the suicidal patient is multidisciplinary. At a minimum, all patients aged twelve years or older entering the Emergency Department for care or admitted to the Hospital will be screened using the Columbia-Suicide Severity Rating Scale (C-SSRS) tool (See Appendix A).

Exceptions

1. If the patient is unable to be assessed upon arrival due to the patient's medical status, i.e., the patient is unconscious, intubated, intoxicated or mentally unable to respond, the screening will be postponed until the patient can be assessed. This screening should be performed as soon as the patient's condition permits.

2. A patient who presents with a complaint related to a current suicide attempt or gesture, regardless of age, is considered to be at risk for suicide, and therefore does not require screening to determine risk. However, assessment will still be completed by a qualified provider to determine severity. Initiate suicide precautions for this patient.

B. Patients whose suicide screening is moderate or high risk will be further assessed, by a qualified provider, using the SAFE-T Protocol with C-SSRS (Columbia Risk and Protective Factors) – Recent (See Appendix B). This assessment directly asks about suicidal ideation, plan, intent, suicidal or self-harm behaviors, risk factors, and protective factors. This assessment will be completed as soon as possible in order to determine the most appropriate care for the patient.

C. Patients at risk for suicide will be reassessed periodically by a qualified provider. Reassessment will also occur if there is a change in status, endorsement of suicidal ideation, and/or suicidal or self-harm behaviors or gestures. Reassessment will follow an evidence-based process, directly asking about suicidal ideation, plan, intent, suicidal or self-harm behaviors, risk factors, and protective factors.

V. PROCEDURE FOR MODERATE RISK SCREEN

Notify qualified provider of moderate risk screen for further evaluation. The qualified provider will utilize the SAFE-T Protocol to determine if any further intervention will be needed at this time and/or at discharge.

VI. PROCEDURE FOR HIGH RISK SCREEN

A. Initiate Suicide Precautions

1. Nursing must complete the Safe Environment Checklist prior to placing patient in room. The checklist should be reviewed at the following times:

   a. At the beginning of each shift.
   b. If staffing changes prior to the end of shift.
   c. If patient transfers to another area.

2. Personal belongings are removed and patient placed in paper scrubs.

3. Notify provider and obtain order for Suicide Precautions.

4. Constant direct observation will be implemented in the ED and Inpatient Units by one-to-one observation by PSM.

5. Exceptions to the one-to-one staffing may occur based on patient's level of consciousness. Document if precautions are modified by the physician.

6. Notify the Nursing Supervisor/DON for assistance in obtaining a PSM. Patient should not be left alone once precautions are initiated.

7. Suicide Precautions can only be discontinued by the provider or qualified mental health professional.

8. Patient and/or family should be given letter explaining the suicide safety measures (ns812).

B. Documentation

1. For the patient being monitored by PSM, the 1:1 Close Observation Flowsheet will be utilized requiring every 15-minute documentation.

2. If restraints are indicated, the restraint policy guidelines should be followed (Administrative Policy 101.21).

3. Document if personal belongings are sent home with family, which is preferable, or being stored at Nurses Station.

4. Department Specific

   a. ED: Nurse will continue to document patient status in psychosocial assessment

   b. Inpatient Units: Document Suicide Precautions and presence of PSM on shift assessment and reassessment. Any changes in behavior should be documented to the appropriate Plan of Care.

5. Education provided to patient/family.

C. Precautionary Measures

1. See Patient Safety Monitor Guidelines. (ns811)

2. Provide a safe environment. See Safe Environment Checklist. (ns810)

3. Provide constant direct supervision.

4. Stay with patient at all times. If tests cannot be performed in patient room, PSM or nurse must accompany patient wherever needed.

5. If patient needs to have a procedure, hand-off should be given and staff made aware of need for constant observation.

6. Staff should ensure patient swallows medications in tablet form.

7. Food should be served on disposable tray with disposable utensils (no knives) and should be checked before and after each meal to prevent any items being left in room.

8. Visitors can be restricted based on the patient's condition and/or to reduce the risk of the patient accessing prohibited items. Visitors should be asked to leave personal belongings in vehicle. If unable to do so, visitor belongings should be given to the PSM upon entering the room and retrieved upon exiting.

D. Discharge, transfer or leaving against medical advice while on suicide precautions.

1. Discharge

   a. A patient may not be discharged while on suicide precautions.

b. Suicide precautions can only be discontinued by the provider or qualified mental health professional.

2. Transfer

a. May not be transferred by family car.

b. Obtain order for transfer to mental health facility and arrange appropriate transportation.

3. Attempting to leave against medical advice

a. Call Code Gray and utilize restraints if patient is a threat to self or others.

b. Notify provider of patient status.

VII. EDUCATION AND COMPETENCY

A. Archbold Medical Center educates and assesses the competence of staff caring for suicidal patients. Only trained personnel will participate in care of patients on suicide precautions. Training is completed during orientation, annually, and as policy changes occur.

B. Providers authorized to assess patients and determine suicide risk must have a working knowledge of this policy.

C. As appropriate to scope of practice and job functions, staff whom perform assessments, monitor patients, and/or provide care to patients on suicide precautions must be trained in the following:

1. Screening and/or assessment of suicidal risk and/or severity.

2. Appropriate interventions based on individualized assessment and severity rating.

3. Appropriate monitoring and documentation including Patient Safety Monitor Guidelines, Close Observation Flowsheet, Safe Environment Checklist, and Patient/Family Education.

VIII. CROSS REFERENCES

A. Restraint and Seclusion – Administrative policy 101.21.

B. Patient's Rights and Responsibilities – Administrative policy 101.05.

IX. FORMS

A. 1:1 Close Observation Flowsheet - ns808, ns809.

B. Patient Safety Monitor Guidelines – ns811.

C. Safe Environment Checklist – ns810.

D. Patient/Family Education – ns812.

X. REFERENCES

A. The Columbia Lighthouse Project/Center for Suicide Risk Assessment (2018). The Columbia Suicide Severity Rating Scale (C-SSRS), SAFE-T with C-SSRS.

B. The Joint Commission (2019) Joint Commission R3 Report: National Patient Safety Goal for Suicide Prevention.

C. The Joint Commission (2020) NPSG 15.01.01.

D. The Joint Commission (2020) Suicide Prevention Resources to Support Joint Commission Accredited organizations implementation of NPSG 15.01.01, revised July, 2020.

E. Greist, J. H., Mundt, J. C., Gwaltney, C. J., Jefferson, J. W., & Posner, K. (2014). Predictive Value of Baseline Electronic Columbia–Suicide Severity Rating Scale (eC–SSRS) Assessments for Identifying Risk of Prospective Reports of Suicidal Behavior During Research Participation. Innovations in Clinical Neuroscience, 11(9-10), 23–31.

XI. JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A ARCHBOLD MEMORIAL, ARCHBOLD BROOKS, ARCHBOLD GRADY, ARCHBOLD MITCHELL, ARCHBOLD LIVING THOMASVILLE, ARCHBOLD LIVING CAMILLA, ARCHBOLD LIVING PELHAM, ARCHBOLD LIVING CAIRO) / ARCHBOLD FOUNDATION, INC./ ARCHBOLD MEDICAL GROUP, INC.

A. As applicable

APPENDIX A

COLUMBIA-SUICIDE SEVERITY
RATING SCALE

Screen Version - Recent

	Past month	
Ask Questions 1 and 2	**YES**	**NO**
1) ***Have you wished you were dead or wished you could go to sleep and not wake up?***		
2) ***Have you actually had any thoughts of killing yourself?***		
If YES to 2, ask questions 3, 4, 5, and 6. If NO to 2, go directly to question 6.		
3) ***Have you been thinking about how you might do this?*** E.g. "*I thought about taking an overdose but I never made a specific plan as to when where or how I would actually do it....and I would never go through with it.* "		
4) ***Have you had these thoughts and had some intention of acting on them?*** As opposed to "*I have the thoughts but I definitely will not do anything about them* ."		
5) ***Have you started to work out or worked out the details of how to kill yourself? Did you intend to carry out this plan?***		

6) ***Have you ever done anything, started to do anything, or prepared to do anything to end your life?***	**YES**	**NO**
Examples: Took pills, tried to shoot yourself, cut yourself, or hang yourself, took out pills but didn't swallow any, held a gun but changed your mind or it was grabbed from your hand, went to the roof but didn't jump, collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, etc.		
If YES, ask: ***Was this within the past three months?***		

- **Low Risk:** No further action necessary
- **Moderate Risk**: Notify qualified provider to determine suicide severity and course of treatment.
- **High Risk**: Notify provider and order Suicide Precautions; ensure 1:1 monitoring and follow Protocol

APPENDIX B

SAFE-T Protocol with C-SSRS (Columbia Risk and Protective Factors) – Recent

Step 1: Identify Risk Factors

C-SSRS Suicidal Ideation Severity (If question 2 is "no" you may skip 3, 4 and 5)	Month
1) Wish to be dead *Have you wished you were dead or wished you could go to sleep and not wake up?*	
2) Current suicidal thoughts *Have you actually had any thoughts of killing yourself?*	
3) Suicidal thoughts w/ Method (w/no specific Plan or Intent or act) *Have you been thinking about how you might do this?*	
4) Suicidal Intent without Specific Plan *Have you had these thoughts and had some intention of acting on them?*	
5) Intent with Plan *Have you started to work out or worked out the details of how to kill yourself? Did you intend to carry out this plan?*	
C-SSRS Suicidal Behavior: *"Have you ever done anything, started to do anything, or prepared to do anything to end your life?"* Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn't swallow any, held a gun but changed your mind or it was grabbed from your hand, went to the roof but didn't jump; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc. If "YES" Was it within the past 3 months?	Lifetime Past 3 Months

Activating Events:
- □ Recent losses or other significant negative event(s) (legal, financial, relationship, etc.)
- □ Pending incarceration or homelessness
- □ Current or pending isolation or feeling alone

Treatment History:
- □ Previous psychiatric diagnosis and treatments
- □ Hopeless or dissatisfied with treatment
- □ Non-compliant with treatment
- □ Not receiving treatment
- □ Insomnia

Other:
- □ _____
- □ _____
- □ _____

Clinical Status:
- □ Hopelessness
- □ Major depressive episode
- □ Mixed affect episode (e.g. Bipolar)
- □ Command Hallucinations to hurt self
- □ Chronic physical pain or other acute medical problem (e.g. CNS disorders)
- □ Highly impulsive behavior
- □ Substance abuse or dependence
- □ Agitation or severe anxiety
- □ Perceived burden on family or others
- □ Homicidal Ideation
- □ Aggressive behavior towards others
- □ Refuses or feels unable to agree to safety plan
- □ Sexual abuse (lifetime)
- □ Family history of suicide

□ **Access to lethal methods:** Ask <u>specifically</u> about presence or absence of a firearm in the home or ease of accessing

Step 2: Identify Protective Factors (Protective factors may not counteract significant acute suicide risk factors)	
Internal: □ Fear of death or dying due to pain and suffering □ Identifies reasons for living □ _____ □ _____	**External:** □ Belief that suicide is immoral; high spirituality □ Responsibility to family or others; living with family □ Supportive social network of family or friends □ Engaged in work or school

Step 3: Specific questioning about Thoughts, Plans, and Suicidal Intent – (see Step 1 for Ideation Severity and Behavior – skip if questions 1-5 are all no)

C-SSRS Suicidal Ideation Intensity (with respect to the most severe ideation 1-5 identified above)	**Month**
Frequency ***How many times have you had these thoughts?*** (1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day	
Duration ***When you have the thoughts how long do they last?*** (1) Fleeting - few seconds or minutes (2) Less than 1 hour/some of the time (3) 1-4 hours/a lot of time (4) 4-8 hours/most of day (5) More than 8 hours/persistent or continuous	
Controllability ***Could/can you stop thinking about killing yourself or wanting to die if you want to?*** (1) Easily able to control thoughts (2) Can control thoughts with little difficulty (3) Can control thoughts with some difficulty (4) Can control thoughts with a lot of difficulty (5) Unable to control thoughts (0) Does not attempt to control thoughts	
Deterrents ***Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of suicide?*** (1) Deterrents definitely stopped you from attempting suicide (2) Deterrents probably stopped you (3) Uncertain that deterrents stopped you (4) Deterrents most likely did not stop you (5) Deterrents definitely did not stop you (0) Does not apply	
Reasons for Ideation ***What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?*** (1) Completely to get attention, revenge or a reaction from others (2) Mostly to get attention, revenge or a reaction from others (3) Equally to get attention, revenge or a reaction from others and to end/stop the pain (4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) (5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) (0) Does not apply	
Total Score	

Step 4: Guidelines to Determine Level of Risk and Develop Interventions to LOWER Risk Level

"The estimation of suicide risk, at the culmination of the suicide assessment, is the quintessential **clinical judgment**, since no study has identified one specific risk factor or set of risk factors as specifically predictive of suicide or other suicidal behavior."
From The American Psychiatric Association Practice Guidelines for the Assessment and Treatment of Patients with Suicidal Behaviors, page 24.

RISK STRATIFICATION	TRIAGE
High Suicide Risk Suicidal ideation with intent or intent with plan **in past month** (C-SSRS Suicidal Ideation #4 or #5) **Or** Suicidal behavior **within past 3 months** (C-SSRS Suicidal Behavior)	☐ **Initiate local psychiatric admission process** ☐ **Stay with patient until transfer to higher level of care is complete** ☐ **Follow-up and document outcome of emergency psychiatric evaluation**
Moderate Suicide Risk Suicidal ideation with method, **WITHOUT plan, intent or behavior in past month** (C-SSRS Suicidal Ideation #3) **Or** Suicidal behavior more than 3 months ago (C-SSRS Suicidal Behavior Lifetime) **Or** Multiple risk factors and few protective factors	☐ **Use clinical judgement to determine if further evaluation is necessary** ☐ **Outpatient Referral**
Low Suicide Risk Wish to die or Suicidal Ideation **WITHOUT method, intent, plan or behavior** (C-SSRS Suicidal Ideation #1 or #2) **Or** Modifiable risk factors and strong protective factors **Or** ☐ No reported history of Suicidal Ideation or Behavior	☐ **Outpatient Referral**

Step 5: Documentation

Risk Level :

[ ] High Suicide Risk
[ ] Moderate Suicide Risk
[ ] Low Suicide Risk

Clinical Note:

- ⌋ Your Clinical Observation
- ⌋ Relevant Mental Status Information
- ⌋ Methods of Suicide Risk Evaluation
- ⌋ Brief Evaluation Summary
  - ⌋ Warning Signs
  - ⌋ Risk Indicators
  - ⌋ Protective Factors
  - ⌋ Access to Lethal Means
  - ⌋ Collateral Sources Used and Relevant Information Obtained
  - ⌋ Specific Assessment Data to Support Risk Determination
  - ⌋ Rationale for Actions Taken and Not Taken
- ⌋ Provision of Crisis Line 1-800-273-TALK(8255)
- ⌋ Implementation of Safety Plan (IfApplicable)

PROVIDER'S ROLE IN PREVENTING AND CONTROLLING INFECTIONS

Hand Hygiene is the number one thing we can do to prevent the spread of infection. We follow the **CDC's guidelines** for hand hygiene:

- Wash hands with soap and water when visibly soiled and after contact with patients with C. difficile.
- When using soap and water rub hands together vigorously for at least 20 seconds before rinsing.
- Alcohol foam or gel hand sanitizer: Apply and rub hands together covering all hands surface until dry.
- Hand Hygiene is monitored with direct observation by unit patient safety officers, nursing leadership, and infection control practitioners and direct observation by independent auditors or "secret shoppers."

Respiratory Hygiene/Cough Etiquette

- Cover your mouth and nose with a tissue when coughing or sneezing.
- Use the nearest waste receptacle to dispose of the tissue after use.
- Perform hand hygiene after having contact with respiratory secretions and contaminated objects/materials.
- Physicians are required to complete annual fit testing for N95 respirator.

Influenza impacts our patients and our staff:

- We have a mandatory **Influenza vaccination policy**. An employee who has not received the vaccine will be required to wear a mask during flu season.
- CDC continues to recommend that unvaccinated people get vaccinated. While some of the viruses spreading this season are different from those in the vaccine, vaccination can still provide protection and might reduce severe outcomes such as hospitalization and death.
- Influenza testing is recommended by the CDC for hospitalized patients with suspected influenza. However, empiric antiviral treatment should be initiated as soon as possible without the need to wait for any influenza testing results. These patients, as well as flu+ patients are placed on droplet precautions with good hand and respiratory hygiene to prevent transmission.
- Testing is not needed for all patients with signs and symptoms of influenza to make antiviral treatment decisions. Once influenza activity has been documented in the community or geographic area, a clinical diagnosis of influenza can be made for outpatients with signs and symptoms consistent with suspected influenza, especially during periods of peak influenza activity in the community.

Reference CDC http://www.cdc.gov/flu/about/season/index.htm

Reference: *Siegel JD, Rhinehart E, Jackson M, Chiarello L, The Healthcare Infection Control Practices Advisory Committee (HIPAC) Management of Multidrug-resistant organisms in healthcare settings 2006*. Available at: http://www.cdc.gov/hicpac/pdf/MDRO/MDROGuideline2006.pdf

- Emerging trends that could lead to an influx of the flu or other infections are communicated via the Infection Control Committee, email, or other hospital channels.

Isolation Precautions:

- Nursing will initiate, based on set criteria, and obtain an order. Patients with Multidrug Resistant Organisms (MDROs) or Toxin Positive C. Diff will remain on precautions throughout the acute care stay.
- Patients on Isolation Precautions do not go to Acute Rehab for therapy unless Infection Control has been involved with a proactive risk assessment and plan for therapy while on isolation. Proactive risk assessments are required before a patient is transferred to Inpatient Rehab (IPR) swing beds, or to Glenn-Mor, Pelham Parkway, and Mitchell Convalescent Center Nursing Home. At transfer, the receiving institution will be made aware of precautions.

Contact Precautions (Gray sign): Patients diagnosed with MDRO (VRE, MRSA, ESBL, KPC, CRE, etc.) large draining wounds, disseminated shingles, lice or patients with a history of VRE colonization

Droplet Precautions (Blue sign): R/O RSV, R/O Meningitis, R/O Pertussis, R/O or confirmed influenza. Yellow masks are needed. Any MDRO in sputum requires contact plus droplet isolation.

Special Contact Precautions (Purple sign): C diff testing/+C diff. 1 specimen is needed for the PCR test. Make sure patient meets criteria for C diff testing.

Airborne Precautions (Green sign): Patients undergoing AFB sputum testing or TB suspects also for disseminated shingles and chicken pox. N-95 respirator required (Must be fit tested for N95 respirator size). MD must document that the patient is no longer a TB suspect when discontinuing airborne precautions.

We have a **Blood borne pathogens exposure** protocol:

- Anytime there is an exposure, an occurrence report is generated.
- We provide first aid to the employee and determine the level of risk for the employee based on source patient diagnosis.
- The paperwork for each packet, low risk or high risk, is available online for you to order. **The only criterion for the designation of high risk** is the source patient is HIV positive, or there is reasonable suspicion that the patient might be.

Infection Control reports **Notifiable Diseases & Conditions mandated by Public Health** for all hospitalized patients. Please notify Infection Control at 228-2869 or 228-2734 as soon as you identify a situation that should be reported to expedite the process.

Infection Control **Reports to National Healthcare Safety Network (NHSN) and Centers for Medicare and Medicaid Services (CMS)**. NHSN provides definitions for the required reporting on:

- Central line associated blood stream infections (CLABSI)
- Catheter associated urinary tract infections (CAUTI)
- C. Diff+ and MRSA bacteremia+ Patients
- Surgical site infections (SSI) for colon surgeries, abdominal hysterectomies, laminectomies, total hips, and total knee procedures.

As physicians, you are our leaders and we look to you to be examples in both hand hygiene and PPE.

COVID-19 impacts our patients and our staff:

The CDC Guidelines for the prevention and spread of COVID-19: The CDC recommends ALL hospital staff wear a mask while inside the facility.

- Wash your hands before putting on your mask
- Wear your mask over your nose and mouth and secure it under your chin
- Fit your mask snugly against the sides of your face
- Make sure you can breath easily
- When you take off your mask, handle it only by the ear loops or ties
- Store your used mask safely to keep it clean between uses
- Wash your cloth mask regularly, preferably in a washing machine

Stay at least 6 feet apart and avoid crowds:

- Stay at least 6 feet from other people. Remember that people can spread the virus even if they do not have symptoms
- Avoid crowds and indoor spaces as much as possible, particularly ones that are not well ventilated

Wash your hands:

- Wash your hands often with soap and water for at least 20 seconds
- If soap and water are not available, use a hand sanitizer that contains at least 60% alcohol
    - Cover all surfaces of your hands and rub them together until they feel dry
- Avoid touching your eyes, nose, mouth until after you wash your hands

Reference CDC https://www.cdc.gov/coronavirus/2019-ncov/your-health/need-to-know.html

Reference CDC http://www.cdc.gov/flu/about/season/index.htm

Reference: *Siegel JD, Rhinehart E, Jackson M, Chiarello L, The Healthcare Infection Control Practices Advisory Committee (HIPAC) Management of Multidrug-resistant organisms in healthcare settings 2006*. Available at: http://www.cdc.gov/hicpac/pdf/MDRO/MDROGuideline2006.pdf

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PHARMACY POLICY MANUAL **POLICY NUMBER: PHM 210**

SUBJECT: Antimicrobial Stewardship **EFFECTIVE: January 2016**

APPROVED: **REVIEWED: November 1, 2020**
Andrea Jarzyniecki, Pharm.D.
Director of Pharmacy **REVISED: November 1, 2018**

I. POLICY

The Antimicrobial Stewardship subcommittee will operate across all Archbold Medical Center campuses. This group will meet quarterly with the goal to review and optimize clinical treatments and patient outcomes through the appropriate use of antimicrobial agents.

II. PURPOSE

The correct use of antimicrobials is a vital element of patient safety and monitoring will help minimize toxicities; incorrect dosing; inappropriate antimicrobial selection and emergence of resistant organisms. The combination of an effective antimicrobial stewardship program with an aggressive infection control program has been shown to be an effective measure in limiting the emergence and transmission of antimicrobial resistance.

III. PROCEDURE

The role of the committee will be to:

1. Conduct drug evaluations and case reviews with intervention and feedback;
2. Review and establish formulary restrictions of select antimicrobial agents
3. Provide education to pharmacy, medical and nursing staff to impart antimicrobial knowledge to enhance appropriate usage of agents
4. Update, develop and implement clinical practice guidelines for antimicrobial treatment and prophylaxis;
5. Promote streamlining or de-escalation of therapy on the basis of culture results
6. Introduce automatic stop orders with assistance from informatics to provide timely notification to the patient's provider.
7. Optimize antimicrobial dosing based on individual patient characteristics, the causative organism, site of infection as well as pharmacokinetic and pharmacodynamic parameters;
8. Support parenteral (IV) to oral conversion when clinically appropriate;
9. Work with Physician's Informatics Committee to establish and maintain an electronic antimicrobial guideline to improve antimicrobial decisions;
10. Provide clinical microbiology data to enable targeted antimicrobial selection and optimization of individual treatment regimens as well as assist infection control efforts in the surveillance of resistant organisms;
11. Monitor the incidence of nosocomial infections and increased resistance and recommend actions for prevention
12. Review antimicrobial prescribing practice for the system and against regional and national usage data;
13. Encourage cost effective prescribing practices through antimicrobial choice and duration;
14. Promote education and accountability for those who fall outside of the approved guidelines

Membership at Archbold Medical Center will be composed of at least:
Critical Care Physician
Clinical Pathologist
Clinical Microbiologist
Clinical Coordinator of Pharmacy
Infection control Physician (as available to participate)
Infection Control nurse
Executive medical sponsor (as required)
Information system specialist (as required)

System hospital (Grady, Mitchell and Brooks)
Membership of system committees will be composed of at least:
Staff Physician
Pharmacy Manager
Director of Nursing
Infection Control nurse

This committee will work to complete each of the following activities during each calendar year.

1. At least one antimicrobial drug evaluation will be performed annually for the system and reported.
2. Quarterly the committees will report Days of Therapy for antimicrobial agents used and take action on any identified issues through education of the provider or the medical staff as a whole.
3. The AMH committee with work with the Physician's Informatics Committee to develop and revise guidelines intended for treatment or prophylaxis with antimicrobial agents.
4. Each system will monitor activity of their staff for:
   De-escalation and best therapy antimicrobial therapy
   Review of therapy at 72 hours
   Conversion to oral therapy where appropriate and renal dosing adjustment
   Utilization of Restricted antibiotics
5. To reduce hospital acquired resistance and reduce other unintended consequences of antimicrobial use by monitoring resistance patterns throughout the system.
6. Provide education to the medical and hospital staff on pertinent issues as they identified.
7. Provide education to the community at least annually on issues pertaining to the use of antimicrobial agents or avoidance of infections.

ARCHBOLD
ADMINISTRATIVE POLICY MANUAL

POLICY NUMBER: 101.20

EFFECTIVE: September 1994

SUBJECT: Pain Management

EXPIRES: When Superseded

APPROVED: _____
President

REVIEWED: October 2023

REVISED: October 2023

I. POLICY

It is the policy of Archbold that patients have the right to optimal pain assessment and management when it does not interfere with the need for observation or is the discomfort associated with pregnancy. It is the responsibility of all clinical staff to assess and periodically reassess the patient for pain and relief from pain. The appropriate scales will be used to assess the patient's pain, an attempt will be made to provide adequate pain relief or in case of chronic pain, measures will be taken to diminish pain. In the Ambulatory settings where non-nursing services are performed, the patient will be advised to contact their physician or go to the Emergency Department. If the patient's condition appears to be on the decline, the clinical staff will ensure that the patient receives emergency care in an appropriate setting.

Effectiveness of interventions are evaluated and modified as necessary. The patient and family are provided with education about pain management that is part of their treatment plan.

II. PURPOSE

Assessment and management of pain is a critical element of the responsibility of the entire health care team. Effective pain assessment and management can remove the adverse psychological and physiological effects of unrelieved pain. Optimal management of the patient experiencing pain enhances healing and promotes both physical and psychological wellness. Patients need to be involved in all aspects of their care including pain management.

III. DEFINITION*

Pain, an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

IV. SPECIAL INSTRUCTIONS

A. Definitions of Pain Scales Attached to Policy:

0 = no pain
1-3 = Mild pain
4-6 = Moderate pain
7-10 = Severe (worst) pain possible

B. Neonates/Infants:

1. On admission, the nurse will assess for pain. Careful assessment and reassessment are necessary to detect presence of pain in infants and to determine appropriate dose and interval of administration.

2. Extreme care should be taken in the assessment of infants receiving opiates due to susceptibility to apnea and respiratory depression.

C. Pediatrics:

Successful pain management depends upon the active involvement of the child and family. On admission, the nurses will assess for pain.

1. Assessment includes child's developmental age, his word for pain, and familial/cultural beliefs.

2. Observation of the behavior of the child includes facial expression, motor response, activity and irritability. An older child may verbalize and perhaps use a simple pain scale (see attached).

3. A child may not understand the relationship between pain assessment and management. Therefore, he may not respond appropriately to the care giver's questions.

4. The supportive presence of a parent or other family member is encouraged.

5. Unexpected acute pain, especially if sudden or associated with altered vital signs, must be immediately evaluated and reported to the physician.

6. Encourage physician to write orders so that pain medication may be withheld if the child is asleep.

7. FLACC Behavioral Pain Scale (NS 479) will be used on pediatric patients' age 0 – 4 years.

8. Child Pain Scale (Wong-Baker Faces Pain Rating Scale)

The Child Pain Scale may be used for children over 4 years of age that cannot express their pain.

Refer to attachment for Wong-Baker Universal Pain Assessment tool.

D. Adolescents/Adults/Geriatrics:

1. On admission the nurse will assess the patient and ask if he or she has pain. If the patient responds "YES", the patient is asked to rate the intensity of the pain using a 0-10 pain scale [0 = no pain and 10 = severe (worst) pain]. The location, quality, onset of pain, present pain management and effects pain has

on daily life are asked. The patient is asked to set a pain goal on admission.

2. Pain is reassessed every shift, when the patient reports pain, and after administration of pain-relieving medications.

3. Pain management may include any or all of the following:

   a. cognitive/behavioral interventions such as relaxation, distraction or imagery.

   b. traditional or round-the-clock dosing.

   c. patient controlled analgesia (PCA).

   d. epidural continuous PCA

   e. physical agents such as massage, heat or cold therapy, TENS therapy, and electrical stimulation.

4. Geriatric patients may present special pain management problems due to their acute and chronic painful diseases. In addition, they have a higher risk of drug to drug interaction as well as disease to drug interaction. Geriatric patients may have multiple medications in their regimen that may potentiate or minimize the effects of analgesics given for pain control. Cognitive impairment and dementia are problems that place geriatric patients at risk for over and under medication.

5. The Pain Scale for Cognitively Impaired, Non-verbal Patients (NS 479) and the Adult Non-Verbal Pain/Ventilator Scale (NS 479) will be used for the cognitively impaired and/or ventilator patients.

E. Special Circumstances with Pain Management:

1. If a patient refuses the prescribed pain medication for the stated pain level, the patient may be offered an ordered pain medication that is indicated for a lower pain score.

2. The patient's physician is notified when pain management intervention is ineffective.

3. If a communication barrier exists, alternative methods will be implemented so that the patient can communicate when he/she is having pain and evaluate effectiveness of pain relief measures. The WONG-BAKER Faces may be used for pediatric patients age 4-13. The FLACC Pain Scale will be used for pediatric patients 0-4 years of age and the Pain Scale for Cognitively Impaired, Non-verbal Patients. The Adult Non-Verbal Pain/Ventilator Scale (NS 479) will be used for the cognitively impaired and/or ventilator patients.

4. Cultural and spiritual beliefs must be evaluated and appropriate care that is

acceptable to patients and families provided.

F. Education of Patients/Families:

1. Explanations of methods used for pain management are provided to patients/families on their level of understanding.

2. Patients are taught that pain management is a part of treatment.

3. Instructions for pain management which include potential limitations and side effects are provided throughout the hospital stay and are documented on the Interdisciplinary Plan of Care.

4. The Clinical Pharmacist may be consulted when patients/families require more in-depth education related to drug therapy.

5. Acute Rehab may be consulted when the patient's treatment modalities include TENS, phonophoresis, iontophoresis, ultrasound, massage, electrical stimulation, and thermotherapy.

6. Discharge Instructions include information that the patient/family needs to know in order to manage pain.

V. DOCUMENTATION

A. Nursing

1. Initial pain assessment is documented on the Admission Assessment or the appropriate assessment.

2. The patient's pain is reassessed every shift and documented on the Nursing shift assessment or the appropriate form.

3. The Universal Pain Assessment Tool (pain intensity scale), FLACC scale (NS 479), the Pain Scale for Cognitively Impaired, Non-verbal Patients (NS 479) or the Adult Non-Verbal Pain/Ventilator Scale (NS 479) is used when pain medications are administered:

a. Pain reassessment should occur within one (1) hour after each pharmacologic intervention.

b. If the patient has pain relief, it is not necessary to document further for this incidence of pain.

c. The Universal Pain Assessment Tool (pain intensity scale) is used to document the patient's response according to the PCA policy when the PCA is in use: Respiratory pattern, sedation level, pain score/pain relief (when awake), side effects and activity.

d. The Epidural Narcotic Analgesia Flow Sheet (RX 154) is used to

document the patient's response according to the PCA policy when the epidural PCA is in use: Respiratory pattern, sedation level, pain score/pain relief (when awake), side effects. Site checks are performed every eight (8) hours.

e. Patients undergoing surgical procedures have pain assessed and reassessment and findings documented on appropriate forms (i.e., moderate sedation forms, PACU forms).

VI. ANCILLARY CLINICAL DEPARTMENTS

A. For inpatients, the staff in ancillary departments notifies the nursing unit that the patient is experiencing pain.

B. Staff in ancillary departments will advise the outpatient in pain to notify his/her physician.

C. For outpatients who are in ancillary departments for routine diagnostic screenings, it is not necessary to assess the patient for pain unless the patient exhibits signs of pain or verbalizes that he/she is in pain. In that case, the patient is advised to notify his/her physician or the staff member may notify the physician.

VII. OUTPATIENT DEPARTMENTS

A. Outpatient departments will abide in intent to this policy.

B. Timeliness of assessment and reassessment and documentation will be established by individual outpatient departments.

VIII. STAFF EDUCATION

A. All relevant health care providers are educated about pain assessment and management including the barriers to reporting pain and using analgesics.

B. Nursing orientation includes education on pain assessment and management. Annual competency for Pain Management is mandatory.

C. Ancillary departments provide education on pain assessment and management in orientation and annually. Annual update includes review of the Pain Management Policy, Pain Management competency tool and survey.

IX. JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A ARCHBOLD MEMORIAL, ARCHBOLD BROOKS, ARCHBOLD GRADY, ARCHBOLD MITCHELL, ARCHBOLD LIVING THOMASVILLE, ARCHBOLD LIVING CAMILLA, ARCHBOLD LIVING PELHAM, ARCHBOLD LIVING CAIRO); ARCHBOLD FOUNDATION, INC.; AND ARCHBOLD MEDICAL GROUP, INC.

A. As applicable.

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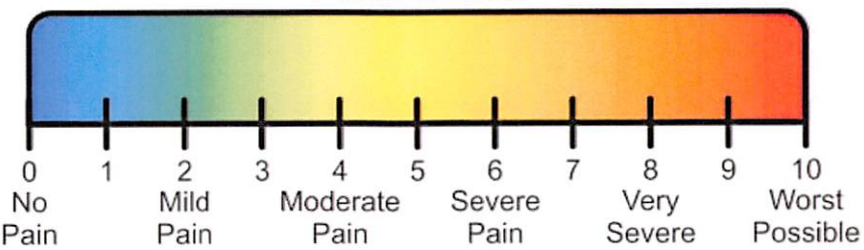
PAIN SEDATION SCALES

Our patient have the right to expect reasonable and appropriate pain management

ADULT PAIN SCALE

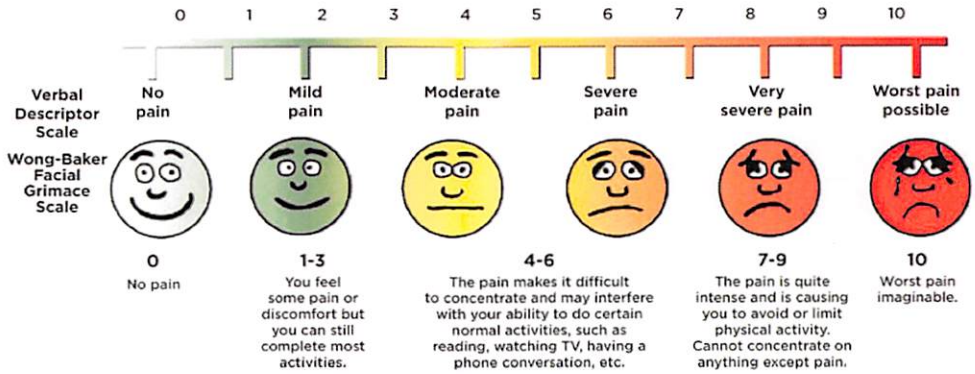
Pain Scale



Numerical pain scale asks patients to rate their pain from 0 – 10, 10 being the worst possible pain. Numerical scales are used for adults, adolescents, and school children.

0= NO PAIN, 1-3 MILD PAIN, 4-6 = MODERATE PAIN, AND 7-10 = SEVERE (WORST) PAIN

WONG-BAKER FACES SCALE



The Wong-Baker FACES Scale uses a series of faces. The clinician must explain that each face shows a person who feels happy or sad because of hurting or not hurting. The patient then

chooses the face that best shows his or her level of hurt. **0 – no pain 1-3 mild pain, 4-6 - moderate pain, 7-10 severe pain.** The FACES Scale is used for children three years and older and elderly adults who are confused or forgetful.

From Wong, D.L., Hockenberry-Eaton, M., Wilson, DI, Winkelstein, M.L., Ahmann, E., DiVito-Thomas, P.A.: Whaley and Wong's Nursing Care of Infants and Children, ed. 6, St. Louis, 1999, p. 2040. Copyrighted by Mosby, Inc. Reprinted by permission.

NS 479 05/16

FLACC PAIN SCALE

FLACC SCALE	0	1	2
FACE	No particular expression or smile	Occasional grimace or frown, withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
LEGS	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
ACTIVITY	Lying quietly, normal position, moves easily.	Squirming, shifting, back and forth, tense	Arched, rigid or jerking
CRY	Normal position or relaxed	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
CONSOLABILITY	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

The **Face, Legs, Activity, Cry, Consolability scale** or **FLACC scale** is a measurement used to assess pain for children between the ages of 0 months and 4 years or individuals that are unable to communicate their pain. Clinical judgement is used to interpret pain/distress behaviors considering the context of the situation to differentiate behavioral distress from pain behavior. The scale is scored in a range of 0–10 with 0 representing no pain. The scale has five criteria, which are each assigned a score of 0, 1 or 2. After totaling the 5 columns, the pain will be ranked as: **0 – no pain 1-3 mild pain, 4-6 - moderate pain, 7-10 severe pain**

FLACC Scale (Extracted from *The FLACC: A behavioral scale for scoring postoperative pain in young children*, by S Merkel and others, 1997, Pediatric Nurse 23(3), p. 293–297)

NS 479 05/16

ADULT NONVERBAL PAIN / VENTILATOR SCALE

Abbreviations: HR=Heart Rate; RR=Respiratory Rate; SBP=Systolic Blood Pressure; Sp02=Pulse Oximetry

Each of the 5 categories is scored from 0-2, which results in a total score between 0 and 10. Document total score by adding numbers from each of 5 categories. After totaling the 5 columns, the pain will be ranked as: **0 – no pain 1-3 mild pain, 4-6 - moderate pain, 7-10 severe pain**

Strong Memorial Hospital, University of Rochester Medical Center, 2004.

Categories	0 – no pain	1	2	Total
FACE	No particular expression or smile	Occasional grimace, tearing, frowning, wrinkled forehead	Frequent grimace, tearing, frowning, wrinkled forehead	
ACTIVITY (MOVEMENT)	Lying quietly, normal position	Seeking attention through movement or slow, cautious movement.	Restless, excessive activity and/or withdrawal reflexes	
GUARDING	Lying quietly, no positioning of hands over areas of body	Splinting areas of the body, tense	Rigid, stiff	
PHYSIOLOGY (VITAL SIGNS)	Stable vital signs	Change in any of the following: SBP>20 mm Hg HR>20/BPM	Change in any of the following: SBP>30 mm Hg HR>25/BPM	
RESPIRATORY	Baseline RR/Sp02 Compliant with ventilator	RR>10 above baseline, or 5% > Sp02 mild asynchrony with ventilator	RR>20 about baseline, or 10% >Sp02 Severe asynchrony with ventilator	
TOTAL				

NS 479 05/16

PAIN SCALE FOR COGNITIVELY IMPAIRED, NON-VERBAL ADULTS

CHECKLIST OF NON-VERBAL PAIN INDICATORS	SCORE
Vocal complaints (moans, groans, grunts, cries, gasps, sighs, says ouch)	
Facial Grimaces and Winces (furrowed brow, narrowed eyes, tightened lips, dropped jaw, clenched teeth, distorted expression)	
Bracing (clutching or holding onto bed/chair, caregiver, or affected area during movement)	
Restlessness (constant or intermittent shifting of position, rocking intermittent hand motions, inability to keep still)	
Rubbing (massaging affected area)	
TOTAL SCORE	

Instructions for use: Total the column: 0 = behavior was not observed 1-2 mild pain if behavior observed briefly, 3- 6 moderate pain, 7-10 - severe pain. After totaling the 5 columns, the pain will be ranked as: **0 – no pain 1-3 mild pain, 4-6 - moderate pain, 7-10 severe pain**

Sources: Feldt KS, Treatment of pain in cognitively impaired versus cognitively intact post hip fractured elders (Doctoral diss.) Minneapolis: University of Minnesota, 1996. Dissertation Abstracts International 57, 09B: 5574; Feldt KS, Checklist of Nonverbal Pain Indicators. Pain Management Nursing 2000;1 (1): 13021.

SEDATION LEVELS

1 – Wide awake	4 – Mostly sleeping
2 – Drowsy	5 – Awakens only when aroused
3 – Dozing intermittantly	6 - Unarousable

NS 479 05/16

SAMHSA
Opioid Overdose Prevention TOOLKIT

Opioid Use Disorder Facts

Five Essential Steps for First Responders

Information for Prescribers

Safety Advice for Patients & Family Members

Recovering From Opioid Overdose

SAMHSA
Substance Abuse and Mental Health Services Administration

TABLE OF CONTENTS

SAMHSA Opioid Overdose Prevention Toolkit

OPIOID USE DISORDER FACTS

SCOPE OF THE PROBLEM

Opioid overdose continues to be a major public health problem in the United States. It has contributed significantly to overdose deaths among those who use or misuse illicit and prescription opioids. In fact, all U.S. overdose deaths involving opioids (i.e., unintentional, intentional, homicide, and undetermined) increased to more than 42,000 deaths in 2016.[1]

WHAT ARE OPIOIDS? Opioids include prescription medications used to treat pain such as morphine, codeine, methadone, oxycodone, hydrocodone, fentanyl, hydromorphone, and buprenorphine, as well as illegal drugs such as heroin and illicit potent opioids such as fentanyl analogs (e.g., carfentanil).

Opioids work by binding to specific receptors in the brain, spinal cord, and gastrointestinal tract. In doing so, they diminish the body's perception of pain. However, opioids can also have an impact on other systems of the body, such as altering mood, slowing breathing, and causing constipation. Opioid receptor binding causes the signs and symptoms of overdose as well as the euphoric effects or "high" with opioid use.

HOW DOES OVERDOSE OCCUR? A variety of effects can occur after a person takes opioids, ranging from pleasure to nausea and vomiting, severe allergic reactions (anaphylaxis), and overdose, in which breathing and heartbeat slow or even stop.

Opioid overdose can be due to many factors. For example, overdose can occur when a patient deliberately misuses a prescription, uses an illicit opioid (such as heroin), or uses an opioid contaminated with other even more potent opioids (such as fentanyl). Overdose can also occur when a patient takes an opioid as directed but the prescriber miscalculated the opioid dose, when an error was made by the dispensing pharmacist, or when the patient misunderstood the directions for use. It can also occur when opioids are taken with other medications—for example, prescribed medications such as benzodiazepines or other psychotropic medications that are used in the treatment of mental disorders—or with illicit drugs or alcohol that may have adverse interactions with opioids. At particular risk are individuals who use opioids and combine them with benzodiazepines, other sedative hypnotic agents, or alcohol, all of which cause respiratory depression.[2]

WHO IS AT RISK? Anyone who uses opioids for long-term management of chronic pain is at risk for opioid overdose, as are individuals who use heroin or misuse prescription pain relievers.[3] Others at risk include those who:

- Are receiving rotating opioid medication regimens (and thus are at risk for incomplete cross-tolerance).
- Have been discharged from emergency medical care following opioid overdose.
- Need opioid pain relievers, coupled with a suspected or confirmed substance use disorder or history of non-medical use of prescription opioids or use of illicit opioids.
- Have completed opioid detoxification or are abstinent for a period of time (and presumably have reduced opioid tolerance and high risk of return to opioid use).
- Have been recently released from incarceration and have a history of opioid use disorder or opioid misuse (and presumably have reduced opioid tolerance and high risk of return to opioid use).

Tolerance develops when someone uses an opioid drug regularly so that his or her body becomes accustomed to the drug and needs a larger or more frequent dose to continue to experience the same effect.

Loss of tolerance occurs when someone stops taking an opioid after long term use. When someone loses tolerance and then takes the opioid drug again, he or she can experience serious adverse effects, including overdose, even if the amount taken had not caused problems in the past.

STRATEGIES TO PREVENT OVERDOSE DEATHS

STRATEGY 1: Encourage providers, persons at high risk, family members, and others to learn how to prevent and manage opioid overdose. Providers should be encouraged to keep their knowledge current about evidence-based practices for the use of opioid analgesics to manage pain, as well as specific steps to prevent and manage opioid overdose.

The Substance Abuse and Mental Health Services Administration (SAMHSA) funds continuing medical education courses that are available to providers at no charge from the Providers Clinical Support System (PCSS) at https://pcssnow.org/.

Helpful information for laypersons on how to prevent and manage overdose is available from Prevent & Protect at http://prevent-protect.org/.

Encourage providers and others to learn about preventing and managing opioid overdose.

STRATEGY 2: Ensure access to treatment for individuals who are misusing opioids or who have a substance use disorder. Effective treatment of substance use disorders can reduce the risk of overdose and help overdose survivors attain a healthier life. Medications for opioid use disorder, as well as counseling and other supportive services, can be obtained at SAMHSA-certified and Drug Enforcement Administration-registered opioid treatment programs and in specialty substance use disorder treatment programs, as well as from physicians and other practitioners including nurse practitioners and physician assistants who are trained to provide care in office-based settings with buprenorphine and naltrexone.

Information on treatment services available in or near your community can be obtained from your state health department, your state alcohol and drug agency, or the SAMHSA Behavioral Health Treatment Services Locator at https://www.findtreatment.samhsa.gov.

Ensure access to treatment for individuals who have a substance use disorder.

STRATEGY 3: Ensure ready access to naloxone. Opioid overdose-related deaths can be prevented when naloxone is administered in a timely manner. (For instructions on how to use naloxone, go to http://prescribetoprevent.org). Naloxone displaces opioids from receptor sites in the brain and reverses respiratory depression that usually is the cause of overdose deaths.[2] Naloxone is an appropriate response for all opioid overdose events, including fentanyl-involved overdoses. Multiple doses of naloxone may be required when the overdose results from ingestion of large amounts of opioids or potent opioids such as fentanyl, carfentanil, or other opioid analogs.[4] (For more information regarding the various formulations of naloxone, see https://www.drugabuse.gov/publications/naloxone-opioid-overdose-life-saving-science/naloxone-opioid-overdose-life-saving-science.)

Expand access to naloxone.

On the other hand, naloxone is not effective in treating overdoses of benzodiazepines, barbiturates, clonidine, GHB, or ketamine. It is also not effective against overdoses of stimulants, such as cocaine and amphetamines (including methamphetamine and MDMA). However, if opioids are taken in combination with other sedatives or stimulants, naloxone may be helpful.

Naloxone injection has been approved by the Food and Drug Administration (FDA) and used for more than 40 years by emergency medical services personnel to reverse opioid overdose and resuscitate

individuals who otherwise might have died in the absence of treatment.[5] Naloxone comes in several forms, including injectable, intranasal, and auto-injector. Injectable naloxone is typically supplied as a kit with a minimum of two doses and two syringes.[6] Brief education on how to administer naloxone using a syringe can be obtained from the provider of the naloxone kit or from http://prescribetoprevent.org/. The FDA has also approved an intranasal naloxone product (a nasal spray) and a naloxone auto-injector that delivers a therapeutic dose of naloxone in an overdose situation. The intranasal spray is a prefilled, needle-free device that requires no assembly. The auto-injector can deliver a dose of naloxone through clothing, if necessary, when placed on the outer thigh.

Prior to 2012, just six states had laws that expanded access to naloxone or limited criminal liability.[7] By mid-2017, every state and the District of Columbia had enacted statutes that provide criminal liability protections to laypersons or first responders who administer naloxone. Forty-six states and the District of Columbia have statutes that provide civil liability protections to laypersons or first responders who administer naloxone. Thirty-seven states have statutes that offer criminal liability protections for prescribing or distributing naloxone. Forty-one states have statutes that offer civil liability protections for prescribing or distributing naloxone, and 46 states have statutes that allow naloxone distribution to third parties or first responders via direct prescription or standing order. To find relevant laws for each state, visit the Prescription Drug Abuse Policy System at http://www.pdaps.org/

Encourage the public to call 911.

STRATEGY 4: Encourage the public to call 911. An individual who is experiencing an opioid overdose needs immediate medical attention. An essential first step is to get help from someone with medical expertise as quickly as possible.[8] Therefore, members of the public should be encouraged to call 911. All they have to say is “Someone is unresponsive and not breathing” and give a specific address and/or description of the location. Thirty-seven states and the District of Columbia have “Good Samaritan” statutes that prevent prosecution for possession of a controlled substance or paraphernalia if emergency assistance is sought for someone who is experiencing an overdose, including an opioid-induced overdose.[9]

Encourage prescribers to use state prescription drug monitoring programs.

STRATEGY 5: Encourage prescribers to use state prescription drug monitoring programs (PDMPs). State PDMPs have emerged as a key strategy for addressing the misuse of prescription opioids and thus preventing opioid overdoses and deaths. Specifically, prescribers can check their state’s PDMP database to determine whether a patient is filling the prescriptions provided and/or obtaining prescriptions for the same or a similar drug from multiple prescribers.

While nearly all states now have operational PDMPs, the programs differ from state to state in terms of the exact information collected, how soon that information is available to prescribers, and who may access the data. Therefore, information about the program in a particular state is best obtained directly from the Prescription Drug Abuse Policy System at http://www.pdaps.org/, the specific state PDMP, or the state’s board of medicine or pharmacy.

RESOURCES FOR COMMUNITIES

Resources that may be useful to local communities and organizations include:

SAMHSA

- National Helpline: 1-800-662-HELP (4357) or 1-800-487-4889 (TDD, for hearing impaired)
- Behavioral Health Treatment Services Locator (search by address, city, or ZIP Code): https://findtreatment.samhsa.gov/
- Buprenorphine Treatment Practitioner Locator (search by address, city, or ZIP Code): https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator
- Single State Agencies for Substance Abuse Services: https://www.samhsa.gov/sites/default/files/ssa-directory.pdf
- State Opioid Treatment Authorities: https://dpt2.samhsa.gov/regulations/smalist.aspx
- SAMHSA Publications Ordering (all SAMHSA Store products are available at no charge): https://store.samhsa.gov; 1-877-SAMHSA-7 (1-877-726-4727)

Centers for Disease Control and Prevention

- Understanding the Epidemic: https://www.cdc.gov/drugoverdose/epidemic
- Poisoning: https://www.cdc.gov/homeandrecreationalsafety/poisoning

Association of State and Territorial Health Officials

- Preventing Opioid Misuse in the States and Territories: http://my.astho.org/opioids/home

National Association of State Alcohol and Drug Abuse Directors

- Opioids Fact Sheet (February 5, 2016): http://nasadad.org/2016/02/opioids-fact-sheet-2016/

Prevent & Protect

- Tools for conducting overdose prevention and naloxone advocacy, outreach, and communication campaigns: http://prevent-protect.org/community-resources-1/

Resources that may be useful to local communities and organizations

FIVE ESSENTIAL STEPS FOR FIRST RESPONDERS

Overdose is common among persons who use illicit opioids such as heroin and among those who misuse medications prescribed for pain such as oxycodone, hydrocodone, methadone, buprenorphine, and morphine. The incidence of opioid overdose is rising nationwide. In 2016, more than 42,000 of the drug overdose deaths in the United States involved some type of opioid, including heroin.[1]

To address the problem, emergency medical personnel, health care professionals, people who use drugs, and other community members who may witness and respond to an overdose are being trained in the use of the opioid antagonist medication naloxone, which can reverse the potentially fatal respiratory depression caused by opioid overdose. (Note that naloxone has no effect on non-opioid overdoses, such as those involving cocaine, benzodiazepines, or alcohol.[10])

The steps outlined in this section are recommended to reduce the number of deaths resulting from opioid overdoses.

STEP 1: EVALUATE FOR SIGNS OF OPIOID OVERDOSE

Signs of **OVERDOSE**, which often results in death if not treated, include:[10]

- Unconsciousness or inability to awaken.
- Slow or shallow breathing or breathing difficulty such as choking sounds or a gurgling/snoring noise from a person who cannot be awakened.
- Fingernails or lips turning blue/purple.

If an opioid overdose is suspected, stimulate the person:

- Call the person's name.
- If this doesn't work, vigorously grind knuckles into the sternum (the breastbone in middle of chest) or rub knuckles on the person's upper lip.
- If the person responds, assess whether he or she can maintain responsiveness and breathing.
- Continue to monitor the person, including breathing and alertness, and try to keep the person awake and alert.

If the person does not respond, call 911, provide rescue breathing if the person is not breathing on their own, and administer one dose of naloxone.

STEP 2: CALL 911 FOR HELP

AN OPIOID OVERDOSE NEEDS IMMEDIATE MEDICAL ATTENTION. An essential step is to get someone with medical expertise to see the person as soon as possible. If no emergency medical services (EMS) or other trained personnel is on the scene, activate the 911 emergency system immediately. All you have to say is "Someone is unresponsive and not breathing." Be sure to give a specific address and/or description of your location. After calling 911, follow the dispatcher's instructions. If appropriate, the 911 operator will instruct you to begin CPR (technique based on rescuer's level of training).

STEP 3: ADMINISTER NALOXONE

If the person overdosing does not respond within 2 to 3 minutes after administering a dose of naloxone, administer a second dose of naloxone.

Naloxone should be administered to anyone who presents with signs of opioid overdose or when opioid overdose is suspected. Naloxone is approved by the Food and Drug Administration (FDA) and has been used for decades by EMS personnel to reverse opioid overdose and resuscitate individuals who have overdosed on opioids. Research has shown that women, older people, and those without obvious signs of opioid use disorder are undertreated with naloxone and, as a result, have a higher death rate.[11] Therefore, it is also important to consider naloxone administration in women and the elderly found unresponsive with opioid overdose.

Naloxone can be given by intranasal spray and by intramuscular (into the muscle), subcutaneous (under the skin), or intravenous injection.[12]

All naloxone products are effective in reversing opioid overdose, including fentanyl-involved opioid overdoses, although overdoses involving potent (e.g., fentanyl) or large quantities of opioids may require more doses of naloxone.

DURATION OF EFFECT. The duration of effect of naloxone depends on dose, route of administration, and overdose symptoms[2] and is shorter than the effects of some opioids. The goal of naloxone therapy should be to restore adequate spontaneous breathing, but not necessarily complete arousal.[2]

More than one dose of naloxone may be needed to revive someone who is overdosing. People who have taken longer acting or more potent opioids may require additional intravenous bolus doses or an infusion of naloxone.[13]

Comfort the person being treated, as withdrawal triggered by naloxone can feel unpleasant. Some people may become agitated or confused, which may improve by providing reassurance and explaining what is happening.

SAFETY OF NALOXONE. The safety profile of naloxone is remarkably high, especially when used in low doses and titrated to effect.[10] When given to individuals who are not opioid intoxicated or opioid dependent, naloxone produces no clinical effects, even at high doses. Moreover, although rapid opioid withdrawal in opioid-tolerant individuals may be unpleasant, it is not life threatening.

Naloxone can be used in life-threatening opioid overdose circumstances in pregnant women.[14]

The FDA has approved an injectable naloxone, an intranasal naloxone, and a naloxone auto-injector as emergency treatments for opioid overdose. People receiving naloxone kits that include a syringe and naloxone ampules or vials should receive brief training on how to assemble and administer the naloxone to the victim. The nasal spray is a prefilled, needle-free device that requires no assembly and that can deliver a single dose into one nostril. The auto-injector is injected into the outer thigh to deliver naloxone to the muscle (intramuscular) or under the skin (subcutaneous). Once turned on, the currently available device provides verbal instruction to the user describing how to deliver the medication, similar to automated defibrillators. Both the nasal spray and naloxone auto-injector are packaged in a carton containing two doses to allow for repeat dosing if needed.

FENTANYL-INVOLVED OVERDOSES. Suspected opioid overdoses, including suspected fentanyl-involved overdoses, should be treated according to standard protocols.[4] However, because of the higher potency of fentanyl and fentanyl analogs compared to that of heroin, multiple doses of naloxone may be required to reverse the opioid-induced respiratory depression from a fentanyl-involved overdose.[4,15,16]

Many anecdotes report more rapid respiratory depression with fentanyl than with heroin, although other reports do not reflect such rapid depression.[17]

Because of these effects, quicker oxygenation efforts and naloxone delivery may be warranted with fentanyl-involved overdoses compared with heroin-only overdoses. However, naloxone is an appropriate response for all opioid overdoses, including fentanyl-involved overdoses.

STEP 4: SUPPORT THE PERSON'S BREATHING

Ventilatory support is an important intervention and may be lifesaving on its own. Rescue breathing can be very effective in supporting respiration, and chest compressions can provide ventilatory support.[18,19] Rescue breathing for adults involves the following steps:

- Be sure the person's airway is clear (check that nothing inside the person's mouth or throat is blocking the airway).
- Place one hand on the person's chin, tilt the head back, and pinch the nose closed.
- Place your mouth over the person's mouth to make a seal and give two slow breaths.
- Watch for the person's chest (but not the stomach) to rise.
- Follow up with one breath every 5 seconds.

Chest compressions for adults involve the following steps:

- Place the person on his or her back.
- Press hard and fast on the center of the chest.
- Keep your arms extended.

STEP 5: MONITOR THE PERSON'S RESPONSE

All people should be monitored for recurrence of signs and symptoms of opioid toxicity for at least 4 hours from the last dose of naloxone or discontinuation of the naloxone infusion. People who have overdosed on long-acting opioids should have more prolonged monitoring.[2,10,13]

Most people respond by returning to spontaneous breathing. The response generally occurs within 2 to 3 minutes of naloxone administration. (Continue resuscitation while waiting for the naloxone to take effect.)[2,10]

Because naloxone has a relatively short duration of effect, overdose symptoms may return.[2,10,13] Therefore, it is essential to get the person to an emergency department or other source of medical care as quickly as possible, even if the person revives after the initial dose of naloxone and seems to feel better.

SIGNS OF OPIOID WITHDRAWAL. The signs and symptoms of opioid withdrawal in an individual who is physically dependent on opioids may include body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection (gooseflesh), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, tearing, insomnia, opioid craving, dilated

pupils, and increased blood pressure. These symptoms are uncomfortable, but not life threatening. After an overdose, a person dependent on opioids should be medically monitored for safety and offered assistance to get into treatment for opioid use disorder.

If a person does not respond to naloxone, an alternative explanation for the clinical symptoms should be considered. The most likely explanation is that the person is not overdosing on an opioid but rather some other substance or may be experiencing a non-overdose medical emergency.

In all cases, support of ventilation, oxygenation, and blood pressure should be sufficient to prevent the complications of opioid overdose and should be given priority if the response to naloxone is not prompt.

DO'S AND DON'TS WHEN RESPONDING TO OPIOID OVERDOSE

- DO attend to the person's breathing and cardiovascular support needs by administering oxygen or performing rescue breathing and/or chest compressions.
- DO administer naloxone and utilize a second dose, if no response to the first dose.
- DO put the person in the "recovery position" on the side, if you must leave the person unattended for any reason.
- DO stay with the person and keep the person warm.
- DON'T slap or forcefully try to stimulate the person; it will only cause further injury. If you cannot wake the person by shouting, rubbing your knuckles on the sternum (center of the chest or rib cage), or light pinching, the person may be unconscious.
- DON'T put the person into a cold bath or shower. This increases the risk of falling, drowning, or going into shock.
- DON'T inject the person with any substance (e.g., saltwater, milk, stimulants). The only safe and appropriate treatment is naloxone.
- DON'T try to make the person vomit drugs that may have been swallowed. Choking or inhaling vomit into the lungs can cause a fatal injury.

NOTE: All naloxone products have an expiration date, so it is important to check the expiration date and obtain replacement naloxone as needed.

INFORMATION FOR PRESCRIBERS

Opioid overdose is a major public health problem. In 2016, more than 42,000 people died of an opioid-related overdose.[1] Overdoses are experienced by both men and women of all ages, ethnicities, and demographic and socioeconomic characteristics and involve both illicit opioids such as heroin and illicitly manufactured fentanyl and prescription opioid analgesics such as oxycodone, hydrocodone, fentanyl, and methadone.[1]

Health care providers can reduce the toll of opioid overdose through:

- Opioid stewardship and implementing the opioid prescribing guidelines of the Centers for Disease Control and Prevention (CDC; https://www.cdc.gov/drugoverdose/prescribing/guideline.html).
- Offering risk reduction messaging and prescribing naloxone when potentially dangerous behaviors or opioid doses are identified.
- Treating opioid use disorder (OUD) when individuals screen positive for the disorder and when their substance use histories and further examination indicate a current OUD.
- Treating opioid overdose emergencies.

Federally funded Substance Abuse and Mental Health Services Administration (SAMHSA) continuing medical education courses are available at no charge at https://pcssnow.org/ and https://www.OpioidPrescribing.com.

OPIOID STEWARDSHIP

The CDC developed guidelines to improve communication between prescribers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including OUD, overdose, and death.[20] The 12 recommendations for prescribing opioids for adults with chronic pain outside of active cancer, palliative, and end-of-life care are targeted toward primary care providers and are organized into three overarching categories.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. If these goals are not met, then the opioid therapy should be tapered and stopped and other approaches should be considered.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy as well as patient and clinician responsibilities for managing therapy**.**

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual

benefits and risks when increasing dosage to =50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to more than 90 MME/day or carefully justify a decision to titrate dosage to more than 90 MME/day.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days will often be sufficient; more than 7 days will rarely be needed.
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate these into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (more than 50 MME/day), or concurrent benzodiazepine use, are present.
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every time a prescription is written to every 3 months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for use of prescribed medications as well as use of other controlled prescription drugs and illicit drugs.
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with OUD.

RISK REDUCTION MESSAGING, OVERDOSE PREVENTION EDUCATION, AND NALOXONE PRESCRIPTION

When potentially harmful behaviors are identified (e.g., high-volume use of opioids; taking opioids in combination with alcohol, benzodiazepines, or other respiratory depressants; using illicit opioids where contents of substance cannot be confirmed), it is important to offer education that can reduce that individual's risk for overdose. Providing basic risk reduction messaging, overdose prevention education, and a naloxone prescription can be lifesaving interventions.

Risk reduction messaging from a prescriber may include information about which other medications a patient is taking that are respiratory depressants; benzodiazepines, anti-seizure medications, and many psychiatric medications are respiratory depressants. Letting

the patient know that mixing these substances with opioids or taking more than prescribed in combination with opioids may increase his or her risk of overdose.

Naloxone competitively binds opioid receptors and is the antidote to acute opioid toxicity. Naloxone will not reverse alcohol, benzodiazepine, or other types of toxicity because it attaches only to the opioid receptors. Community-based naloxone distribution programs have not been shown to increase drug use and have, in fact, been shown to increase treatment engagement. Most patients respond positively to naloxone prescriptions, and some report additional positive behavioral changes following overdose education and naloxone prescription.[21] Naloxone prescriptions could be (1) a naloxone kit containing naloxone vials, syringes, and needles; (2) intranasal naloxone spray, which delivers a single dose of naloxone into one nostril via a prefilled intranasal spray; or (3) a naloxone auto-injector, which delivers a single dose of naloxone to the outer thigh via a handheld auto-injector.[12]

Patients who are candidates for naloxone include individuals:[20]

- With a history of overdose.
- With a history of substance use disorder.
- Who are taking benzodiazepines with opioids.
- Who are at risk for returning to a high dose to which they are no longer tolerant (e.g., former inmates recently released from prison, patients leaving detoxification facilities).
- Who are taking higher dosages of opioids (more than 50 MME/day).

It may also be advisable to suggest that the at-risk patient create an "overdose plan" to share with friends, partners, and/or caregivers. Such a plan would contain information on the signs of overdose and how to administer naloxone or otherwise provide emergency care (as by calling 911). Examples of patient handouts in seven languages are available from the State of California Department of Consumer Affairs and can be found at http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml.

OUD TREATMENT

If a patient has an OUD, arrange for and/or provide treatment. Treating OUD with Food and Drug Administration (FDA)-approved medications (methadone, buprenorphine with or without naloxone, and naltrexone) is an evidence-based approach. Methadone treatment for OUD can be provided only in licensed opioid treatment programs (OTPs). Buprenorphine can be prescribed by physicians, nurse practitioners, and physician assistants who have completed additional training and have obtained a waiver to prescribe this medication. Naltrexone is an injectable medication that can be prescribed by any provider with prescribing authority. It is recommended that each medication be prescribed in conjunction with behavioral and psychosocial treatment.[15] For more information on these medications, see SAMHSA's *Medication-Assisted Treatment of Opioid Use Disorder Pocket Guide* in the resources section or visit https://store.samhsa.gov/product/Medication-Assisted-Treatment-of-Opioid-Use-Disorder-Pocket-Guide/SMA16-4892PG. To identify treatment providers in your area, visit SAMHSA's Behavioral Treatment Services Locator at https://findtreatment.samhsa.gov/ or SAMHSA's Buprenorphine Treatment Practitioner Locator at https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator.

TREATING OPIOID OVERDOSE

In the time it takes for an overdose to become fatal, it is possible to reverse the respiratory depression and other effects of opioids through respiratory support and administration of the opioid antagonist naloxone.[10] Naloxone is approved by the FDA and has been used for decades to reverse overdose and resuscitate individuals who have overdosed on opioids. The routes of administration for naloxone are intravenous, intranasal, intramuscular, and subcutaneous. All naloxone products are effective in reversing opioid overdose, including fentanyl-involved opioid overdoses, although fentanyl-involved overdoses may require more naloxone.

The safety profile of naloxone is remarkably high, especially when used in low doses and titrated to effect.[2] If given to individuals who are not opioid intoxicated or opioid dependent, naloxone produces no clinical effects, even at high doses. Moreover, although rapid opioid withdrawal in opioid-tolerant patients may be unpleasant, it is not life threatening.

Naloxone should be part of an overall approach to known or suspected opioid overdose that incorporates the steps below.

RECOGNIZE THE SIGNS OF OVERDOSE. An opioid overdose requires rapid diagnosis. The most common signs of overdose include:[10]

- Unconsciousness or inability to awaken orally or upon sternal rub.
- Slow or shallow breathing or breathing difficulty such as choking sounds or a gurgling/snoring noise from a patient who cannot be awakened.
- Fingernails or lips turning blue/purple.
- Slow heartbeat and/or low blood pressure.

SUPPORT RESPIRATION. Supporting respiration is a critical intervention for opioid overdose and may be lifesaving on its own. Begin CPR (technique based on rescuer's level of training).[19] Ideally, individuals who are experiencing opioid overdose should be ventilated with oxygen before naloxone is administered to reduce the risk of acute lung injury.[2]

ADMINISTER NALOXONE. Naloxone competitively binds opioid receptors and is the antagonist of choice for the reversal of acute opioid toxicity. Naloxone should be administered to anyone who presents with signs of opioid overdose or when opioid overdose is suspected. Naloxone can be given by injection intranasally, intramuscularly, subcutaneously, or intravenously.[12]

PREGNANT PATIENTS. Naloxone can be used in life-threatening opioid overdose circumstances in pregnant women.[14]

MONITOR THE PATIENT'S RESPONSE. Patients should be monitored for reemergence of signs and symptoms of opioid toxicity for at least 4 hours following the last dose of naloxone; however, patients who have overdosed on long-acting opioids require more prolonged monitoring.[2,13]

Most patients respond to naloxone by returning to spontaneous breathing, with mild withdrawal symptoms.[2] The response generally occurs within 2 to 3 minutes of naloxone administration. Continue rescue breathing while waiting for the naloxone to take effect.

The duration of effect of naloxone depends on dose and route of administration and is shorter than the effects of some opioids. Patients should be observed after administration for reemergence of overdose symptoms. The goal of naloxone therapy should be restoration of adequate spontaneous breathing, but not necessarily complete arousal.[22]

More than one dose of naloxone may be required to revive the patient. Those who have

taken longer-acting opioids or opioid partial agonists may require additional doses, additional intravenous bolus doses, or an infusion of naloxone.[13] Therefore, it is essential to get the person to an emergency department or other source of acute care as quickly as possible, even if the person revives after the initial dose of naloxone and seems to feel better.

SIGNS OF OPIOID WITHDRAWAL. Withdrawal triggered by naloxone can feel unpleasant. Some people may become agitated or confused, which may improve by providing reassurance and explaining what is happening. The signs and symptoms of opioid withdrawal in an individual who is physically dependent on opioids may include body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection (gooseflesh), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, tearing, insomnia, opioid craving, dilated pupils, and increased blood pressure.[23] These symptoms are uncomfortable, but not life threatening unless vomiting and diarrhea result in extreme dehydration. After an overdose, a person dependent on opioids should be medically monitored for safety and offered treatment for OUD.

NO REPONSE TO NALOXONE. If a patient does not respond to naloxone, an alternative explanation for the clinical symptoms should be considered. The most likely explanation is that the person is not overdosing on an opioid but rather some other substance or may even be experiencing a non-overdose medical emergency.

Support of ventilation, oxygenation, and blood pressure should be sufficient to prevent the complications of opioid overdose and should be given the highest priority if the patient's response to naloxone is not prompt.

FENTANYL-INVOLVED OVERDOSE. Suspected opioid overdoses, including suspected fentanyl-involved overdoses, should be treated according to standard protocols.[16,17] However, because of the higher potency of fentanyl and fentanyl analogs compared to that of heroin, larger doses of naloxone may be required to reverse the opioid-induced respiratory depression from a fentanyl-involved overdose.[11,15,16,17]

Many anecdotal accounts report more rapid respiratory depression with fentanyl than with heroin, although other reports do not reflect such rapid depression.[17]

Because of these effects, quicker oxygenation efforts and naloxone delivery may be warranted compared to heroin-only overdose. However, naloxone is an appropriate response for all opioid overdoses, including fentanyl-involved overdoses.

NOTE: All naloxone products have an expiration date. It is important to check the expiration date and obtain replacement naloxone as needed.

LEGAL AND LIABILITY CONSIDERATIONS

Health care professionals who are concerned about legal risks associated with prescribing naloxone may be reassured that prescribing naloxone to manage opioid overdose is consistent with the drug's FDA-approved indication, resulting in no increased liability so long as the prescriber adheres to general rules of professional conduct. Most state laws and regulations now permit physicians to prescribe naloxone to a third party, such as a caregiver.[8] More information on state policies is available from the Prescription Drug Abuse Policy System's Naloxone Overdose Prevention Laws web page (http://www.pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139) or from individual state medical boards.

CLAIMS CODING AND BILLING

Most private health insurance plans, Medicare, and Medicaid cover naloxone for the treatment of opioid overdose, but policies vary by state. The cost of take-home naloxone should not be a prohibitive factor. Many community pharmacies stock naloxone routinely, and those that do not can always order it. If you are caring for a large population of patients who are likely to benefit from naloxone, you may wish to notify the pharmacy when you implement naloxone prescribing as a routine practice.

The codes for Screening, Brief Intervention, and Referral to Treatment (SBIRT) can be used to bill time for counseling a patient about how to recognize overdose and how to administer naloxone. Billing codes for SBIRT are as follows:

- Commercial Insurance: CPT 99408 (15 to 30 minutes), 99409 (greater than 30 minutes)
- Medicare: G0396 (15 to 30 minutes), G0397 (greater than 30 minutes)
- Medicaid: H0049 (alcohol and/or drug screening), H0050 (alcohol and/or drug screening, brief intervention, per 15 minutes)

For counseling and instruction on the safe use of opioids, including the use of naloxone outside the context of SBIRT services, the provider should document the time spent in medication education and use the E&M (Evaluation and Management) code that accurately captures the time and complexity. For example, for new patients deemed appropriate for opioid pharmacotherapy and when a substantial and an appropriate amount of additional time is used to provide a separate service such as behavioral counseling (e.g., opioid overdose risk assessment, naloxone administration training), consider using modifier–25 in addition to the E&M code.

In addition, when using an evidence-based opioid use disorder or overdose risk factor assessment tool/screening instrument, CPT Code 99420 (Administration and interpretation of health risk assessment instrument) can be used for patients with commercial insurance.

RESOURCES FOR PRESCRIBERS

Additional information on prescribing opioids for chronic pain is available at the following websites:

- https://www.opioidprescribing.com: Sponsored by the Boston University School of Medicine, with support from SAMHSA, the OpioidPrescribing.org site presents course modules on various aspects of prescribing opioids for chronic pain. Continuing medical education credits are available at no charge.
- https://pcssnow.org/: Sponsored by the American Academy of Addiction Psychiatry in collaboration with other specialty societies and with support from SAMHSA, the Providers Clinical Support System offers multiple resources related to opioid prescribing and the diagnosis and management of OUD. The site also is the source for Drug Addiction Treatment Act of 2000 waiver education requirements.
- https://www.drugabuse.gov/nidamed-medical-health-professionals/cmece-activities#opioids: NIDAMED's mission is to disseminate science-based resources to health professionals on the causes and consequences of drug use and addiction, and advances in pain management. Continuing medical education credits are available at no charge.
- https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm163647.htm: The Risk Evaluation and Mitigation Strategy website provides physician training and patient education on OUD treatment medications as required by the FDA for extended-release and long-acting opioid analgesics.
- http://prescribetoprevent.org: Compiled by prescribers, pharmacists, public health workers, lawyers, and researchers working on overdose prevention and naloxone access, this privately funded site provides health care providers with resources to educate patients on how to reduce overdose risk and provide naloxone rescue kits to patients.
- https://store.samhsa.gov/product/Medication-Assisted-Treatment-of-Opioid-Use-Disorder-Pocket-Guide/SMA16-4892PG: SAMHSA's *Medication-Assisted Treatment for Opioid Use Disorder Pocket Guide* provides practical information for clinicians on medications to treat OUD.
- https://store.samhsa.gov/product/SMA18-5063FULLDOC: SAMHSA's Treatment Improvement Protocol 63: *Medications for Opioid Use Disorders* provides in-depth information for health care and addiction professionals, policymakers, patients, and families.

WHAT ARE OPIOIDS?

Opioids include prescription medications used to treat pain such as morphine, codeine, methadone, oxycodone, hydrocodone, fentanyl, hydromorphone, and buprenorphine, as well as illicit drugs such as heroin.

Opioids work by binding to specific receptors in the brain, spinal cord, and gastrointestinal tract. In doing so, they diminish the body's perception of pain. However, opioids can also have an impact on other systems of the body, such as altering mood, slowing breathing, and causing constipation. Opioid receptor binding causes the signs and symptoms of overdose as well as the euphoric effects or "high" with opioid use.

A variety of effects can occur after a person takes opioids, ranging from pleasure to nausea and vomiting, severe allergic reactions (anaphylaxis), and overdose, in which breathing and heartbeat slow or even stop.

Opioid overdose can be due to many factors. For example, overdose can occur when a patient deliberately misuses a prescription, uses an illicit opioid (such as heroin), or uses an opioid contaminated with other even more potent opioids (such as fentanyl). Overdose can also occur when a patient takes an opioid as directed but the prescriber miscalculated the opioid dose, when an error was made by the dispensing pharmacist, or when the patient misunderstood the directions for use. It can also occur when opioids are taken with other medications—for example, prescribed medications such as benzodiazepines or other psychotropic medications that are used in the treatment of mental disorders—or with illicit drugs or alcohol that may have adverse interactions with opioids. At particular risk are individuals who use opioids and combine them with benzodiazepines, other sedative hypnotic agents, or alcohol, all of which cause respiratory depression.[2,24]

PREVENTING OVERDOSE

If you are concerned about your own use of opioids, don't wait! Talk with the health care professionals who prescribed the medications for you. If you are concerned about family members or friends, urge them to talk to whoever prescribed their medications.

Effective treatment of an opioid use disorder can reduce the risk of overdose and help a person who is misusing or addicted to opioid medications attain a healthier life. Opioid use disorder is a chronic disease, much like heart disease. An evidence-based practice for treating opioid addiction is the use of Food and Drug Administration-approved medications, along with counseling and other supportive services. These services are available at Substance Abuse and Mental Health Services Administration (SAMHSA)-certified and Drug Enforcement Administration-registered opioid treatment programs and from specialty substance use disorder treatment programs. In addition, physicians and other practitioners, including nurse practitioners and physician assistants who are trained to provide treatment for opioid addiction in office-based and other settings with medications such as buprenorphine/naloxone and naltrexone, may be available in your community. For more information, see the Resources section at the end of this toolkit.

IF YOU SUSPECT AN OVERDOSE

An opioid overdose requires immediate medical attention. An essential first step is to get help from someone with medical expertise as soon as possible. **Call 911 immediately** if you or someone you know exhibits any of the signs listed below. All you have to say is "Someone is unresponsive and not breathing." Give a specific address and/or description of your location.

Signs of **OVERDOSE,** which is a life-threatening emergency, include the following:

- The face is extremely pale and/or clammy to the touch.
- The body is limp.
- Fingernails or lips have a blue or purple cast.
- The person is vomiting or making gurgling noises.
- The person cannot be awakened from sleep or cannot speak.
- Breathing is very slow or stopped.
- The heartbeat is very slow or stopped.

Signs of **OVERMEDICATION**, which may progress to overdose, include:

- Unusual sleepiness or drowsiness.
- Mental confusion, slurred speech, or intoxicated behavior.
- Slow or shallow breathing.
- Extremely small “pinpoint” pupils.
- Slow heartbeat or low blood pressure.
- Difficulty being awakened from sleep.

WHAT IS NALOXONE?

Naloxone is an antidote to opioid overdose. It is an opioid antagonist that is used to reverse the effects of opioids. Naloxone works by blocking opioid receptor sites. It is not effective in treating overdoses of benzodiazepines, barbiturates, clonidine, GHB, or ketamine. It is also not effective in treating overdoses of stimulants such as cocaine and amphetamines (including methamphetamine and MDMA). However, if opioids are taken in combination with other sedatives or stimulants, naloxone may be helpful.

Suspected fentanyl-involved overdoses should be treated with naloxone.[17] However, because of the higher potency of fentanyl and fentanyl analogs compared to that of heroin, larger doses of naloxone may be required to reverse the opioid-induced respiratory depression from a fentanyl-involved overdose.[11,15,17] Quicker oxygenation efforts and naloxone delivery may be warranted compared to heroin-only overdose.

NALOXONE STORAGE

Store naloxone in a safe and quickly accessible place at room temperature and protected from light. Keep all medicine in a safe place where children or pets cannot reach it.

SUMMARY: HOW TO AVOID OPIOID OVERDOSE

1. Take medication only if it has been prescribed to you by your doctor. Make sure to tell your doctor about all medications you are taking.
2. Do not take more medication or take it more often than instructed.
3. Call your doctor if your pain gets worse.
4. Never mix pain medications with alcohol, sleeping pills, or any illicit substance.
5. Learn the signs of overdose and how to use naloxone to keep an overdose from becoming fatal.
6. Teach your family members and friends how to respond to an overdose.
7. Dispose of unused medication properly.

READ MORE. The Food and Drug Administration’s naloxone webpage provides more information at https://www.fda.gov/-drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm472923.htm.

RESOURCES FOR OVERDOSE SURVIVORS AND FAMILY MEMBERS

Survivors of opioid overdose have experienced a life-changing and traumatic event. They have had to deal with the emotional consequences of overdosing, which can involve embarrassment, guilt, anger, and gratitude, all accompanied by the discomfort of opioid withdrawal. Most need the support of family and friends to take the next steps toward recovery.

While many factors can contribute to opioid overdose, it is almost always an accident. Moreover, the underlying problem that led to opioid use—most often pain or substance use disorder—still exists and continues to require attention.[14]

The individual who has experienced an overdose is not the only one who has endured a traumatic event. Family members often feel judged or inadequate because they could not prevent the overdose. It is important for family members to work together to help the overdose survivor obtain the help that he or she needs.

FINDING A NETWORK OF SUPPORT

As with any health condition, it is not a sign of weakness to admit that a person or a family cannot deal with overdose and its associated issues without help. It takes real courage to reach out to others for support and to connect with members of the community to get help.

Health care providers, including those who specialize in treating substance use disorders, can provide structured, therapeutic support and feedback.

If the survivor's underlying problem is pain, referral to a pain specialist may be in order. If it is addiction, the patient should be referred to an addiction specialist for assessment and treatment by a physician specializing in the treatment of opioid addiction in a residential treatment program or in a federally certified opioid treatment program. In each case, counseling can help the individual manage his or her problems in a healthier way. The path to recovery can be a dynamic and challenging process, but there are ways to help.

In addition to receiving support from family and friends, overdose survivors can access a variety of community-based organizations and institutions, such as:

- Health care and behavioral health providers.
- Peer-to-peer recovery support groups such as Narcotics Anonymous.
- Faith-based organizations.
- Educational institutions.
- Neighborhood groups.
- Government agencies.
- Family and community support programs.

RESOURCES

Substance Abuse and Mental Health Services Administration (SAMHSA)

- National Helpline: 1-800-662-HELP (4357) or 1-800-487-4889 (TDD, for hearing impaired)
- Behavioral Health Treatment Services Locator (search by address, city, or ZIP Code): https://findtreatment.samhsa.gov/
- Buprenorphine Treatment Practitioner Locator (search by address, city, or ZIP Code): https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator
- Single State Agencies for Substance Abuse Services: https://www.samhsa.gov/sites/default/files/ssa-directory.pdf
- State Opioid Treatment Authorities: https://dpt2.samhsa.gov/regulations/smalist.aspx
- SAMHSA Publications Ordering (all SAMHSA Store products are available at no charge): https://store.samhsa.gov; 1-877-SAMHSA-7 (1-877-726-4727)

Centers for Disease Control and Prevention (CDC)

- Understanding the Epidemic: https://www.cdc.gov/drugoverdose/epidemic
- Poisoning: https://www.cdc.gov/homeandrecreationalsafety/poisoning
- CDC Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/drugoverdose/prescribing/guideline.html

Faces & Voices of Recovery

- Shaping the Future of Recovery: https://facesandvoicesofrecovery.org/

Project Lazarus

- Learn About the Project Lazarus Model: https://www.projectlazarus.org

Harm Reduction Coalition

- Main Page: http://www.harmreduction.org

Prevent & Protect

- Tools for conducting overdose prevention and naloxone advocacy, outreach, and communication campaigns: http://prevent-protect.org/community-resources-1/

Prescribe to Prevent

- Prescribe Naloxone, Save a Life: http://prescribetoprevent.org

SAMHSA does not specifically endorse any group, and appropriateness should be determined at the local level. Many groups are appropriate for loved ones and family members. Referrals are encouraged to groups that have received explicit endorsements from those who have been intimately affected by opioid use and overdose.

- Grief Recovery After a Substance Passing is for those who have lost a loved one: http://grasphelp.org/.
- Learn 2 Cope is for families with loved ones who have a substance use disorder: https://www.learn2cope.org/.
- The International Overdose Awareness Day website has a list of worldwide events: https://www.overdoseday.com/.

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SAMHSA

Substance Abuse and Mental Health Services Administration

HHS Publication No. (SMA) 18 4742. First printed 2013. Revised 2014, 2016, 2018

Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

- ☐ Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- ☐ Check that non-opioid therapies tried and optimized.
- ☐ Discuss benefits and risks (eg, addiction, overdose) with patient.
- ☐ Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
- ☐ Set criteria for stopping or continuing opioids.
- ☐ Assess baseline pain and function (eg, PEG scale).
- ☐ Schedule initial reassessment within 1–4 weeks.
- ☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If RENEWING without patient visit

- ☐ Check that return visit is scheduled ≤3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- ☐ Assess pain and function (eg, PEG); compare results to baseline.
- ☐ Evaluate risk of harm or misuse:
  - Observe patient for signs of over-sedation or overdose risk.
    - – If yes: Taper dose.
  - Check PDMP.
  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    - – If yes: Refer for treatment.
- ☐ Check that non-opioid therapies optimized.
- ☐ Determine whether to continue, adjust, taper, or stop opioids.
- ☐ Calculate opioid dosage morphine milligram equivalent (MME).
  - If ≥50 MME/day total (≥50 mg hydrocodone; ≥33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid ≥90 MME/day total (≥90 mg hydrocodone; ≥60 mg oxycodone), or carefully justify; consider specialist referral.
- ☐ Schedule reassessment at regular intervals (≤3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (**PDMP**): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores
(30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your **pain** in the past week?*
0="no pain", 10="worst you can imagine"

Q2: *What number from 0–10 describes how, during the past week, pain has interfered with your **enjoyment of life**?*
0="not at all", 10="complete interference"

Q3: *What number from 0–10 describes how, during the past week, pain has interfered with your **general activity**?*
0="not at all", 10="complete interference"

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

CS273808A

TO LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

ARCHBOLD
ADMINISTRATIVE POLICY MANUAL

POLICY NUMBER: 101.27

EFFECTIVE: September 2002

SUBJECT: Disclosing Unanticipated Adverse or Serious Reportable Events to Patients and Families

EXPIRES: When Superseded

REVIEWED: October 2023

APPROVED: _____
President

REVISED: October 2023

I. POLICY

Archbold Medical Center requires that patients and family members or designated representatives be fully informed of unanticipated adverse or serious reportable events, also known as never events, that reach patients under the following circumstances:

A. When there is clear or potential clinical significance.

B. When some unintended act or substance reaches the patient resulting in harm.

The decision to disclose will depend on the circumstances of the event.

II. PURPOSE

To describe the expectations and process for disclosing unanticipated adverse events to patients and families in accordance with Leapfrog's 9 Standards for Never Events Management (National Quality Forum).

III. SCOPE

This policy applies to all Archbold Medical Center physicians, nurses and other healthcare providers involved with patient care.

Related Policies: Sentinel Event/Root Cause Analysis and Reporting – Policy 101.17
Occurrence Reporting – Policy 110.22
Risk Management Reporting and Investigation Protocol for Significant Adverse, Sentinel, or Serious Reportable Events- Policy 101.48

IV. DEFINITIONS

ADVERSE EVENT: An adverse event is a patient safety event involving unintended actual or potential physical or psychological injury to a patient or that otherwise adversely affects the quality of service, operations, or reputation of the Medical Center. This includes:

- System error (latent error or failure) that reaches the patient.
- Unintended individual error.
- Events or acts with either actual or potential negative consequences for the patient.
- Errors of judgement and errors of action or inaction.

V. INSTRUCTIONS

Who should disclose an unanticipated adverse event?

It is recommended the attending physician should disclose the unanticipated adverse event; however, there may be times when it is appropriate for another healthcare provider to disclose the unanticipated adverse event. In this situation, disclosure should be coordinated with the attending physician. All disclosures should be coordinated through Risk Management of the Medical Center and the senior reporting officer of the individual entity. In the event the physician chooses not to disclose, a consult to the Chief of Staff and consult with the Chief Medical Officer or other appropriate personnel will be made. The Chief of Staff and/or the Chief Medical Officer or other appropriate personnel will have the authority to disclose to the patient/family. At least one other hospital staff person (clinician or administrative) should be present at the time of an initial disclosure and at subsequent planned discussions as appropriate.

When should unanticipated adverse events be disclosed?

As soon as reasonably possible after the adverse event occurred or is discovered or at the conclusion of a preliminary investigation/team meeting to gather the facts of the event.

What adverse events should be disclosed?

Any occurrence where patients are harmed by medical intervention. Examples of adverse events to be disclosed include but are not limited to the following (Refer to Policy 101.48 for list of adverse/serious reportable events):

- Major permanent or temporary loss of bodily function
- Infant abduction
- Infant discharged to the wrong family
- Actual or possible rape or sexual assault (by another patient or staff member)
- Hemolytic transfusion reaction
- Surgery on the wrong patient, body part, or wrong site
- Any other event equally significant to the above.

When there is uncertainty about the need to disclose an adverse event to a patient, Risk Management should be consulted.

Disclosure is a process. Do not feel compelled to answer all questions at the first meeting with the patient and/or family. Disclose only what is known at the time of the discussion. Avoid speculation.

Avoid attributing blame to specific individuals, but accept responsibility for actions and outcomes. Adverse events and errors are, however, rarely solely due to the action or inaction of a single individual.

An apology or an expression of sorrow is often appropriate and not necessarily an admission of guilt. Doing so at an early stage in the disclosure process can help prevent bad feelings and unnecessary legal or professional complaints.

Where the adverse event is particularly serious and/or unexpected, a family-team meeting, if done in an open and prompt way, with all relevant documentation and charts on hand can be helpful to clear the air of any worries of a "cover-up." Careful documentation of what is said by all parties in such meetings is essential. Appropriate hospital representatives may be involved in such meetings. Such meetings will be coordinated by Risk Management.

Emphasizing what will be done to prevent the same thing from happening to another patient may offer solace to affected patients/families.

What should the disclosure include?

- Truthful and compassionate explanation of the event including the time, place, circumstances, and the potential and actual consequences of the event for the patient, to the extent known
- Proximate cause of the event, if known
- Apology for the occurrence of the event as appropriate
- Assurance that a full analysis will take place or is currently in process
- Description of actions taken, if any, to identify system issues which may have contributed to the event and to prevent the same or similar events from occurring
- Name of individuals who will manage ongoing care of the patient
- Name of individuals who will manage ongoing communication with the family, including names and contact numbers of individuals to whom the patient and family members may address questions, complaints or concerns
- Description of process to waive costs directly related to the event
- Disclosure Policy 101.27 is available to patient, family, or payer upon request.

Documentation guidelines for each discussion with the patient or family

A note should be made in the chart at the time of disclosure listing the following elements:

- Time, date and place of discussion.
- Names and relationships of those present (or those on the phone) and of staff.
- Documentation of discussion of unanticipated outcome.
- Documentation of an offer to be of assistance (including persons/agencies provided as referral) and the response to it.
- Documentation of any follow-up conversations.
- Documentation of designated contact in Risk Management for assistance.

What resources are available to staff during this process?

Clinical Support:

When a major adverse event has taken place, the clinician is encouraged to seek support from the President of John D. Archbold Memorial Hospital, Chief Medical Officer, and Risk Management. The information should also be reported to the appropriate reporting officer/supervisor of nursing. If the adverse event occurred at a system hospital, the system hospital administrator should also be involved. We encourage the discussion of the event and its personal impact. If desired, resources are available within the Employee Assistance Program.

VI. JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A ARCHBOLD MEMORIAL, ARCHBOLD BROOKS, ARCHBOLD GRADY, ARCHBOLD MITCHELL, ARCHBOLD LIVING THOMASVILLE, ARCHBOLD LIVING CAMILLA, ARCHBOLD LIVING PELHAM, ARCHBOLD LIVING CAIRO); ARCHBOLD FOUNDATION, INC.; AND ARCHBOLD MEDICAL GROUP, INC.

A. As applicable

□AMH □BCH □GGH □MCH □GMNH □MCC □PPNH

ARCHBOLD MEDICAL CENTER
NURSING POLICY MANUAL

POLICY NUMBER: 59.0

EFFECTIVE: 2/25/92

SUBJECT: PHYSICIAN NOTIFICATION OF CHANGE IN PATIENT'S CONDITION.

EXPIRES: WHEN

REVIEWED: 9/16
REVISED: 9/15

APPROVED:_____
Amy Griffin, RN
VP of Patient Care Services

I. PURPOSE

To define the process used to notify the physician of a significant change in a patient's condition.

II. POLICY

It is the policy of Archbold Medical Center that all nursing personnel are responsible for reporting significant changes in a patient's condition immediately to the Charge Nurse who will notify the physician.

III. SPECIAL INSTRUCTIONS

A. All nursing personnel will report any significant change in the condition of a patient immediately to the Charge Nurse

.

B. The Charge Nurse will assess the patient and confer with the nurse providing care to the patient. The provider will be notified as appropriate and the Critical Assessment Team (CAT) or Code Blue can be called as necessary.

C. If a provider is paged for a change in a patient's condition, the provider should respond within 5 minutes. If there is no response within 5 minutes, they are to be called again. If the provider does not return the second call, the nursing supervisor or other designee should be notified. Other resources available are physicians within the group, in-house hospitalists (where applicable) or the Emergency Department provider.

D. If there is a Critical change in the patient's condition, the nurse will call a CAT. ICU nurses will page the hospitalist entering 911.

E. If change in condition warrants patient to be seen by Provider, Provider should respond within 20 minutes. Nurse should communicate specific details of patient condition and needs to the provider. If the physician does not respond within that 20 minute timeframe, follow the procedure as above (C) to ensure the emergency needs of the patient are met.

F. If the patient's condition continues to deteriorate despite orders received and the nurse is uncomfortable with the prescribed orders, the Nursing Supervisor or other designee should be notified. The physician should be made aware of the nurse's concerns and need to be seen. If the nurse continues to be concerned and feels

there is a life threatening situation, he/she should follow the procedure as above (C) to ensure the emergency needs of the patient are met.

G. Documentation of attempts to notify and notification with outcomes will be included in the nurses' notes.

H. Any licensed nurse may notify a physician of a change in a patient's condition if the Charge Nurse is not available to do so or has not done so in a timely manner.

HELPFUL CHECKLIST FOR CALLING PHYSICIANS

☐ 1. HAVE I ASSESSED THIS PATIENT MYSELF BEFORE I CALL?

☐ 2. ARE THERE PRE-WRITTEN ORDERS?

☐ 3. DO I HAVE ON HAND ---

- ☐ THE CHART?
- ☐ CURRENT LIST OF MEDICATIONS?
- ☐ MOST RECENT VITAL SIGNS?
- ☐ MOST RECENT LAB VALUES AVAILABLE?
- ☐ CODE STATUS

☐ 4. HAVE I READ THE MOST RECENT MD PROGRESS NOTES?

☐ 5. IF BETWEEN 11P-7A, HAVE I DISCUSSED THIS WITH THE NIGHT SUPERVISOR/CHARGE NURSE?

☐ 6. WHEN READY TO CALL PHYSICIAN, REMEMBER TO:

- ☐ IDENTIFY MYSELF, UNIT, PATIENT, ROOM NUMBER _____
- ☐ KNOW THE ADMITTING DIAGNOSIS AND DATE OF SURGERY _____
- ☐ BRIEFLY STATE THE PROBLEM, WHAT IT IS, WHEN IT HAPPENED OR STARTED, AND HOW SEVERE IT IS _____ _____ _____

☐ 7. DOCUMENTATION

- ☐ DR. _____ CALLED AT _____AM / PM
  DETAILS OF CONDITION _____ _____ _____

(ATTACH ADMINISTATION POLICY NO. 101.26)

□AMH □BCH □GGH □MCH □GMNH □MCC □PPNH

ARCHBOLD MEMORIAL HOSPITAL
NURSING POLICY MANUAL

POLICY NO. 139.0

EFFECTIVE DATE: NOVEMBER/2005

SUBJECT: CRITICAL ASSESSMENT TEAM (CAT)

EXPIRES: SUPERSEDED

APPROVED: _____
Amy Griffin, RN
VP of Patient Care Services

REVIEWED: 5/16

REVISED: 7/14

I. PURPOSE

To establish a resource for a rapid assessment of an inpatient with acute status changes. The goal of the CAT is to improve inpatient outcomes by providing a means for rapid and timely intervention of a declining patient.

II. CRITERIA GUIDELINES FOR INITIATING THE CAT

Any or all of the criteria meets the guidelines for initiating the CAT. The key to using the guidelines properly is the identification of a sudden acute change:

A. Acute and persistent changes in heart rate
B. Acute changes in blood pressure
C. Acute change in respiratory rate
D. Acute and persistent change in saturation < 90% with oxygen
E. Acute change in level of consciousness
F. Need for additional clinical opinion: Concerned, Unsure, Safety concern.

III. CAT STRUCTURE

The CAT is a team of clinicians who will bring critical care expertise to the declining patient's bedside/area. The CAT will consist of an ACLS trained Critical Care RN and an ACLS trained Respiratory Care Professional (RCP), the nurse caring for the patient, and the House Supervisor. The Critical Care Unit and the Respiratory Services Department are responsible for having a designated CAT responder on all shifts.

IV. ACTIVATION OF THE CAT

A. Any nurse may call for the CAT when rapid assessment and intervention is deemed necessary for a declining patient based on the criteria guidelines.
B. After a brief assessment, the nurse shall dial the operator by pressing the #6 and request the CAT and location needed or use responder system at Archbold.
C. Switchboard personnel, upon receiving a notification of a CAT event will page the CAT members to the appropriate location or use of responder will activate CAT members.
D. The primary nurse will place a call to the attending physician or designee to notify of patient's condition.

V. CAT RESPONSIBILITIES

A. A Critical Care RN, RCP, and phlebotomist and Hospitalist will respond to the page within 10 minutes.
B. The primary nurse or charge nurse shall have prepared for the team: The CAT documentation record, the patient's chart, current medications and recent vital signs.

C. The primary nurse must remain at the patient bedside and assist the CAT.

D. The primary nurse should be prepared to provide the following information upon arrival of the CAT:

What prompted the CAT call?
Current HR, RR, BP, Temp and SpO_2
Interventions already attempted & results
Code Status
Allergies
Pertinent Medications
Pertinent History
Recent Diagnostic Tests

E. The Critical Care RN is deemed team leader and will perform the initial assessment and assist the floor nurse with: physician communication, obtaining appropriate orders and initiation of physician orders.

F. The RCP will perform a complete respiratory assessment and initiate intervention as appropriate per policy guidelines.

G. The team will collaborate assessment findings and recommendations for intervention, immediately implement treatment or diagnostic services as appropriate per policy, call a Code Blue and initiate ACLS procedures as appropriate per Code Blue policy, assist with implementation of physician orders and assist transport of patient if necessary.

VI. ASSESSMENT GUIDELINES

The CAT will follow the IHI recommended SBAR process for assessing and communicating. SBAR is an acronym for **S**ituation, **B**ackground, **A**ssessment and **R**ecommendation.

A. The primary nurse will get a sample of the patient's history for the initial assessment.

Signs and symptoms
Allergies
Medications
Past medical/surgical history
Last meal
Events precipitating this occurrence

B. The Critical Care RN will perform the initial assessment to include and/or consider:

Vital signs
Blood glucose
Cardiac rhythm
Neurological status
Fluid status
Level of function
Skin condition
Swallow
Pain
Anxiety
Recent medication history
Lab values
Diagnostic test results

C. The RCP will perform the initial respiratory assessment to include and/or consider:

Breath sounds
Work of breathing
Ventilatory pattern and status
Chest assessment
Oxygenation
Airway clearance
Ventilation
Recent respiratory history (last treatment given)
Past respiratory history
LOC
Recent medication history
Pain and/or anxiety
Pertinent lab values
Pertinent diagnostic test results

VII. CAT IMMEDIATE INTERVENTIONS

A. The RCP may initiate the following prior to physician contact:

Measurement of oxygen saturation
Oral Suctioning
Placement of an oral airway
Oxygen application
Arterial Blood gas puncture and analysis
Cardiac monitoring

B. The RN may initiate the following prior to the physician contact:

Measurement of oxygen saturation
12 lead EKG
Cardiac monitoring
Oxygen application
Fingerstick Blood Glucose test
Establish Intravenous access

VIII. CAT EQUIPMENT

The following supplies and equipment may be needed:

A. Personal protective equipment should be available at the bedside.
B. Oxygen.
C. Suction regulator and canister, tubing, yankauer.
D. Suction regulator or unit
E. ABG kits
F. Hand-held nebulizer
G. Pulse oximeter
H. BP manometer and thermometer
I. EKG machine
J. Code cart and defibrillator should the event progress to a Code Blue
K. Medications as ordered
L. Doppler

IX. CAT DOCUMENTATION

A. The CAT will document on the designated CAT Documentation Record.
B. The nurse will properly transcribe physician orders in the patients' chart and MAR as indicated.
C. The document will be filed in the patient's chart under the progress notes section.
D. A copy submitted to the ICU Director.
E. The Code Blue Committee will review the CAT responses to identify opportunities for education and/or improvement.

X. COMMUNICATION

The Critical Care RN will communicate the assessment findings and recommendations of the team to the physician in the SBAR format.

ARCHBOLD MEDICAL CENTER
ADMINISTRATIVE POLICY MANUAL

POLICY NUMBER: 101.38

EFFECTIVE: May 2006

SUBJECT: Falls Prevention Program

EXPIRES: When Superseded

APPROVED: _____
President

REVIEWED: May 2023

REVISED: May 2023

I. PURPOSE

To provide maximum patient safety with established, standardized guidelines through the falls prevention program resulting in a reduction of adverse fall-events.

II. POLICY

Recognize that patients are individuals and risk factors for falls vary. The assessment of fall risks and implementation of fall prevention strategies are performed upon admission and throughout hospitalization. Ongoing fall prevention is achieved through effective multidisciplinary teamwork, evaluation and reassessment, referral, and communication between healthcare team members.

III. DEFINITIONS

A. A fall is defined as loss of upright position that results in landing on the floor, ground, or an object or furniture, or a sudden, uncontrolled, unintentional, non-purposeful, downward displacement of the body to the floor/ground or hitting another object like a chair or stair, excluding falls resulting from violent blows or other purposeful actions. (U.S. VA). According to CMS, an episode where a resident lost his/her balance and would have fallen, if not for staff/family intervention, is considered a fall (near miss) and should be reported.

B. A potential or actual fall may be defined as (but not limited to) any occurrence in which any of the following takes place:

1. A patient is found on the floor; unless evidence suggests otherwise, a fall is considered to have occurred.

2. A patient slides to the floor unassisted.

3. A patient rolls off a bed or chair and onto the floor.

4. A patient falls off or out of any equipment or apparatus used for therapy or transfer (e.g., wheelchair, stretcher).

5. A patient trips or slips and complains of or sustains a bodily injury.

6. A patient, visitor, or family member reports a fall.

7. A controlled fall or slump in which the patient is assisted to the floor by a hospital employee

IV. PROCEDURE

A. Assess all patients, ≥ 13 years of age, upon admission and reassess each shift, when transferred to another floor/unit, or if a fall occurs during hospitalization using the fall risk rating scale. The initial assessment will be performed by a licensed nurse using the Fall Rating and Functional Screen on the Admission Assessment.

B. Essential components of risk identification include the following risk factors:

1. Falls history
2. Mobility
3. Mentation
4. Medication
5. Chronic illness
6. Elimination

C. A fall risk score of 5 or greater will place the patient at high risk for falls.

D. Patient will be automatically placed on fall precautions if they have had a recent fall/condition/drug/diagnosis that may place the patient at risk for a fall. This includes, but is not limited to, patients utilizing a PCA, post-op patients, seizures, fainting, history or diagnosis of CVA with motor deficits.

E. If the patient is identified as high risk, a falls packet will be obtained. The packet includes a yellow armband that will be placed on the patient's wrist, yellow name tag placed outside the room door, Patient Fall Prevention brochure and a patient/family notification letter. Non-skid socks will also be provided to patients to assist with gait stability. Interventions that may be used to prevent falls are to keep bed in low position, ensure bed brakes are locked, keep call light within reach, check patient frequently, activate bed alarm, make sure night light is functional, and keep the room clutter free. Fall prevention plans are individualized based on the patient's risk factors and functional status. Other interventions may be utilized as well as those listed above.

F. Surgical/Procedural Areas:

1. All patients in the surgical/procedural areas are considered to be at high risk for falls due to the effects of surgical/procedural preparation, medications received and the procedure performed.

2. Previously stated measures will be implemented for patient safety.

G. Children <13 years of age will be placed automatically in fall prevention program (caregiver/parent must be present).

H. An electronic plan of care will be developed for the patient using nursing diagnosis potential for injury related to falls.

I If a patient is a fall risk and is to be transported within the system, the Secretary/Charge Nurse is to specify in the order comments section (for the transport team) that the patient is at risk for falls. The transporter will then assure the area to which the patient is transported understands the patient is a fall risk.

J. Restraints should not be used as a fall prevention measure unless the situation is considered an emergency. If restraints are used, Administrative Policy 101.21 will be followed by the licensed health care provider to ensure patient's safety.

K. In the event of a patient fall, a licensed healthcare provider will perform an assessment, and the primary physician/provider will be notified. If patient has bruising, swelling, abnormality, new pain, or change in pain, it will be reported to the physician/provider. Special consideration should be made if the patient has had recent orthopedic/neuro surgery. If the patient has recently taken or currently taking an anticoagulant, the provider should be alerted when notified of the fall.

L. An online occurrence report should be completed for all patient falls as described by the definition of a fall. Refer to Administrative Policy 110.22. The following is a guide for the reported incident severity level in the online occurrence reporting system:

1. Severity level 0 – No injuries; circumstances had the potential to cause harm (intentional slumps, controlled falls, eased to the floor by staff).

2. Severity level 1 – Event occurred but resulted in no harm/damage (patient actually fell but acquired no injury).

3. Severity level 2 – Event resulted in temporary or minor harm/damage; additional monitoring may be required (bruise, abrasion, skin tear, laceration, etc.).

4. Severity level 3 – Event resulted in permanent harm/damage; additional monitoring, prolonged stay (fractures, dislocations, etc.).

5. Severity level 4 – Event resulted in death.

V. DOCUMENTATION

A. Fall Risk Assessment will be completed on admission, with every shift assessment, and upon patient transfer to another nursing unit in the electronic medical record. If down time occurs, NS549 should be used for documentation.

The "Post Fall Documentation" assessment in the electronic medical record should be completed. Document any pertinent clinical changes, nursing intervention, safety precautions, patient and family instructions, and date and time of physician notifications.

C. Document safety measures used to prevent harm to patients assessed at risk for falls.

D. A post fall huddle will also occur, involving staff on the unit where the fall occurred. This is a time for staff to discuss why the fall may have occurred and how the fall could have been prevented in order to promote patient safety.

VI. The outpatient setting, with the exception of outpatient surgical/procedural areas, will determine if fall prevention measures are necessary based on presentation, ongoing observation, and diagnosis of each patient. Prevention measures will be individualized to meet the needs of each patient.

VII JOHN D. ARCHBOLD MEMORIAL HOSPITAL, INC. (INCLUDING OPERATIONS D/B/A BROOKS COUNTY HOSPITAL, GRADY GENERAL HOSPITAL, MITCHELL COUNTY HOSPITAL, GLENN MOR NURSING HOME, MITCHELL CONVALESCENT CENTER, PELHAM PARKWAY NURSING HOME)/ ARCHBOLD FOUNDATION, INC./ ARCHBOLD HEALTH SERVICES, INC./ ARCHBOLD MEDICAL ENTERPRISES, INC./ARCHBOLD MEDICAL GROUP, INC.

A. As applicable

XII. MEDICAL STAFF DISASTER ASSIGNMENTS

A. All physicians shall report to the Emergency Department to receive post assignments. No physician will perform any duties other than those assigned.

B. The Incident Commander in the hospital and the Chief Executive Officer of the hospital will work as a team to coordinate activities and directions. (Incident Commander: Administrator on Call; CEO; or the CEO designee)

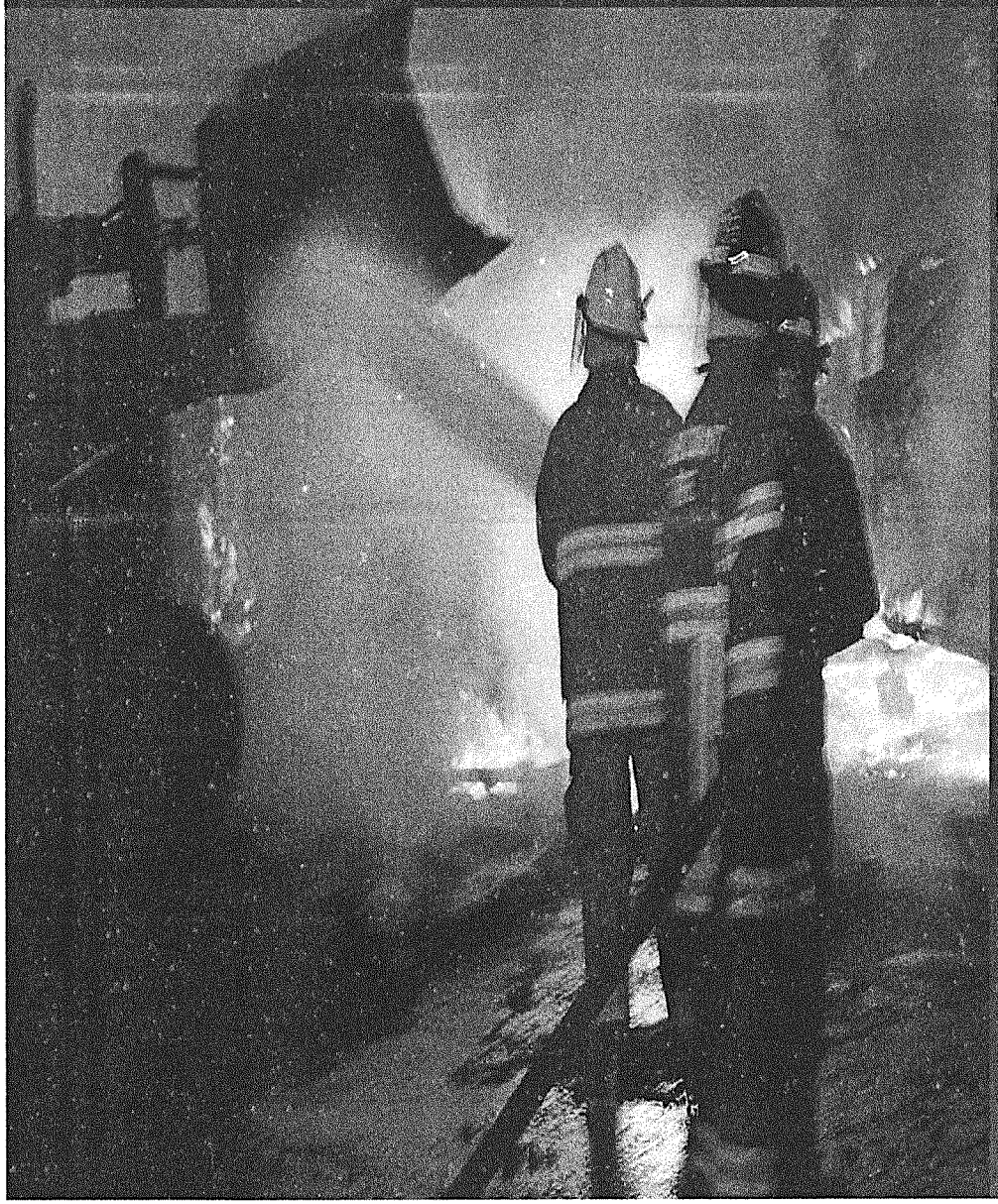
C. In cases of evacuation of patients from one section of the hospital to another, or evacuation from hospital premises, the Incident Commander during the disaster will authorize the movement of patients.

D. All policies concerning patient care will be the joint responsibility of the Chief of Medicine/Family Medicine, Ob-Gyn/Pediatrics, Emergency Medicine, Surgery/Anesthesiology and Supportive & Diagnostic Departments and the Chief Executive Officer of the hospital and in their absence, the duty Chief and alternate in administration, or next in line of authority, respectively.

E. All physicians on the medical staff of Archbold Hospital specifically agree to relinquish direction of the professional care of their patients, service or private, to the Emergency Medicine and Surgery Department Chair in case of such emergencies.

Annual Safety Update

CODE RED



- Fire
- R.A.C.E.
  - R- Rescue or Remove Patient
  - A- Alert Others
    - Pull fire alarm
  - C- Contain Fire
  - E- Extinguish Fire

How Do I Fight The Fire?

- Remove Debris
- Close Doors
- P.A.S.S.
  - Pull The Pin
  - Aim
  - Squeeze The Handle
  - Sweep At The Base of Fire

SAFETY/EMERGENCY PREPAREDNESS

Safety and emergency preparedness are of utmost importance at the Medical Center. Listed below are the emergency codes used. Should you be here when a code is called, immediately find your supervisor/preceptor or a staff member and do as you are told.

Code Black Bomb Threat

If there is a true bomb emergency, the hospital operator will announce "Code Black" 3 times followed by instructions.

Code Blue/ Code Blue Peds CPR

These codes are used when a cardiac or respiratory arrest occurs. Code Blue indicates adult and Code Blue Ped indicates pediatric. All of our staff have been trained in CPR and the proper response in the hospital setting. The hospital operator will announce "Code Blue and the location of the victim 3 times. (Code Blue room 101)" If you are in a patient's room or alone with a patient, and the patient has no pulse or respiration, notify someone in charge immediately to determine if the patient is a "No Code". If not, CPR should be initiated immediately and the code protocol activated. This is done by dialing 6 on the nearest telephone and advising the operator of the exact location of the incident. Each area has a "crash cart" specifically stocked for code situations. An Ambu bag and code kit are located on the top of these carts. Please locate them and become familiar with them. The quicker the CPR is administered the better the outcome for the patient. Please remain in your designated area during this event.

Code Decon Decontamination

Many materials found in the community and hospital can be health hazards if not managed properly. Many governmental regulations require the safe handling, transportation, use, and storage of these materials. The hospital has also taken action to reduce the threat of internal hazardous materials exposure by limiting the amounts of chemicals stored at the facility and within the departments. In light of these regulations and safe practices, accidents will occur. The hospital trains staff members working with hazardous materials in proper utilization and handling, thus decreasing the likelihood of an incident within the hospital.

Code Green

Manpower Needed

The Code Green Emergency Call System is established to provide help to personnel for assisting with the care of patients and their families. Code Green is a twenty-four (24) hour emergency code to be used only in the situation whereby the hospital personnel in the immediate area needs assistance with a client such as lifting or moving a client, and in extreme cases, the physical health of the person or others is in danger or where for some other impelling reason extra manpower is needed immediately. Mitigation for manpower assistance is difficult; however, the hospital has purchased equipment to assist staff in lifting patients.

A Code Green may be called after an unruly patient overwhelms security staff and additional assistance is needed. The hospital has a close relationship with local law enforcement to assist as needed.

Code Grey Violent Event

Violence is random and unpredictable. This makes mitigation of these events difficult if not impossible. Through increased overall security, staff alertness, s and observations the risk can be lessened. Limited access doors are in areas of higher risk with general video monitoring of the facility. Additionally, we have a visible presence of security officers roving the facility and campus.

Code Silver Extreme Violent Event

Extreme violence is random and very unpredictable. This makes mitigation of these events difficult if not impossible. Through increased overall security, staff alertness, and observations the risk can be lessened. Limited access doors are in areas of higher risk with general video monitoring of the facility. Additionally, we have a visible presence of security officers roving the facility and campus. We use the standard set forth by the US Department of Homeland security on how to respond to this event with avoid, barricade, and fight.

Code Lockdown Secure the Building

It is the policy of this facility to provide a safe environment for our patients and visitors. Code Lock-Down will be announced to alert hospital staff in the event the Hospital needs to be secured to prevent unauthorized entry or exit.

Code Orange Hazardous Materials

Many materials found in the community and hospital can be health hazards if not managed properly. Many governmental regulations require the safe handling, transportation, use, and storage of these materials. The hospital has also taken action to reduce the threat of internal hazardous materials exposure by limiting the amounts of chemicals stored at the facility and within the departments. In light of these regulations and safe practices, accidents will occur. The hospital trains staff members working with hazardous materials in proper utilization and handling, thus decreasing the likelihood of an incident within the hospital.

Code Pink Infant Abduction

Used for a child up to the age of 12 years old is kidnapped. The operator will announce, "Code Pink: followed by the age and the sex of the child. (Ex. Code Pink, zero, female) Upon activation of this code, all hospital entrances and exits are closed and no one is allowed in or out of the building until "Code Pink all clear" has been announced 3 times by the operator. During this event, all staff members will be searching for a person with an infant or child fitting the description given by the victim. If the victim is an infant or small child, any items that are of sufficient size to conceal the child will also be searched. Please remain in your clinical area until the "Code Pink all clear" has been announced.

Code Red Fire

This is the code for fire or smoke, one of the most life-threatening situations that can occur in any healthcare facility. Every hospital employee receives fire safety education on an annual basis as well as frequently conducted drills. There is a good possibility that you will be here during a drill. The hospital operator will announce "Code Red" and the location 3 times. The staff will ask patients and visitors to remain in the patient's room with the door closed. If you are leaving any area of the hospital when the announcement is made DO NOT GET ON AN ELEVATOR and DO NOT WALK THROUGH CLOSED FIRE DOORS, remain where you are. Should you discover a fire, DO NOT SHOUT FIRE. Remove people from the room or immediate vicinity, close the door and pull the fire alarm. Once the fire has been contained and no danger exists, the hospital operator will announce "Code Red all clear" 3 times. Please look for the fire alarm boxes and fire extinguishers wherever you are in the hospital.

Code Triage

This code is used in the event of a disaster. Our hospital has a disaster plan designed to provide care for a large number of people. Twice a year the hospital conducts a disaster drill. Each department and nursing unit is assigned certain duties, such as setting up a first aid station. The hospital operator will announce "Code Triage" 3 times followed by an explanation and instructions for visitors and hospital staff.

Code Weather Severe Weather

Thunderstorm warnings, tornado watch, tornado warnings.

mln
FACT SHEET
KNOWLEDGE • RESOURCES • TRAINING

A Prescriber's Guide to Medicare Prescription Drug (Part D) Opioid Policies

What's Changed?

No substantive content updates.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

Medicare Part D opioid policies encourage collaboration among Part D plans, prescribers, and pharmacies to:

- Manage opioid use
- Prevent misuse
- Reduce serious adverse risks
- Promote safe prescribing practices

Prescribers like you play a vital role in identifying and managing potential opioid overuse in the Part D population. Medicare drug plans can help by alerting you about unusual patterns in prescription claims.

Our Medicare Part D opioid policies include:

- Real-time safety alerts when pharmacies dispense opioid prescriptions
- Drug management programs (DMPs) to identify and manage high-risk opioid use

Real-Time Safety Alerts at the Pharmacy

Part D plans use safety alerts, or pharmacy claim edits, to help prevent unsafe drug usage. Pharmacists review the safety alerts when they dispense the medication. Safety alerts are typically for:

- Drug interactions
- Therapeutic duplication
- Potentially incorrect drug dosage

There are 4 different opioid-specific safety alerts and actions you can take to help your patients:

1. **Seven-day supply limit for opioid naïve patients**

- This alert limits initial opioid fills for Part D patients who haven't filled an opioid prescription recently, such as within the past 60 days, to a supply of 7 days or less.
- This alert shouldn't affect patients who already take opioids. It may occur for those who enroll in a new plan that doesn't know their current prescription information.
- Pharmacists can dispense partial quantities of an opioid prescription consistent with state and federal regulations.
- Once the patient fills an initial opioid prescription, including a partial fill up to a 7-day supply, additional prescriptions filled within the plan's look back window aren't subject to the 7-day limit.
- Consider requesting a coverage determination before prescribing an opioid if the patient will need more than a 7-day supply and hasn't filled an opioid prescription recently.

2. Opioid care coordination alert at 90 morphine milligram equivalent (MME)

- This alert triggers when a patient's cumulative MME per day for all of their opioid prescriptions reaches or exceeds 90 MME.
- The pharmacist may call to confirm the dose and medical need for the prescription that prompts the alert, even if it's below 90 MME.
- This consultation usually occurs once per plan year. Your staff or a covering physician may confirm medical necessity on your behalf. Once confirmed, the pharmacist can then document the consultation so the claim can pay.
- Some plans use this alert only when the patient also uses multiple opioid prescribers or pharmacies. The pharmacist may tell you if a patient's MME is increasing or if there are other opioid prescribers.

3. Concurrent opioid and benzodiazepine use or duplicative long-acting opioid therapy

- This alert triggers when a patient fills multiple long-acting opioids or opioids and benzodiazepines
- The pharmacist may conduct additional safety reviews and may contact you
- The pharmacist can enter an override code that allows the claim to pay

4. Optional Safety Alert at 200 MME or more

- Plans may use this alert when a patient's cumulative opioid daily dosage reaches or exceeds 200 MME with or without multiple opioid prescribers or pharmacies
- This alert stops the pharmacy from processing the prescription under Part D unless it's overridden due to an exemption or the plan authorizes coverage through a coverage determination or appeal

Safety alerts aren't prescribing limits. You and your patient make decisions to taper or discontinue prescription opioids. If a prescription triggers an opioid safety alert that shouldn't apply, the pharmacist can enter or request an override that allows the claim to pay per the exemptions below.

Coverage Determinations

If an opioid safety alert can't be resolved at the point-of-sale (POS), the pharmacist will provide the patient with a written copy of the standardized CMS pharmacy notice, Medicare Prescription Drug Coverage and Your Rights.

The patient, their representative, or their prescriber has the right to request a standard or expedited coverage determination from the plan at any time, including before the pharmacy gets the prescription.

Coverage determination requests meet the criteria for expedited review if you show, or the plan decides, that applying the standard timeframe may seriously jeopardize the patient's life, health, or ability to regain maximum function.

Timeframes are as follows:

- Standard: no later than 72 hours after the plan gets the request
- Expedited: no later than 24 hours after the plan gets the request

Drug Management Programs (DMPs)

All Part D plans have a DMP that limits access to controlled substances that are frequently abused drugs, currently defined as opioids and benzodiazepines, for patients at risk for prescription drug abuse or misuse. The goal of DMPs is better care coordination for safer use of these drugs.

CMS or Part D plans identify potential at-risk patients based on opioid use involving multiple doctors and pharmacies or a history of opioid-related overdose. Plans must review all potential at-risk patients and must ask your opinion before implementing a limitation. Your input is a key component of DMPs. By responding to the plan quickly, you can make sure that your patients get the care they need while reducing the need for appeals.

During case management, the plan may ask you:

- Are the prescribed opioid medications appropriate, medically necessary, and safe for the patient's medical condition and treatment
- Is the patient at risk for misusing or abusing opioids or benzodiazepines
- Would 1 of the DMP coverage limitations help you better manage your patient's prescription drug use

There are 3 coverage limitations available under a DMP:

- **Patient-specific POS claim alert:** restricts all frequently abused drugs or sets limitations to specific drugs or specific amounts. The plan will attempt to get your agreement for this limitation, but can implement it if you don't respond.
- **Pharmacy limitation:** requires the patient to get prescriptions for frequently abused drugs at certain pharmacies. The plan will attempt to get your agreement for this limitation, but can implement it if you don't respond. Patients can generally choose, and update, their preferred pharmacies.
- **Prescriber limitation:** requires the patient to get their prescriptions from certain prescribers. Patients can generally choose, and update, their preferred prescribers. The plan can't implement this limitation unless the selected prescribers agree.

After conducting case management, the plan will decide whether the patient is at risk and whether to implement a coverage limitation. If the plan determines the patient is at risk, it will notify the patient in writing that it intends to implement a coverage limitation.

The patient, their representative, or you on their behalf may respond to the notice. After 30 days, the plan will send the patient a second notice confirming the coverage limitation and its duration. The plan can put coverage limitations in place for 1 year and extend them for another year for a total of 2 years. If the plan determines the patient isn't at risk, it will send a notice confirming that no coverage limitation will be implemented.

Plans must make reasonable efforts to send copies of all DMP notices to involved prescribers.

Appealing an At-risk Determination

A patient, their representative, or you on their behalf may request an expedited or standard appeal ("redetermination") of an at-risk determination, as well as any coverage determination, made under a DMP. An appeal request must be made within 60 calendar days from the date of the second written notice.

Redetermination timeframes are as follows:

- Standard: no later than 7 days after the plan gets the request
- Expedited: no later than 72 hours after the plan gets the request

Exemptions

Patients in long-term care facilities, those getting hospice, palliative, or end-of-life care, those with sickle cell disease, or those being treated for active cancer-related pain are exempt from opioid safety alerts and DMPs.

These policies don't impact access to medication-assisted treatment (MAT) such as buprenorphine.

How You Can Help

Ongoing communication among the pharmacist, plan, and prescriber is critical. You can protect your patients' access to medically necessary prescription drug therapy by:

- Responding to calls and case management notices as soon as possible
- Educating on-call prescribers and office staff
- Requesting a coverage determination before prescribing

Many patients may not understand the risk of using opioids and may underestimate their chances of overdosing. You may want to consider co-prescribing naloxone, and talk with your patients about:

- The risks of an accidental overdose
- Whether opioids are the best treatment
- If there are other options to help manage their pain with less risk

You should also consider assessing your patients' behavioral health care needs as part of overall pain management, including screening for opioid use disorder or the need for MAT.

Prescriber Resources

- CDC's Opioid Prescribing Guideline
- HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics
- HHS Opioids Webpage
- Improving Drug Utilization Review Controls in Part D
- MLN Matters® Article SE19011
- Opioid Treatment Programs (OTP)
- Resources to Reduce Opioid Misuse

Patient Resources

- Pain Management Insurance Coverage
- Safer Use of Opioid Pain Medication

Medicare Fraud & Abuse: Prevent, Detect, Report

Table of Contents

Table of Contents (cont.)

Updates

- Note: No substantiative content updates.

Medicare Fraud and Abuse: A Serious Problem That Needs Your Attention

Although no precise measure of health care fraud exists, those who exploit Federal health care programs can cost taxpayers billions of dollars while putting beneficiaries' health and welfare at risk. The impact of these losses and risks magnifies as Medicare continues to serve a growing number of beneficiaries.

Most physicians try to work ethically, provide high-quality patient medical care, and submit proper claims. Trust is core to the physician-patient relationship. Medicare also places enormous trust in physicians. Medicare and other Federal health care programs rely on physicians' medical judgment to treat patients with appropriate, medically necessary services, and to submit accurate claims for Medicare-covered health care items and services.

You play a vital role in protecting the integrity of the Medicare Program. To combat fraud and abuse, you must know how to protect your organization from engaging in abusive practices and violations of civil or criminal laws. This booklet provides the following tools to help protect the Medicare Program, your patients, and yourself:

- Medicare fraud and abuse examples
- Overview of fraud and abuse laws
- Government agencies and partnerships dedicated to preventing, detecting, and fighting fraud and abuse
- Resources for reporting suspected fraud and abuse

Help Fight Fraud by Reporting It

The Office of Inspector General (OIG) Hotline accepts tips and complaints from all sources on potential fraud, waste, and abuse. View instructional videos about the OIG Hotline operations, as well as reporting fraud to the OIG.

Health care professionals who exploit Federal health care programs for illegal, personal, or corporate gain create the need for laws that combat fraud and abuse and ensure appropriate, quality medical care.

Physicians frequently encounter the following types of business relationships that may raise fraud and abuse concerns:

- Relationships with payers
- Relationships with fellow physicians and other providers
- Relationships with vendors

These key relationships and other issues addressed in this booklet apply to all physicians, regardless of specialty or practice setting.

What Is Medicare Fraud?

Medicare **fraud** typically includes any of the following:

- Knowingly submitting, or causing to be submitted, false claims or making misrepresentations of fact to obtain a Federal health care payment for which no entitlement would otherwise exist
- Knowingly soliciting, receiving, offering, or paying remuneration (e.g., kickbacks, bribes, or rebates) to induce or reward referrals for items or services reimbursed by Federal health care programs
- Making prohibited referrals for certain designated health services

Case Studies

To learn about real-life cases of Medicare fraud and abuse and the consequences for culprits, visit the Medicare Fraud Strike Force webpage.

Anyone can commit health care fraud. Fraud schemes range from solo ventures to widespread activities by an institution or group. Even organized crime groups infiltrate the Medicare Program and operate as Medicare providers and suppliers. Examples of Medicare fraud include:

- Knowingly billing for services at a level of complexity higher than services actually provided or documented in the medical records
- Knowingly billing for services not furnished, supplies not provided, or both, including falsifying records to show delivery of such items
- Knowingly ordering medically unnecessary items or services for patients
- Paying for referrals of Federal health care program beneficiaries
- Billing Medicare for appointments patients fail to keep

Defrauding the Federal Government and its programs is illegal. Committing Medicare fraud exposes individuals or entities to potential criminal, civil, and administrative liability, and may lead to imprisonment, fines, and penalties.

Criminal and civil penalties for Medicare fraud reflect the serious harms associated with health care fraud and the need for aggressive and appropriate intervention. Providers and health care organizations involved in health care fraud risk being excluded from participating in all Federal health care programs and losing their professional licenses.

What Is Medicare Abuse?

Abuse describes practices that may directly or indirectly result in unnecessary costs to the Medicare Program. Abuse includes any practice that does not provide patients with medically necessary services or meet professionally recognized standards of care.

The difference between “fraud” and “abuse” depends on specific facts, circumstances, intent, and knowledge.

Examples of Medicare abuse include:

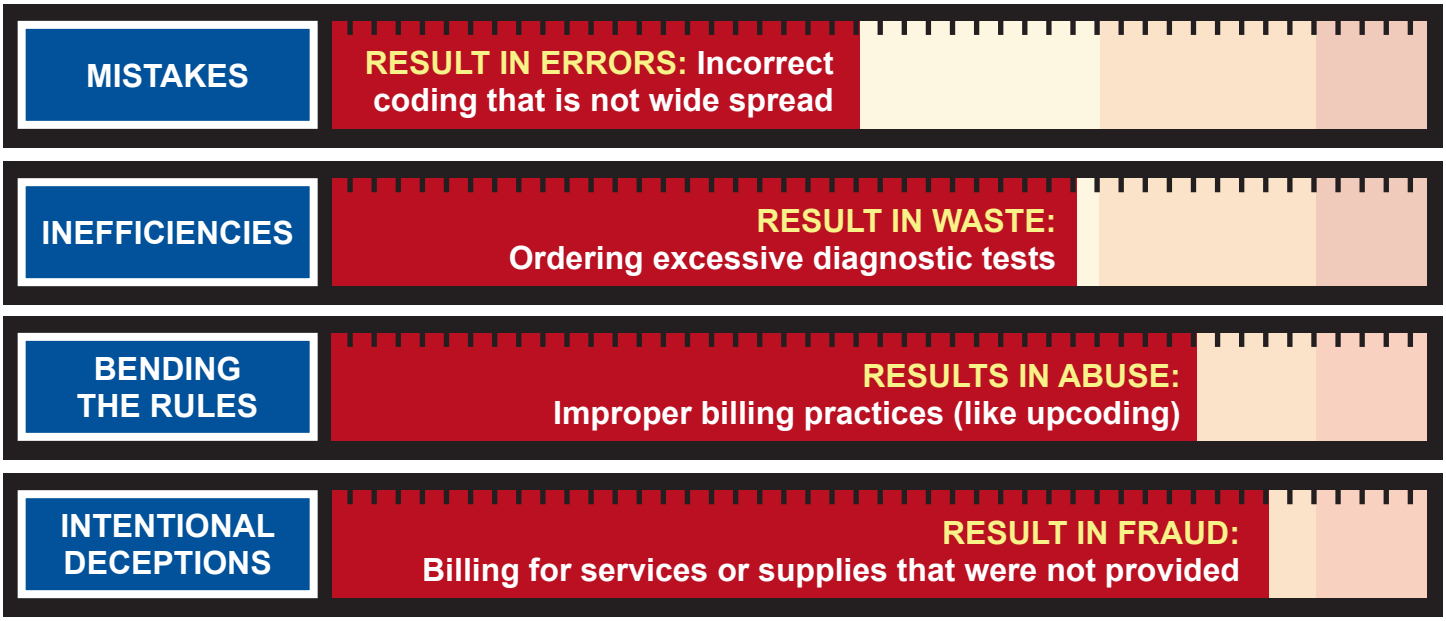
- Billing for unnecessary medical services

- Charging excessively for services or supplies
- Misusing codes on a claim, such as upcoding or unbundling codes. Upcoding is when a provider assigns an inaccurate billing code to a medical procedure or treatment to increase reimbursement.

Medicare abuse can also expose providers to criminal and civil liability.

Program integrity includes a range of activities targeting various causes of improper payments. Figure 1 shows examples along the range of possible types of improper payments.

Figure 1. Types of Improper Payments*



*The types of improper payments in Figure 1 are strictly examples for educational purposes, and the precise characterization of any type of improper payment depends on a full analysis of specific facts and circumstances. Providers who engage in incorrect coding, ordering excessive diagnostic tests, upcoding, or billing for services or supplies not provided may be subject to administrative, civil, or criminal liability.

Medicare Fraud and Abuse Laws

Federal laws governing Medicare fraud and abuse include the:

- False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Physician Self-Referral Law (Stark Law)
- Social Security Act, which includes the Exclusion Statute and the Civil Monetary Penalties Law (CMPL)
- United States Criminal Code

Fraud and Abuse in Medicare Part C, Part D, and Medicaid

In addition to Medicare Part A and Part B, Medicare Part C and Part D and Medicaid programs prohibit the fraudulent conduct addressed by these laws.

These laws specify the criminal, civil, and administrative penalties and remedies the government may impose on individuals or entities that commit fraud and abuse in the Medicare and Medicaid Programs.

Violating these laws may result in nonpayment of claims, Civil Monetary Penalties (CMP), exclusion from all Federal health care programs, and criminal and civil liability.

Government agencies, including the U.S. Department of Justice (DOJ), the U.S. Department of Health & Human Services (HHS), the HHS Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), enforce these laws.

Federal Civil False Claims Act (FCA)

The civil FCA, 31 United States Code (U.S.C.) Sections 3729–3733, protects the Federal Government from being overcharged or sold substandard goods or services. The civil FCA imposes civil liability on any person who **knowingly** submits, or **causes** the submission of, a false or fraudulent claim to the Federal Government.

The terms "knowing" and "knowingly" mean a person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information related to the claim. **No specific intent to defraud is required to violate the civil FCA.**

Examples: A physician knowingly submits claims to Medicare for medical services not provided or for a higher level of medical services than actually provided.

Penalties: Civil penalties for violating the civil FCA may include recovery of up to **three** times the amount of damages sustained by the Government as a result of the false claims, plus financial penalties per false claim filed.

Additionally, under the criminal FCA, 18 U.S.C. Section 287, individuals or entities may face criminal penalties for submitting false, fictitious, or fraudulent claims, including fines, imprisonment, or both.

Anti-Kickback Statute (AKS)

The AKS, 42 U.S.C. Section 1320a-7b(b), makes it a crime to **knowingly and willfully** offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward patient referrals or the generation of business involving any item or service reimbursable by a Federal health care program. When a provider offers, pays, solicits, or receives unlawful **remuneration**, the provider violates the AKS.

Anti-Kickback Statute vs. Stark Law

Refer to the Comparison of the Anti-Kickback Statute and Stark Law handout.

NOTE: Remuneration includes anything of value, such as cash, free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.

Example: A provider receives cash or below-fair-market-value rent for medical office space in exchange for referrals.

Penalties: Criminal penalties and administrative sanctions for violating the AKS may include fines, imprisonment, and exclusion from participation in the Federal health care program. Under the CMPL, penalties for violating the AKS may include **three** times the amount of the kickback.

The "safe harbor" regulations, 42 Code of Federal Regulations (C.F.R.) Section 1001.952, describe various payment and business practices that, although they potentially implicate the AKS, are not treated as offenses under the AKS if they meet certain requirements specified in the regulations. Individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.

Physician Self-Referral Law (Stark Law)

The Physician Self-Referral Law, 42 U.S.C. Section 1395nn, often called the Stark Law, prohibits a physician from referring patients to receive "designated health services" payable by Medicare or Medicaid to an entity with which the physician or a member of the physician's immediate family has a financial relationship, unless an exception applies.

Example: A physician refers a beneficiary for a designated health service to a clinic where the physician has an investment interest.

Penalties: Penalties for physicians who violate the Stark Law may include fines, CMPs for each service, repayment of claims, and potential exclusion from participation in the Federal health care programs.

Criminal Health Care Fraud Statute

The Criminal Health Care Fraud Statute, 18 U.S.C. Section 1347 prohibits **knowingly and willfully** executing, or attempting to execute, a scheme or lie in connection with the delivery of, or payment for, health care benefits, items, or services to either:

- Defraud any health care benefit program
- Obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the control of, any health care benefit program

Example: Several doctors and medical clinics conspire in a coordinated scheme to defraud the Medicare Program by submitting medically unnecessary claims for power wheelchairs.

Penalties: Penalties for violating the Criminal Health Care Fraud Statute may include fines, imprisonment, or both.

Exclusion Statute

The Exclusion Statute, 42 U.S.C. Section 1320a-7, requires the OIG to exclude individuals and entities convicted of any of the following offenses from participation in all Federal health care programs:

- Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid
- Patient abuse or neglect
- Felony convictions for other health care-related fraud, theft, or other financial misconduct
- Felony convictions for unlawful manufacture, distribution, prescription, or dispensing controlled substances

The OIG also may impose permissive exclusions on other grounds, including:

- Misdemeanor convictions related to health care fraud other than Medicare or Medicaid fraud, or misdemeanor convictions for unlawfully manufacturing, distributing, prescribing, or dispensing controlled substances
- Suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity
- Providing unnecessary or substandard services
- Submitting false or fraudulent claims to a Federal health care program
- Engaging in unlawful kickback arrangements
- Defaulting on health education loan or scholarship obligations

Excluded providers may not participate in the Federal health care programs for a designated period. If you are excluded by OIG, then Federal health care programs, including Medicare and Medicaid, will not pay for items or services that you furnish, order, or prescribe. Excluded providers may not bill directly for treating Medicare and Medicaid patients, and an employer or a group practice may not bill for an excluded provider's services. At the end of an exclusion period, an excluded provider must seek reinstatement; reinstatement is not automatic.

The OIG maintains a list of excluded parties called the List of Excluded Individuals/Entities (LEIE).

Civil Monetary Penalties Law (CMPL)

The CMPL, 42 U.S.C. Section 1320a-7a, authorizes OIG to seek CMPs and sometimes exclusion for a variety of health care fraud violations. Different amounts of penalties and assessments apply based on the type of violation. CMPs also may include an assessment of up to **three** times the amount claimed for each item or service, or up to **three** times the amount of remuneration offered, paid, solicited, or received. Violations that may justify CMPs include:

- Presenting a claim you know, or should know, is for an item or service not provided as claimed or that is false and fraudulent
- Violating the AKS
- Making false statements or misrepresentations on applications or contracts to participate in the Federal health care programs

CMP Inflation Adjustment

Each year, the Federal Government adjusts all CMPs for inflation. The adjusted amounts apply to civil penalties assessed after August 1, 2016, and violations after November 2, 2015. Refer to 45 C.F.R. Section 102.3 for the yearly inflation adjustments.

Physician Relationships With Payers

The U.S. health care system relies heavily on third-party payers to pay the majority of medical bills on behalf of patients. **When the Federal Government covers items or services rendered to Medicare and Medicaid beneficiaries, the Federal fraud and abuse laws apply.** Many similar State fraud and abuse laws apply to your provision of care under State-financed programs and to private-pay patients.

Accurate Coding and Billing

As a physician, payers trust you to provide medically necessary, cost-effective, quality care. You exert significant influence over what services your patients get. You control the documentation describing services they receive, and your documentation serves as the basis for claims you submit. Generally, Medicare pays claims based solely on your representations in the claims documents.

When you submit a claim for services provided to a Medicare beneficiary, you are filing a bill with the Federal Government and certifying you earned the payment requested and complied with the billing requirements. If you knew or should have known the submitted claim was false, then the attempt to collect payment is illegal. Examples of improper claims include:

- Billing codes that reflect a more severe illness than actually existed or a more expensive treatment than was provided
- Billing medically unnecessary services
- Billing services not provided
- Billing services performed by an improperly supervised or unqualified employee
- Billing services performed by an employee excluded from participation in the Federal health care programs
- Billing services of such low quality they are virtually worthless
- Billing separately for services already included in a global fee, like billing an evaluation and management service the day after surgery

Physician Documentation

Maintain accurate and complete medical records and documentation of the services you provide. Ensure your documentation supports the claims you submit for payment. **Good documentation practices help to ensure your patients get appropriate care and allow other providers to rely on your records for patients' medical histories.**

The Medicare Program may review beneficiaries' medical records. Good documentation helps address any challenges raised about the integrity of your claims. You may have heard the saying regarding malpractice litigation: "If you didn't document it, it's the same as if you didn't do it." The same can be said for Medicare billing.

Accuracy of Medical Record Documentation

For more information on physician documentation, refer to the Evaluation and Management Services guide, Complying With Medical Record Documentation Requirements fact sheet, and an OIG video on the Importance of Documentation.

Upcoding

Medicare pays for many physician services using Evaluation and Management (E/M) codes. New patient visits generally require more time than established patient follow-up visits. Medicare pays new patient E/M codes at higher reimbursement rates than established patient E/M codes.

Example: Billing an established patient follow-up visit using a higher-level E/M code, such as a comprehensive new-patient office visit.

Another example of E/M upcoding is misusing modifier –25. Modifier –25 allows additional payment for a significant, separately identifiable E/M service provided on the same day of a procedure or other service. Upcoding occurs when a provider uses modifier –25 to claim payment for a medically unnecessary E/M service, an E/M service not distinctly separate from the procedure or other service provided, or an E/M service not above and beyond the care usually associated with the procedure.

Physician Relationships With Other Providers

Anytime a health care business offers you something for free or below fair market value, ask yourself, "**Why?**"

Physician Investments in Health Care Business Ventures

Some physicians who invest in health care business ventures with outside parties (for instance, imaging centers, laboratories, equipment vendors, or physical therapy clinics) refer more patients for the services provided by those parties than physicians who do not invest. These business relationships may improperly influence or distort physician decision-making and result in the improper steering of patients to a therapy or service where a physician has a financial interest.

Excessive and medically unnecessary referrals waste Federal Government resources and can expose Medicare beneficiaries to harm from unnecessary services. Many of these investment relationships have serious legal risks under the AKS and Stark Law.

Physician Investments

For more information on physician investments, refer to the OIG's:

- Special Fraud Alert: Joint Venture Arrangements
- Special Fraud Alert: Physician-Owned Entities
- Special Advisory Bulletin: Contractual Joint Ventures

If someone invites you to invest in a health care business whose products you might order or to which you might refer your patients, ask yourself the following questions. If you answer "yes" to any of them, you should carefully consider the reasons for your investment.

- Is the investment interest offered to you in exchange for a nominal capital contribution?
- Is the ownership share offered to you larger than your share of the aggregate capital contributions made to the venture?
- Is the venture promising you high rates of return for little or no financial risk?
- Is the venture, or any potential business partner, offering to loan you the money to make your capital contribution?
- Are you promising or guaranteeing to refer patients or order items or services from the venture?
- Are you more likely to refer patients for the items and services provided by the venture if you make the investment?
- Does the venture have sufficient capital from other sources to fund its operations?

Physician Recruitment

Hospitals and other health systems may provide a physician-recruitment incentive to induce you to relocate to the hospital's geographic area, join its medical staff, and establish a practice to help serve a community's medical needs. Often, such recruitment efforts fill a legitimate "clinical gap" in a medically underserved area where attracting physicians may be difficult in the absence of financial incentives.

However, in some communities, especially ones with multiple hospitals, hospitals fiercely compete for patients. To gain referrals, some hospitals may offer illegal incentives to you or to the established physician practice you join in the hospital's community. This means the competition for your loyalty can cross the line into an illegal arrangement with legal consequences for you and the hospital.

A hospital may pay you a fair market-value salary as an employee or pay you fair market value for specific services you render to the hospital as an independent contractor. However, the hospital may **not** offer you money, provide you free or below-market rent for your medical office, or engage in similar activities designed to influence your referral decisions. **Admit your patients to the hospital best suited to care for their medical conditions or to the hospital your patients select based on their preference or insurance coverage.**

Within very specific parameters of the Stark Law and subject to compliance with the AKS, hospitals may provide relocation assistance and practice support under a properly structured recruitment arrangement to assist you in establishing a practice in the hospital's community. If a hospital or physician practice separately or jointly recruit you as a new physician to the community, they may offer a recruitment package. Unless you are a hospital employee, you cannot negotiate for benefits in exchange for an implicit or explicit promise to admit your patients to a specific hospital or practice setting. Seek knowledgeable legal counsel if a prospective business relationship requires you to admit patients to a specific hospital or practice group.

Physician Relationships With Vendors

Free Samples

Many drug and biologic companies provide free product samples to physicians. It is legal to give these samples to your patients free of charge, but it is illegal to sell the samples. The Federal Government has prosecuted physicians for billing Medicare for free samples. If you choose to accept free samples, you need reliable systems in place to safely store the samples and ensure samples remain separate from your commercial stock.

Pharmaceutical and Medical Device Industries Codes of Ethics

Both the pharmaceutical industry, through the Pharmaceutical Research and Manufacturers of America (PhRMA), and the medical device industry, through the Advanced Medical Technology Association (AdvaMed), adopted codes of ethics regarding relationships with health care professionals. For more information, visit the PhRMA Code on Interactions With Health Care Professionals and the AdvaMed Code of Ethics.

Relationships With the Pharmaceutical and Medical Device Industries

Some pharmaceutical and device companies use sham consulting agreements and other arrangements to buy physician loyalty to their products. As a practicing physician, you may have opportunities to work as a consultant or promotional speaker for the drug or device industry. For every financial relationship offered to you, evaluate the link between the services you can provide and the compensation you will get. Test the appropriateness of any proposed relationship by asking yourself the following questions:

- Does the company **really** need **your** specific expertise or input?
- Does the company's monetary compensation to you represent a **fair, appropriate,** and **commercially reasonable** exchange for your services?
- Is it possible the company is paying for **your loyalty,** so you prescribe its drugs or use its devices?

If your contribution is your time and effort or your ability to generate useful ideas and the payment you receive is fair-market-value compensation for your services without regard to referrals, then, depending on the circumstances, you may legitimately serve as a bona fide consultant. **If your contribution is your ability to prescribe a drug, use a medical device, or refer patients for services or supplies, the potential consulting relationship likely is one you should avoid as it could violate fraud and abuse laws.**

Transparency in Physician-Industry Relationships

Although some physicians believe free lunches, subsidized trips, and gifts do not affect their medical judgment, research shows these types of privileges can influence prescribing practices.

Federal Open Payments Program

The Federal Open Payments Program highlights financial relationships among physicians, teaching hospitals, and drug and device manufacturers. Drug, device, and biologic companies must publicly report nearly all gifts or payments made to physicians.

Industry Relationships

For more information on distinguishing between legitimate and questionable industry relationships, refer to the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers.

The Federal Open Payments Program requires pharmaceutical and medical device manufacturers to publicly report payments to physicians and teaching hospitals. CMS posts Open Payments data on June 30 each year, including payments or other transfers of value and ownership or investment interest reports. CMS closely monitors this process to ensure integrity in the reported data.

Publicly available information about you includes:

- Activities such as speaking engagements
- Educational materials such as text books or journal reprints
- Entertainment
- Gifts
- Meals
- Participation in a paid advisory board
- Travel expenses

CMS does not require physicians to register with, or send information to, Federal Open Payments. However, CMS encourages your help to ensure accurate information by doing the following:

- Register with the Open Payments Program and subscribe to the electronic mailing list for Program updates
- Review the information manufacturers and GPOs submit on your behalf
- Work with manufacturers and GPOs to settle data issues about your Open Payments profile

Conflict-of-Interest Disclosures

Many of the relationships discussed in this booklet are subject to conflict-of-interest disclosure policies. Even if the relationships are legal, you may be obligated to disclose their existence. Rules about disclosing and managing conflicts of interest come from a variety of sources, including grant funders, such as states, universities, and the National Institutes of Health (NIH), and from the U.S. Food and Drug Administration (FDA) when you submit data to support marketing approval for new drugs, devices, or biologics.

If you are uncertain whether a conflict exists, ask yourself if you would want the arrangement to appear in the news.

Continuing Medical Education (CME)

You are responsible for your CME to maintain State licensure, hospital privileges, and board certification. Drug and device manufacturers sponsor many educational opportunities for physicians. **It is important to distinguish between CME sessions that are educational and sessions that constitute marketing by a drug or device manufacturer.** If speakers recommend prescribing a drug when there is no FDA approval or prescribing a drug for children when the FDA has approved only adult use, independently seek out the empirical data supporting these recommendations.

NOTE: Although physicians may prescribe drugs for off-label uses, it is illegal under the Federal Food, Drug, and Cosmetic Act for drug manufacturers to promote off-label drug use.

FDA Bad Ad Program

Drugs, biologics, medical devices, and other promotional advertisements must be truthful, not misleading, and limited to approved uses. The FDA requests physicians' assistance in identifying misleading advertisements through its Bad Ad Program. If you spot advertising violations, report them to the FDA by calling 877-RX-DDMAC (877-793-3622) or by emailing BadAd@fda.gov.

Watch What To Do About Misleading Drug Ads for more information.

Compliance Programs for Physicians

Physicians treating Medicare beneficiaries should establish a compliance program. Establishing and following a compliance program helps physicians avoid fraudulent activities and submit accurate claims. The following seven components provide a solid basis for a physician practice compliance program:

1. Conduct internal monitoring and auditing
2. Implement compliance and practice standards
3. Designate a compliance officer or contact
4. Conduct appropriate training and education
5. Respond appropriately to detected offenses and develop corrective action
6. Develop open lines of communication with employees
7. Enforce disciplinary standards through well-publicized guidelines

Compliance Programs for Physicians

For more information on compliance programs for physicians, visit the OIG Compliance webpage or watch this Compliance Program Basics video.

Medicare Anti-Fraud and Abuse Partnerships and Agencies

Government agencies partner to fight fraud and abuse, uphold the integrity of the Medicare Program, save and recoup taxpayer funds, reduce health care costs, and improve the quality of health care.

Health Care Fraud Prevention Partnership (HFPP)

The HFPP is a voluntary public-private partnership among the Federal Government, State agencies, law enforcement, private health insurance plans, and health care anti-fraud associations. The HFPP fosters a proactive approach to detect and prevent health care fraud through data and information sharing.

Centers for Medicare & Medicaid Services (CMS)

CMS is the Federal agency within HHS that administers the Medicare Program, Medicaid Program, State Children's Health Insurance Program (SCHIP), Clinical Laboratory Improvement Amendments (CLIA), and several other health-related programs.

To prevent and detect fraud and abuse, CMS works with individuals, entities, and law enforcement agencies, including:

- Accreditation Organizations (AO)
- Medicare beneficiaries and caregivers
- Physicians, suppliers, and other health care providers
- State and Federal law enforcement agencies, including the OIG, Federal Bureau of Investigation (FBI), DOJ, State Medicaid Agencies, and Medicaid Fraud Control Units (MFCU)

To support its efforts to prevent, detect, and investigate potential Medicare fraud and abuse, CMS also partners with a selection of contractors.

Table 1. Contractor Efforts to Prevent, Detect, and Investigate Fraud and Abuse

Contractor	Role
Comprehensive Error Rate Testing (CERT) Contractors	Help calculate the Medicare Fee-For-Service (FFS) improper payment rate by reviewing claims to determine if they were paid properly
Medicare Administrative Contractors (MAC)	Process claims and enroll providers and suppliers
Medicare Drug Integrity Contractors (MEDIC)	Monitor fraud, waste, and abuse in the Medicare Parts C and D Programs. Beginning January 2, 2019, the Centers for Medicare & Medicaid Services (CMS) will have two Medicare Drug Integrity Contractors (MEDICs), the National Benefit Integrity (NBI MEDIC) and the Investigations (I-MEDIC).
Recovery Audit Program Recovery Audit Contractors (RACs)	Reduce improper payments by detecting and collecting overpayments and identifying underpayments

Table 1. Contractor Efforts to Prevent, Detect, and Investigate Fraud and Abuse (cont.)

Contractor	Role
Zone Program Integrity Contractors (ZPIC) Formerly called Program Safeguard Contractors (PSC)	Investigate potential fraud, waste, and abuse for Medicare Parts A and B; Durable Medical Equipment Prosthetics, Orthotics, and Supplies; and Home Health and Hospice
Unified Program Integrity Contractors (UPIC)	Combine and integrate Medicare and Medicaid Program Integrity audit and investigation work functions into a single contract

Within CMS, the Center for Program Integrity (CPI) promotes the integrity of Medicare through audits, policy reviews, and identifying and monitoring program vulnerabilities. CPI oversees CMS' collaboration with key stakeholders on program integrity issues related to detecting, deterring, monitoring, and combating fraud and abuse.

In 2010, HHS and CMS launched the Fraud Prevention System (FPS), a state-of-the-art predictive analytics technology that runs predictive algorithms and other analytics nationwide on all Medicare FFS claims prior to payment to detect potentially suspicious claims and patterns that may constitute fraud and abuse.

In 2012, CMS created the Program Integrity Command Center to bring together Medicare and Medicaid officials, clinicians, policy experts, CMS fraud investigators, and the law enforcement community, including the OIG and FBI. The Command Center gathers these experts to develop and improve intricate predictive analytics that identify fraud and mobilize a rapid response. CMS connects instantly with its field offices to evaluate fraud allegations through real-time investigations. Previously, finding substantiating evidence of a fraud allegation took days or weeks; now it can take only hours.

Office of the Inspector General (OIG)

The OIG protects the integrity of HHS' programs and the health and welfare of program beneficiaries. The OIG operates through a nationwide network of audits, investigations, inspections, evaluations, and other related functions. The Inspector General is authorized to, among other things, exclude individuals and entities who engage in fraud or abuse from participation in all Federal health care programs, and to impose CMPs for certain violations.

Health Care Fraud Prevention and Enforcement Action Team (HEAT)

The DOJ, OIG, and HHS established HEAT to build and strengthen existing programs combatting Medicare fraud while investing new resources and technology to prevent and detect fraud and abuse. HEAT expanded the DOJ-HHS Medicare Fraud Strike Force, which targets emerging or migrating fraud schemes, including fraud by criminals masquerading as health care providers or suppliers.

General Services Administration (GSA)

The GSA consolidated several Federal procurement systems into one new system: the System for Award Management (SAM). SAM includes information on entities that are:

- Debarred or proposed for debarment
- Disqualified from certain types of Federal financial and non-financial assistance and benefits
- Disqualified from receiving Federal contracts or certain subcontracts
- Excluded or suspended from the Medicare Program

Report Suspected Fraud

Table 2. Where Should You Report Fraud and Abuse?

If You Are a…	Report Fraud to…
Medicare Beneficiary	For any complaint: • **CMS Hotline**: Phone: 1-800-MEDICARE (1-800-633-4227) or TTY 1-877-486-2048 AND • **OIG Hotline**: Phone: 1-800-HHS-TIPS (1-800-447-8477) or TTY 1-800-377-4950 Fax: 1-800-223-8164 Online: Forms.oig.hhs.gov/hotlineoperations/index.asp Mail: U.S. Department of Health & Human Services Office of Inspector General ATTN: OIG Hotline Operations P.O. Box 23489 Washington, DC 20026 For Medicare Part C (Medicare Advantage) or Part D (Prescription Drug Plans) complaints: • 1-877-7SafeRx (1-877-772-3379)
Medicare Provider	• **OIG Hotline**: Phone: 1-800-HHS-TIPS (1-800-447-8477) or TTY 1-800-377-4950 Fax: 1-800-223-8164 Online: Forms.oig.hhs.gov/hotlineoperations/index.asp Mail: U.S. Department of Health & Human Services Office of Inspector General ATTN: OIG Hotline Operations P.O. Box 23489 Washington, DC 20026 OR • Contact your MAC

Table 2. Where Should You Report Fraud and Abuse? (cont.)

If You Are a…	Report Fraud to…
Medicaid Beneficiary or Provider	• **OIG Hotline**: Phone: 1-800-HHS-TIPS (1-800-447-8477) or TTY 1-800-377-4950 Fax: 1-800-223-8164 Online: Forms.oig.hhs.gov/hotlineoperations/index.asp Mail: U.S. Department of Health & Human Services Office of Inspector General ATTN: OIG Hotline Operations P.O. Box 23489 Washington, DC 20026 OR • Your Medicaid State Agency: State MFCUs are listed in the National Association of Medicaid Fraud Control Units (NAMFCU)

If you prefer to report fraud and abuse **anonymously** to the **OIG Hotline**, the OIG record systems collect no information that could trace the complaint to you. However, lack of contact information may prevent OIG's comprehensive review of the complaint, so the OIG encourages you to provide contact information for possible follow-up.

Medicare and Medicaid beneficiaries can learn more about protecting themselves and spotting fraud by contacting their local Senior Medicare Patrol (SMP) program.

For questions about Medicare billing procedures, billing errors, or questionable billing practices, contact your MAC.

Where to Go for Help

When considering a billing practice; entering into a particular business venture; or pursuing any employment, consulting, or other personal services relationship, evaluate the arrangement for potential compliance problems. Consider the following list of resources to assist with your evaluation:

Medical Identity Theft

For more information, refer to the Medical Identity Theft & Medicare Fraud brochure.

Legal Counsel

- Experienced health care lawyers can analyze your issues and provide a legal evaluation and risk analysis of the proposed venture, relationship, or arrangement.
- The Bar Association in your state may maintain a directory of local attorneys who practice in the health care field.

Professional Organizations

- Your state or local medical society may be a good resource for issues affecting physicians and may keep listings of health care attorneys in your area.
- Your specialty society may have information on additional risk areas specific to your type of practice.

CMS

- MAC medical directors are a valuable source of information on Medicare coverage policies and appropriate billing practices. Contact your MAC for more information.
- CMS issues advisory opinions to parties seeking advice on the Stark Law. For more information, visit the CMS Advisory Opinions webpage.

OIG

- For more information on OIG compliance recommendations and discussions of fraud and abuse risk area, refer to OIG's Compliance Program Guidance. Visit OIG's Compliance Education Materials for more information.
- OIG issues advisory opinions to parties who seek advice on the application of the Anti-Kickback Statute, Civil Monetary Penalties Law, and Exclusion Statute. For more information, visit the OIG Advisory Opinions webpage.

What to Do if You Think You Have a Problem

If you think you are engaged in a problematic relationship or have been following billing practices you now realize are wrong:

- Immediately stop submitting problematic bills
- Seek knowledgeable legal counsel
- Determine what money you collected in error from patients and from the Federal health care programs and report and return overpayments
- Unwind the problematic investment by freeing yourself from your involvement
- Separate yourself from the suspicious relationship
- Consider using OIG's or CMS' self-disclosure protocols, as applicable

OIG Provider Self-Disclosure Protocol

The OIG Provider Self-Disclosure Protocol is a vehicle for providers to voluntarily disclose self-discovered evidence of potential fraud. The protocol allows providers to work with the Government to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation.

CMS Self-Referral Disclosure Protocol (SRDP)

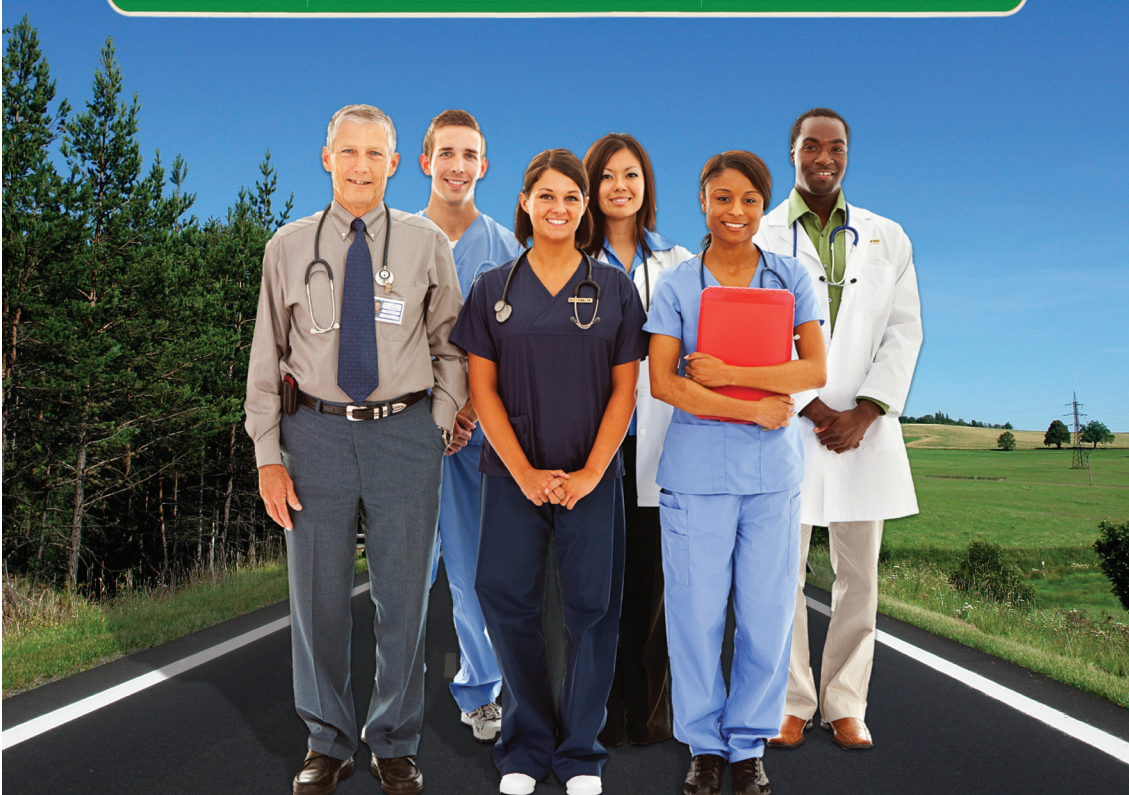
The SRDP enables health care providers and suppliers to self-disclose actual or potential Stark Law violations.

Resources

- CMS Fraud Prevention Toolkit
- Center for Program Integrity: Protecting the Medicare & Medicaid Programs from Fraud, Waste & Abuse
- Help Fight Medicare Fraud
- Medicaid Program Integrity Education
- OIG Contact Information
- OIG Fraud Information
- Physician Self-Referral

A Roadmap for New Physicians

Avoiding Medicare and Medicaid Fraud and Abuse



U.S. Department of Health & Human Services
Office of Inspector General

Table of Contents

Introduction

Most physicians strive to work ethically, render high-quality medical care to their patients, and submit proper claims for payment. Society places enormous trust in physicians, and rightly so. Trust is at the core of the physician-patient relationship. When our health is at its most vulnerable, we rely on physicians to use their expert medical training to put us on the road to a healthy recovery.

The Federal Government also places enormous trust in physicians. Medicare, Medicaid, and other Federal health care programs rely on physicians' medical judgment to treat beneficiaries with appropriate services. When reimbursing physicians and hospitals for services provided to program beneficiaries, the Federal Government relies on physicians to submit accurate and truthful claims information.

The presence of some dishonest health care providers who exploit the health care system for illegal personal gain has created the need for laws that combat fraud and abuse and ensure appropriate quality medical care. This brochure assists physicians in understanding how to comply with these Federal laws by identifying "red flags" that could lead to potential liability in law enforcement and administrative actions. The information is organized around three types of relationships that physicians frequently encounter in their careers:

I. Relationships with payers,

II. Relationships with fellow physicians and other providers, and

III. Relationships with vendors.

The key issues addressed in this brochure are relevant to all physicians, regardless of specialty or practice setting.

Fraud and Abuse Laws

The five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL). Government agencies, including the Department of Justice, the Department of Health & Human Services Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), are charged with enforcing these laws. As you begin your career, it is crucial to understand these laws not only because following them is the right thing to do, but also because violating them could result in criminal penalties, civil fines, exclusion from the Federal health care programs, or loss of your medical license from your State medical board.

False Claims Act [31 U.S.C. §§ 3729–3733]

The civil FCA protects the Government from being overcharged or sold shoddy goods or services. **It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.** Filing false claims may result in fines of up to three times the programs' loss plus $11,000 per claim filed. Under the civil FCA, each instance of an item or a service billed to Medicare or Medicaid counts as a claim, so fines can add up quickly. The fact that a claim results from a kickback or is made in violation of the Stark law also may render it false or fraudulent, creating liability under the civil FCA as well as the AKS or Stark law.

Under the civil FCA, no specific intent to defraud is required. The civil FCA defines "knowing" to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Further, the civil FCA contains a whistleblower provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any recoveries. Whistleblowers could be current or ex-business partners, hospital or office staff, patients, or competitors.

There also is a criminal FCA (18 U.S.C. § 287). Criminal penalties for submitting false claims include imprisonment and criminal fines. Physicians have gone to prison for submitting false health care claims. OIG also may impose administrative civil monetary penalties for false or fraudulent claims, as discussed below.

Anti-Kickback Statute [42 U.S.C. § 1320a-7b(b)]

The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (*e.g.*, drugs, supplies, or health care services for Medicare or Medicaid patients). Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. **In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime.** The statute covers the payers of kickbacks—those who offer or pay remuneration—as well as the recipients of kickbacks—those who solicit or receive remuneration. Each party's intent is a key element of their liability under the AKS.

Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the Federal health care programs. Under the CMPL, physicians who pay or accept kickbacks also face penalties of up to $50,000 per kickback plus three times the amount of the remuneration.

Safe harbors protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution. To be protected by a safe harbor, an arrangement must fit squarely in the safe harbor and satisfy all of its requirements. Some safe harbors address personal services and rental agreements, investments in ambulatory surgical centers, and payments to *bona fide* employees.

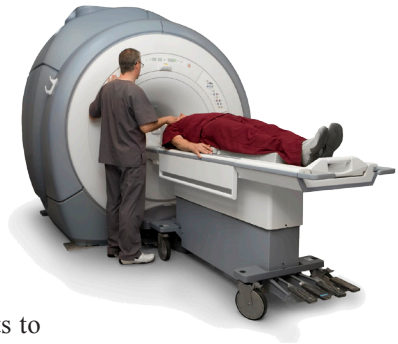
For additional information on safe harbors, see "OIG's Safe Harbor Regulations" available at http://oig.hhs.gov/fraud/safeharborregulations.asp.

As a physician, you are an attractive target for kickback schemes because you can be a source of referrals for fellow physicians or other health care providers and suppliers. You decide what drugs your patients use, which specialists they see, and what health care services and supplies they receive.

Many people and companies want your patients' business and would pay you to send that business their way. Just as it is illegal for you to take money from providers and suppliers in return for the referral of your Medicare and Medicaid patients, it is illegal for you to pay others to refer their Medicare and Medicaid patients to you.

Kickbacks in health care can lead to:

- Overutilization
- Increased program costs
- Corruption of medical decisionmaking
- Patient steering
- Unfair competition



The kickback prohibition applies to all sources of referrals, even patients. For example, where the Medicare and Medicaid programs require patients to pay copays for services, you are generally required to collect that money from your patients. Routinely waiving these copays could implicate the AKS and you may not advertise that you will forgive copayments. However, you are free to waive a copayment if you make an individual determination that the patient cannot afford to pay or if your reasonable collection efforts fail. **It is also legal to provide free or discounted services to uninsured people.**

Besides the AKS, the beneficiary inducement statute (42 U.S.C. § 1320a-7a(a)(5)) also imposes civil monetary penalties on physicians who offer remuneration to Medicare and Medicaid beneficiaries to influence them to use their services.

The Government does not need to prove patient harm or financial loss to the programs to show that a physician violated the AKS. A physician can be guilty of violating the AKS even if the physician actually rendered the service and the service was medically necessary. **Taking money or gifts from a drug or device company or a durable medical equipment (DME) supplier is not justified by the argument that you would have prescribed that drug or ordered that wheelchair even without a kickback.**

Physician Self-Referral Law [42 U.S.C. § 1395nn]

The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. For example, if you invest in an imaging center, the Stark law requires the resulting financial relationship to fit within an exception or you may not refer patients to the facility and the entity may not bill for the referred imaging services.

"Designated health services" are:

- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- DME and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. The Stark law prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals. Penalties for physicians who violate the Stark law include fines as well as exclusion from participation in the Federal health care programs.

For more information, see CMS's Stark law Web site available at http://www.cms.gov/physicianselfreferral/.

Exclusion Statute [42 U.S.C. § 1320a-7]

OIG is legally required to exclude from participation in all Federal health care programs individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid; (2) patient abuse or neglect; (3) felony convictions for other health-care-related fraud, theft, or other financial misconduct; and (4) felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances. OIG has discretion to exclude individuals and entities on several other grounds, including misdemeanor convictions related to health care fraud other than Medicare or Medicaid fraud or misdemeanor convictions in connection with the unlawful manufacture, distribution, prescription, or dispensing of controlled substances; suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; engaging in unlawful kickback arrangements; and defaulting on health education loan or scholarship obligations.

If you are excluded by OIG from participation in the Federal health care programs, then Medicare, Medicaid, and other Federal health care programs, such as TRICARE and the Veterans Health Administration, will not pay for items or services that you furnish, order, or prescribe. **Excluded physicians may not bill directly for treating Medicare and Medicaid patients, nor may their services be billed indirectly through an employer or a group practice.** In addition, if you furnish services to a patient on a private-pay basis, no order or prescription that you give to that patient will be reimbursable by any Federal health care program.

For more information, see OIG's Special Advisory Bulletin entitled "The Effect of Exclusion From Participation in Federal Health Care Programs" available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm.

You are responsible for ensuring that you do not employ or contract with excluded individuals or entities, whether in a physician practice, a clinic, or in any capacity or setting in which Federal health care programs may reimburse for the items or services furnished by those employees or contractors. This responsibility requires screening all current and prospective employees and contractors against OIG's List of Excluded Individuals and Entities. This online database can be accessed from OIG's Exclusion Web site. If you employ or contract with an excluded individual or entity and Federal health care program payment is made for items or services that person or entity furnishes, whether directly or indirectly, you may be subject to a civil monetary penalty and/or an obligation to repay any amounts attributable to the services of the excluded individual or entity.


For more information, see OIG's exclusion Web site available at http://oig.hhs.gov/fraud/exclusions.asp.

Civil Monetary Penalties Law [42 U.S.C. § 1320a-7a]

OIG may seek civil monetary penalties and sometimes exclusion for a wide variety of conduct and is authorized to seek different amounts of penalties and assessments based on the type of violation at issue. Penalties range from $10,000 to $50,000 per violation. Some examples of CMPL violations include:

- presenting a claim that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- presenting a claim that the person knows or should know is for an item or service for which payment may not be made;
- violating the AKS;
- violating Medicare assignment provisions;
- violating the Medicare physician agreement;
- providing false or misleading information expected to influence a decision to discharge;
- failing to provide an adequate medical screening examination for patients who present to a hospital emergency department with an emergency medical condition or in labor; and
- making false statements or misrepresentations on applications or contracts to participate in the Federal health care programs.

I. Physician Relationships With Payers

During residency, you probably are not focused on who pays for your patients' care. Once you start practicing, it is important to understand who the payers are. The U.S. health care system relies heavily on third-party payers, and, therefore, your patients often are not the ones who pay most of their medical bills. Third-party payers include commercial insurers and the Federal and State governments. **When the Federal Government covers items or services rendered to Medicare and Medicaid beneficiaries, the Federal fraud and abuse laws apply.** Many States also have adopted similar laws that apply to your provision of care under State-financed programs and to private-pay patients. Consequently, you should recognize that the issues discussed here may apply to your care of all insured patients.

Accurate Coding and Billing

Payers trust you, as a physician, to provide necessary, cost-effective, and quality care. You exert significant influence over what services your patients receive, you control the documentation describing what services they actually received, and your documentation serves as the basis for bills sent to insurers for services you provided. The Government's payment of claims is generally based solely on your representations in the claims documents.

Because the Government invests so much trust in physicians on the front end, Congress provided powerful criminal, civil, and administrative enforcement tools for instances when unscrupulous providers abuse that trust. The Government has broad capabilities to audit claims and investigate providers when it has a reason to suspect fraud. Suspicion of fraud and abuse may be raised by irregular billing patterns or reports from others, including your staff, competitors, and patients.

When you submit a claim for services performed for a Medicare or Medicaid beneficiary, you are filing a bill with the Federal Government and certifying that you have earned the payment requested and complied with the billing requirements. If you knew or should have known that the submitted claim was false, then the attempt to collect unearned money constitutes a violation. A common type of false claim is "upcoding," which refers to using billing codes that reflect a more severe illness than actually existed or a more expensive treatment than was provided. Additional examples of improper claims include:

- billing for services that you did not actually render;
- billing for services that were not medically necessary;
- billing for services that were performed by an improperly supervised or unqualified employee;
- billing for services that were performed by an employee who has been excluded from participation in the Federal health care programs;
- billing for services of such low quality that they are virtually worthless; and
- billing separately for services already included in a global fee, like billing for an evaluation and management service the day after surgery.

CAUTION CAUTION CAUTION CAUTION CAUTION CAUTION CAUTION

Upcoding

Medicare pays for many physician services using Evaluation and Management (commonly referred to as "E&M") codes. New patient visits generally require more time than follow-up visits for established patients, and therefore E&M codes for new patients command higher reimbursement rates than E&M codes for established patients. An example of upcoding is an instance when you provide a follow-up office visit or follow-up inpatient consultation but bill using a higher level E&M code as if you had provided a comprehensive new patient office visit or an initial inpatient consultation.

Another example of upcoding related to E&M codes is misuse of Modifier 25. Modifier 25 allows additional payment for a separate E&M service rendered on the same day as a procedure. Upcoding occurs if a provider uses Modifier 25 to claim payment for an E&M service when the patient care rendered was not significant, was not separately identifiable, and was not above and beyond the care usually associated with the procedure.

CAUTION CAUTION CAUTION CAUTION CAUTION CAUTION CAUTION

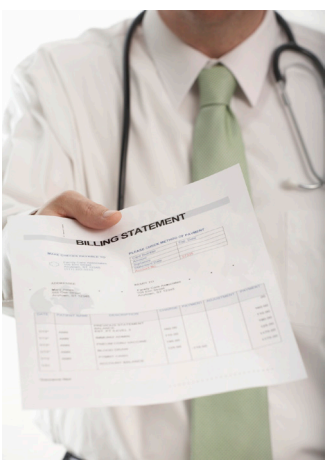
Case Examples of Fraudulent Billing

• A psychiatrist was fined $400,000 and permanently excluded from participating in the Federal health care programs for misrepresenting that he provided therapy sessions requiring 30 or 60 minutes of face-to-face time with the patient, when he had provided only medication checks for 15 minutes or less. The psychiatrist also misrepresented that he provided therapy sessions when in fact a non-licensed individual conducted the sessions.

• A dermatologist was sentenced to 2 years of probation and 6 months of home confinement and ordered to pay $2.9 million after he pled guilty to one count of obstruction of a criminal health care fraud investigation. The dermatologist admitted to falsifying lab tests and backdating letters to referring physicians to substantiate false diagnoses to make the documentation appear that his patients had Medicare-covered conditions when they did not.

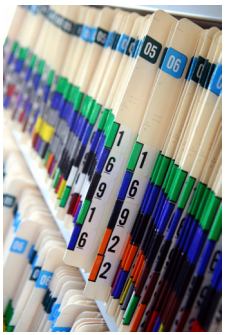
• A cardiologist paid the Government $435,000 and entered into a 5-year Integrity Agreement with OIG to settle allegations that he knowingly submitted claims for consultation services that were not supported by patient medical records and did not meet the criteria for a consultation. The physician also allegedly knowingly submitted false claims for E&M services when he had already received payment for such services in connection with previous claims for nuclear stress testing.

• An endocrinologist billed routine blood draws as critical care blood draws. He paid $447,000 to settle allegations of upcoding and other billing violations.



Physician Documentation

Physicians should maintain accurate and complete medical records and documentation of the services they provide. Physicians also should ensure that the claims they submit for payment are supported by the documentation. The Medicare and Medicaid programs may review beneficiaries' medical records. **Good documentation practice helps ensure that your patients receive appropriate care from you and other providers who may rely on your records for patients' past medical histories.** It also helps you address challenges raised against the integrity of your bills. You may have heard the saying regarding malpractice litigation: "If you didn't document it, it's the same as if you didn't do it." The same can be said for Medicare and Medicaid billing.



For more information on physician documentation, see CMS's Documentation Guidelines for Evaluation and Management Services available at http://www.cms.gov/MLNEdWebGuide/25_EMDOC.asp.

Enrolling as a Medicare and Medicaid Provider With CMS

CMS is the Federal agency that administers the Medicare program and monitors the Medicaid programs run by each State. To obtain reimbursement from the Government for services provided to Federal health care program beneficiaries, you must:

1. **Obtain a National Provider Identifier (NPI).** An NPI is a unique health identifier for health care providers. You may apply for your NPI at https://nppes.cms.hhs.gov/NPPES/Welcome.do.
2. **Complete the appropriate Medicare Enrollment Application.** During the enrollment process, CMS collects information to ensure that you are qualified and eligible to enroll in the Medicare Program. Information about Medicare provider enrollment is available at http://www.cms.gov/MedicareProviderSupEnroll/.
3. **Complete your State-specific Medicaid Enrollment Application.** Information about Medicaid provider enrollment is available from your State Medicaid agency.

Once you become a Medicare and/or Medicaid provider, you are responsible for ensuring that claims submitted under your number are true and correct.

For tips you can share with your patients on how they can protect themselves from medical identity theft, see OIG's brochure entitled "Tips to Avoid Medical ID Theft" available at http://oig.hhs.gov/fraud/IDTheft/OIG_Medical_Identity_Theft_Brochure.pdf.

Prescription Authority

The Drug Enforcement Administration (DEA) is a Department of Justice agency responsible for enforcing the Controlled Substances Act. When you prepare to enter practice, you probably will apply for a DEA number that authorizes you to write prescriptions for controlled substances. You also will apply for your State medical license and any additional credentials your State requires for you to write prescriptions. You must ensure that you write prescriptions only for lawful purposes.

Case Examples of Misuse of Physician Provider and Prescription Numbers

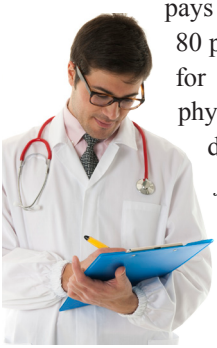
• A physician was ordered to pay $50,000 in restitution to the Government for falsely indicating on his provider number application that he was running his own practice when, in fact, a neurophysiologist was operating the practice and paying the physician a salary for the use of his number.

• An osteopathic physician was sentenced to 10 years in prison and ordered to pay $7.9 million in restitution after she accepted cash payments for signing preprinted prescriptions and Certificates of Medical Necessity for motorized wheelchairs for beneficiaries she never examined. More than 60 DME companies received Medicare and Medicaid payments based on her fraudulent prescriptions.

• An internal medicine physician pled guilty to Medicare fraud and to conspiring to dispense oxycodone, morphine, hydrocodone, and alprazolam. The physician allowed unauthorized and non-medical employees at his pain center to prescribe drugs using his pre-signed blank prescription forms. Prescriptions were issued in his name without adequate physical exams, proper diagnoses, or consideration of alternative treatment options. He paid $317,000 in restitution to the Government.

Assignment Issues in Medicare Reimbursement

Most physicians bill Medicare as participating providers, which is referred to as "accepting assignment." Each year, Medicare promulgates a fee schedule setting the reimbursement for each physician service. Once beneficiaries satisfy their annual deductible, Medicare pays 80 percent of the fee schedule amount and the beneficiary pays 20 percent. Participating providers receive the Medicare program's 80 percent directly from the Medicare program and bill the beneficiary for the remaining 20 percent. Accepting assignment means that the physician accepts the Medicare payment plus any copayment or deductible Medicare requires the patient to pay *as the full payment for the physician's services and that the physician will not seek any extra payment* (beyond the copayment or deductible) from the patient. Medicare participating physicians may not bill Medicare patients extra for services that are already covered by Medicare. Doing so is a violation of a physician's assignment agreement and can lead to penalties.



The second, less common, way to obtain Medicare reimbursement is to bill as a non-participating provider. Non-participating providers do not receive direct payment from the Medicare program. Rather, they bill their patients and the patients seek reimbursement from Medicare. Although non-participating providers are not subject to the assignment rules, they still must limit the dollar amount of their charges to Medicare patients. Generally, non-participating providers may not charge Medicare beneficiaries more than 15 percent in excess of the Medicare fee schedule amount. It is illegal to charge patients more than the limiting charge established for physicians' services.

Excluded providers may not receive Medicare payment either as participating or non-participating providers.

You may see advertisements offering to help you convert your practice into a "boutique," "concierge," or "retainer" practice. Many such solicitations promise to help you work less, yet earn more money. **If you are a participating or non-participating physician, you may not ask Medicare patients to pay a second time for services for which Medicare has already paid.** It is legal to charge patients for services that are not covered by Medicare. However, charging an "access fee" or "administrative fee" that simply allows them to obtain Medicare-covered services from your practice constitutes double billing.

Case Example of a Physician Violating an Assignment Agreement by Charging Beneficiaries Extra Fees

• A physician paid $107,000 to resolve potential liability for charging patients, including Medicare beneficiaries, an annual fee. In exchange for the fee, the physician offered: (1) an annual physical; (2) same- or next-day appointments; (3) dedicated support personnel; (4) around-the-clock physician availability; (5) prescription facilitation; (6) expedited and coordinated referrals; and (7) other amenities at the physician's discretion. The physician's activities allegedly violated the assignment agreement because some of the services outlined in the annual fee were already covered by Medicare.

II. Physician Relationships With Fellow Providers: Physicians, Hospitals, Nursing Homes, Etc.

Any time a health care business offers something to you for free or at below fair market value, you always should ask yourself, "*Why?*" For example, if a DME supplier offers to give you cash or to pay for your summer vacation, you should suspect that the supplier is trying to induce you to refer your patients to that vendor. If a laboratory offers to decorate your patient waiting room, you should suspect that it is trying to induce you to send your lab business its way.

For more information on physician relationships with:

fellow providers, see OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" available at http://oig.hhs.gov/authorities/docs/physician.pdf;

hospitals, see OIG's "Supplemental Compliance Program Guidance for Hospitals" available at http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf; and

nursing homes, see OIG's "Supplemental Compliance Program Guidance for Nursing Facilities" available at http://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf.

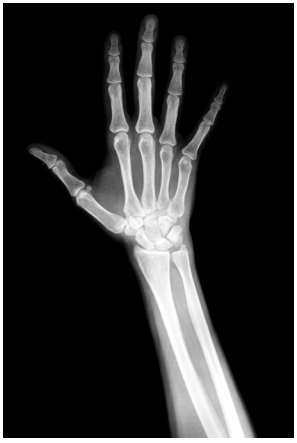
Physician Investments in Health Care Business Ventures

Some have observed that physicians who invest in health care business ventures with outside parties (*e.g.*, imaging centers, labs, equipment vendors, or physical therapy clinics) refer more patients for the services provided by those parties than physicians who do not invest. Maybe this disproportionate utilization partly reflects the physicians' belief in the value of the services or technology, prompting the investments in the first place. However, there also is a risk that the physicians' belief in the value of the services or technology is less a cause than an effect of the investment interest. The physician investors' disproportionate utilization may be motivated partly by the physicians' ability to profit from the use of the ancillary services. These business relationships can sometimes unduly influence or distort physician decisionmaking and result in the improper steering of a patient to a particular therapy or source of services in which a physician has a financial interest. **Excessive and medically unnecessary referrals waste Government and beneficiary money and**

can expose beneficiaries to harm from unnecessary services. Many of these investment relationships have serious legal risks under the AKS and Stark law.

If you are invited to invest in a health care business whose products you might order or to which you might refer your patients, you should ask the following questions. If the answer is "yes" to any of them, you should consider carefully whether you are investing for legitimate reasons.

- ? Are you being offered an investment interest for a nominal capital contribution?
- ? Will your ownership share be larger than your share of the aggregate capital contributions made to the venture?
- ? Is the venture promising you high rates of return for little or no financial risk?
- ? Is the venture or any potential business partner offering to loan you the money to make your capital contribution?
- ? Are you being asked to promise or guarantee that you will refer patients or order items or services from the venture?
- ? Do you believe you will be more likely to refer more patients for the items and services provided by the venture if you make the investment?
- ? Do you believe you will be more likely to refer to the venture just because you made the investment?
- ? Will the venture have sufficient capital from other sources to fund its ongoing operations?



For more information on physician investments, see:

OIG's Special Fraud Alert entitled "Joint Venture Arrangements" available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html;

OIG's Special Advisory Bulletin on contractual joint ventures available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf; and

OIG's "Supplemental Compliance Program Guidance for Hospitals" available at http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf.

Case Examples Involving Kickbacks for Referrals and Self-Referrals

CASE EXAMPLES

• Nine cardiologists paid the Government over $3.2 million for allegedly engaging in a kickback scheme. The cardiologists received salaries under clinical faculty services agreements with a hospital under which, the Government alleged, they did not provide some or any of the services. In exchange, the cardiologists referred their patients to the hospital for cardiology services. Two of the physicians also pled guilty to criminal embezzlement charges involving the same conduct.

• A physician paid the Government $203,000 to settle allegations that he violated the physician self-referral prohibition in the Stark law for routinely referring Medicare patients to an oxygen supply company he owned.

Physician Recruitment

A hospital will sometimes provide a physician with a recruitment incentive to induce the physician to relocate to the hospital's geographic area, become a member of its medical staff, and establish a practice that helps serve that community's medical needs. Often, such recruitment efforts are legitimately designed to fill a "clinical gap" in a medically underserved area to which it may be difficult to attract physicians in the absence of financial incentives. However, as you begin planning your professional future and perhaps receiving recruitment offers, you need to be aware that in some communities, especially ones with multiple hospitals, the competition for patients can be fierce. Some hospitals may offer illegal inducements to you, or to the established physician practice you join in the hospital's community, to gain referrals. This means that the competition for your loyalty can cross the line into illegal arrangements for which *both you and the hospital* can be liable.

Recruitment arrangements are of special interest to graduating residents and fellows. Within very specific parameters specified in the Stark law and subject to compliance with the AKS, hospitals may provide relocation assistance and practice support under a properly structured recruitment arrangement to assist you in establishing a practice in the hospital's community. Alternatively, a hospital may pay you a fair market value salary as an employee or pay you fair market value for specific services you render to the hospital as an independent contractor. However, the hospital may not offer you money, provide you free or below-market rent for your medical office, or engage in similar activities designed to influence your referral decisions. **You should admit your patients to the hospital best suited to care for their particular medical conditions or to the hospital your patient selects based on his or her preference or insurance coverage.** As noted, if a hospital or physician practice seperately or jointly is recruiting you as a new physician to the community, you may be offered a recruitment package. But, you may not negotiate for benefits in exchange for a promise—implicit or explicit—that you will admit your patients to a specific hospital or practice setting unless you are a hospital employee. You should seek knowledgeable legal counsel if someone with whom you are entering into a relationship requires you to admit patients to a specific hospital or practice group.

Tips for Medical Directors

If you choose to accept a medical directorship at a nursing home or other facility, you must be prepared to assume substantial professional responsibility for the care delivered at the facility. As medical director, patients (both your own patients and the patients of other attending physicians) and their families count on you, and State and Federal authorities may hold you accountable as well. To do this job well, you should:

- actively oversee clinical care in the facility;
- lead the medical staff to meet the standard of care;
- ensure proper training, education, and oversight for physicians, nurses, and other staff members; and
- identify and address quality problems.

Case Examples of Medical Directorship Issues

• A physician group practice paid the Government $1 million and entered into a 5-year Corporate Integrity Agreement to settle alleged violations of the AKS, FCA, and Stark law related to medical directorships with a medical center. Allegedly, the agreements were not in writing, the physicians were paid more than fair market value for the services they rendered, and the payment amounts were based on the value of referrals the physicians sent to the medical center.

• Two orthopedic surgeons paid $450,000 and $250,000 to settle allegations related to improper medical directorships with a company that operated a diagnostic imaging center, a rehabilitation facility, and an ambulatory surgery center. The company allegedly provided the physicians with valuable compensation, including free use of the corporate jet, under the medical directorship agreements, which required the physicians to render limited services in return. The agreements with the physicians allegedly called for redundant services and served to encourage the physicians to refer their patients to the facilities operated by the company.

III. Physician Relationships With Vendors

Free Samples

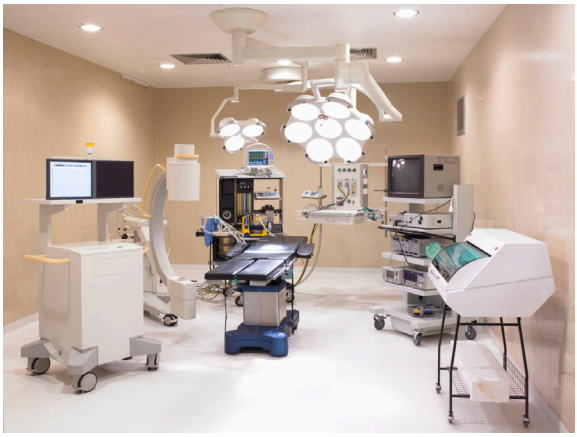
Some physicians welcome visits from pharmaceutical salespeople, while other physicians prefer not to directly engage with industry representatives. If you decide to make your practice accessible to salespeople, you probably will be offered product samples. Many drug and biologic companies provide physicians with free samples that the physicians may give to patients free of charge. **It is legal to give these samples to your patients for free, but it is illegal to sell the samples.** The Government has prosecuted physicians for billing Medicare for free samples. Opinions differ on whether sampling practices ultimately increase or decrease patients' long-term drug costs. If you choose to accept samples, you will need reliable systems in place to safely store the samples and ensure that samples are not commingled with your commercial stock.

Case Example Involving Drug Samples

• Several urologists pled guilty to charges of conspiracy, paid restitution in the tens of thousands of dollars, and received sanctions against their medical licenses for billing Medicare for injectable prostate cancer drugs they received for free from two pharmaceutical companies. The pharmaceutical companies paid $1.4 billion for their part of the alleged scheme to give urologists free samples and encourage them to bill Medicare at an inflated price. The pharmaceutical companies also provided urologists with additional inducements to use their drugs over the competitor's products, including drug rebates, education grants, volume discounts, free goods, and debt forgiveness.

Relationships With the Pharmaceutical and Medical Device Industries

Physician-industry collaboration can produce important medical advances. However, some pharmaceutical and device companies have used sham consulting agreements and other arrangements to buy physician loyalty to their products. Such illegal arrangements induce physicians to prescribe or use products on the basis of that loyalty to the company or to get more money from the company, rather than because it is the best treatment for the patient.



As a practicing physician, you may have opportunities to work as a consultant or promotional speaker for the drug or device industry. For every financial relationship offered to you, evaluate the link between the services you can provide and the compensation you will receive. Test the propriety of any proposed relationship by asking yourself the following questions:

- ? Does the company *really* need *my* particular expertise or input?
- ? Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?
- ? Is it possible the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?

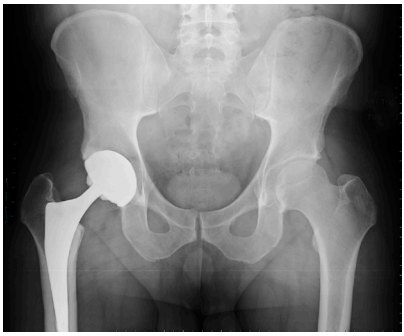
A good discussion that assists in distinguishing between legitimate and questionable industry relationships is located in the OIG's "Compliance Program Guidance for Pharmaceutical Manufacturers" available at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.

If your contribution is your time and effort or your ability to generate useful ideas and the payment you receive is fair market value compensation for your services without regard to referrals, then, depending on the circumstances, you may legitimately serve as a *bona fide* consultant. **If your contribution is your ability to prescribe a drug or use a medical device or refer your patients for particular services or supplies, the proposed consulting arrangement likely is one you should avoid as it could violate fraud and abuse laws.**

For example, if a drug company offers to pay you and a hundred other "thought leaders" to attend a conference in the Bahamas without requiring preparatory work on your part or information about your expertise in the field (other than the fact that you are a licensed physician), you should be suspicious that the company is attempting to influence you to prescribe its drug.

Case Example of Kickbacks in the Device Industry

• Four orthopedic device manufacturers paid $311 million to settle kickback and false claims allegations that the companies bribed surgeons to recommend their hip and knee surgical implant products. The companies allegedly would award physicians with vacations, gifts, and annual "consulting fees" as high as $200,000 in return for the physicians' endorsements of their implants or use of them in operations. Many of the individual orthopedic surgeons at the receiving end of the kickbacks are the subject of ongoing investigations by the Government. One orthopedic surgeon recently paid $650,000 to resolve allegations that the surgeon accepted payments from device manufacturers to use their hip and knee implants.



Transparency in Physician-Industry Relationships

Although some physicians believe that free lunches, subsidized trips, and gifts do not affect their medical judgment, research shows that these types of perquisites can influence prescribing practices. Recent pharmaceutical company settlements with the Department of Justice and OIG require "transparency" in physician-industry relationships, whether by requiring the pharmaceutical company to provide the Government with a list of physicians whom the company paid and/or by requiring ongoing public disclosure by the company of physician payments. **The public will soon know what gifts and payments a physician receives from industry.** The Patient Protection and Affordable Care Act of 2010 requires drug, device, and biologic companies to publicly report nearly all gifts or payments they make to physicians beginning in 2013.

Academic institutions also may impose various restrictions on the interactions their faculty members or affiliated physicians have with industry. These and other considerations may factor into your decision about whether you want to conduct industry-sponsored research; serve as a consultant or director for a drug, biologic, or device company; apply for industry-sponsored educational or research grants; or engage in other relationships with industry.

Both the pharmaceutical industry (through PhRMA) and the medical device industry (through AdvaMed) have adopted codes of ethics for their respective industries regarding relationships with health care professionals. Both codes are available online.

Conflict-of-Interest Disclosures

Many of the relationships discussed in this brochure are subject to conflict-of-interest disclosure policies. Even if the relationships are legal, you may have an obligation to disclose their existence. Rules about disclosing and managing conflicts of interest come from a variety of sources, including grant funders, such as States, universities, and the National Institutes of Health, and from the Food and Drug Administration (FDA) when data are submitted to support marketing approval for new drugs, devices, or biologics. To "manage" your conflicts of interest, consider the conflicts policies that affect your professional activities, candidly disclose any industry money subject to these policies, and adhere to restrictions on your activities. If you are uncertain whether a conflict exists, ask someone. You always can apply the "newspaper test" and ask yourself whether you would want the arrangement to appear on the front page of your local newspaper.

Continuing Medical Education

After finishing your formal graduate medical training, you will assume greater responsibility for your continuing medical education (CME) to maintain State licensure, hospital privileges, and board certification. Drug and device manufacturers sponsor many educational opportunities for physicians. **It is important to distinguish between CME sessions that are educational in nature and sessions that constitute marketing by a drug or device manufacturer.** Industry satellite programs that occur concurrently with a society meeting are generally promotional, even if the primary speaker is a physician who is well known in the field. You should be circumspect about a discussion that focuses on a particular brand drug or device, as opposed to all the treatment alternatives for a specific condition.

For example, if speakers recommend use of a drug to treat conditions for which there is no FDA approval or use of a drug by children when FDA has approved only adult use, you should independently seek out the empirical data that support these recommendations. **Note that although physicians may prescribe drugs for off-label uses, it is illegal under the Federal Food, Drug, and Cosmetic Act for drug manufacturers to promote off-label uses of drugs.**

Advertisements and other promotional materials for drugs, biologics, and medical devices must be truthful, not misleading, and limited to approved uses. FDA is requesting physicians' assistance in identifying misleading advertisements through its Bad Ad Program. If you spot advertising violations, you should report them to FDA by calling 877-RX-DDMAC (877-793-3622) or by emailing badad@fda.gov.

If you are invited to serve as faculty for industry-sponsored CME, ask yourself the following questions:

- Does the sponsor *really* need *my* particular expertise or input?
- Does the amount of money the sponsor is offering seem fair and appropriate for the educational value I will add to the presentation?
- Is it possible the sponsor is paying me for my loyalty so that I will prescribe its drugs or use its devices?
- Does the sponsor prepare a slide deck and speaker notes, or am I free to set the content of the lecture?

Compliance Programs for Physicians

Establishing and following a compliance program will help physicians avoid fraudulent activities and ensure that they are submitting true and accurate claims. The following seven components provide a solid basis upon which a physician practice can create a voluntary compliance program:

1. Conduct internal monitoring and auditing.
2. Implement compliance and practice standards.
3. Designate a compliance officer or contact.
4. Conduct appropriate training and education.
5. Respond appropriately to detected offenses and develop corrective action.
6. Develop open lines of communication with employees.
7. Enforce disciplinary standards through well-publicized guidelines.

With the passage of the Patient Protection and Affordable Care Act of 2010, physicians who treat Medicare and Medicaid beneficiaries will be required to establish a compliance program.

For more information on compliance programs for physicians, see OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" available at http://oig.hhs.gov/authorities/docs/physician.pdf.

Where To Go for Help

When you are considering whether or not to engage in a particular billing practice; enter into a particular business venture; or pursue an employment, consulting, or other personal services relationship, it is prudent to evaluate the arrangement for potential compliance problems. The following is a list of possible resources that can help you.

- Experienced health care lawyers can analyze your issues and provide a legal evaluation and risk analysis of the proposed venture, relationship, or arrangement.

- The Bar Association in your State may have a directory of attorneys in your area who practice in the health care field.
- Your State or local medical society may be a good resource for issues affecting physicians and may have listings of health care lawyers in your area.
- Your specialty society may have information on additional risk areas specific to your type of practice.
- CMS's local contractor medical directors are a valuable source of information on Medicare coverage policies and appropriate billing practices. The contact information for local contractors is available at http://www.cms.gov/MLNGenInfo/30_contactus.asp.
- CMS's "Medicare Physician Guide: A Resource for Residents, Practicing Physicians, and Other Health Care Professionals" available at http://www.cms.gov/MLNProducts/downloads/physicianguide.pdf, provides an overview of the Medicare program and information on Medicare reimbursement and payment policies.
- The OIG's Web site, available at http://oig.hhs.gov, provides substantial fraud and abuse guidance.
- As discussed above, OIG issues Compliance Program Guidance documents that include compliance recommendations and discussions of fraud and abuse risk areas. These guidance documents are available at http://oig.hhs.gov/fraud/complianceguidance.asp.
- OIG issues advisory opinions to parties who seek advice on the application of the AKS, CMPL, and Exclusion Authorities. Information on how to request an OIG advisory opinion and links to previously published OIG advisory opinions are available at http://oig.hhs.gov/fraud/advisoryopinions.asp.
- CMS issues advisory opinions to parties who seek advice on the Stark law. Information on how to request a CMS advisory opinion and links to previously published CMS advisory opinions are available at http://www.cms.gov/PhysicianSelfReferral/95_advisory_opinions.asp.

What To Do If You Think You Have a Problem

If you are engaged in a relationship you think is problematic or have been following billing practices you now realize were wrong:

- Immediately cease filing the problematic bills.
- Seek knowledgeable legal counsel.
- Determine what money you collected in error from your patients and from the Federal health care programs and report and return overpayments.
- Unwind the problematic investment.
- Disentangle yourself from the suspicious relationship.
- Consider using OIG's or CMS's self-disclosure protocols.

OIG Provider Self-Disclosure Protocol

The OIG Provider Self-Disclosure Protocol is a vehicle for physicians to voluntarily disclose self-discovered evidence of potential fraud. The protocol allows providers to work with the Government to avoid the costs and disruptions entailed in a Government-directed investigation. For more information on the OIG Provider Self-Disclosure Protocol, see http://oig.hhs.gov/fraud/selfdisclosure.asp.

Case Examples of Physician Liabilities Resolved Under the OIG Provider Self-Disclosure Protocol

• A Minneapolis physician paid $53,400 and resolved liability for violating his Medicare assignment agreement by charging patients a yearly fee for services, some of which were covered by Medicare.

• A Florida physician paid $100,000 and resolved liability related to referring patients to a lab owned by his brother.

• A neurosurgery practice paid $10,000 and resolved liability for employing an individual who was excluded from participation in the Federal health care programs.

What To Do If You Have Information About Fraud and Abuse Against Federal Health Care Programs

If you have information about fraud and abuse against Federal health care programs, use the OIG Fraud Hotline to report that information to the appropriate authorities. The Hotline allows the option of reporting anonymously.

Phone:	1-800-HHS-TIPS (1-800-447-8477)
Fax:	1-800-223-8164
Email:	HHSTIPS@oig.hhs.gov
TTY:	1-800-377-4950
Mail:	Office of Inspector General Department of Health & Human Services Attn: HOTLINE P.O. Box 23489 Washington, DC 20026

For additional information about the Hotline, visit the OIG Web site at http://oig.hhs.gov/fraud/hotline/.

June 2020

CMS Roadmap

STRATEGY TO FIGHT THE OPIOID CRISIS

Opioids killed more than 47,000 in 2018, or over 130 people per day.[1]

32% of all opioid overdose deaths involve a prescription opioid.[2]

PRESCRIPTION OPIOID USE AND MISUSE

When used correctly under a health care provider's direction, prescription opioids are **helpful** for treating pain.

The CDC has issued **a guideline** for safe prescribing of opioids in primary care.[3]

An estimated **10.3 million** people misused prescription opioids in 2018[4]—putting them at risk for dependence and opioid use disorder.

3 out of 4 people who used heroin misused prescription opioids first.[5]

OPIOID USE DISORDER

Over **two million** people have an opioid use disorder.[1]

Treatment options exist, including medication-assisted treatment (MAT)[6], and naloxone prescribing for people at risk.[7]

Only 20% of people with opioid use disorder (OUD) receive treatment.[3]

KEY AREAS OF CMS FOCUS

As one of the largest payers of healthcare services, CMS has a vital role in addressing the opioid epidemic and is focused on three key areas:

PREVENTION

Manage pain using a safe and effective range of treatment options that rely less on prescription opioids

TREATMENT

Expand access to treatment for opioid use disorder

DATA

Use data to target prevention and treatment efforts and to identify fraud and abuse

SUCCESSES SO FAR

COVERAGE

CMS coverage policies now ensure some form of MAT across all CMS programs. Starting January 1, 2020, for the first time, Medicare covers methadone for MAT and related services furnished by opioid treatment programs (OTPs). On January 21, 2020, Medicare coverage expanded to include acupuncture for certain beneficiaries with chronic low back pain.

BEST PRACTICES

While implementation of drug management programs (DMPs) by Part D sponsors has been optional since 2019, 87% have already adopted them to address opioid overutilization among their enrollees.[8] Implementation of DMPs by Part D sponsors will be mandatory in CY 2022. In 2020, for the first time, all plans have at least one naloxone product on a non-branded tier.

DATA

CMS published a data book containing new, nationwide Medicaid data on substance use disorder (SUD) prevalence and treatment, helping researchers and policymakers better evaluate and improve treatment for Medicaid beneficiaries.

TRACKING

Due to policies promoting safer use, the number of Medicare beneficiaries receiving higher doses of opioids (≥ 90 morphine milligram equivalents (MME) for at least one day) declined by 45% between 2016 and 2019.

AWARENESS

CMS sent 25,000 letters from 2017 to 2019 to Medicare clinicians to compare their prescribing practices to those of their peers and to emphasize patient-centered care and safety.

ACCESS

As of June 2020, CMS approved 28 state Medicaid 1115 demonstrations to improve access to opioid use disorder treatment, including new flexibility to cover inpatient and residential treatment.

MOVING FORWARD

PREVENTION

Significant progress has been made in identifying inappropriate prescribing patterns

TREATMENT

Medicare, Medicaid, and private health plans provide some coverage for pain and opioid use disorder treatments

DATA

Data provides insight into doctor, pharmacy, and patient use of prescription opioids and effectiveness of treatment

CMS CAN BUILD ON THESE EFFORTS TO FURTHER:

1. **Identify** and stop inappropriate prescribing of opioids
2. **Enhance** screening for OUD to get people the support they need earlier
3. **Focus** best practices education and support resources on hardest hit areas

1. **Ensure** access to treatment across CMS programs
2. **Give** patients options for a broader range of treatments
3. **Support** innovation through new delivery models and by sharing best practices

1. **Understand** opioid use and misuse patterns across populations
2. **Promote** sharing of actionable data across continuum of care
3. **Monitor** trends to assess impact of prevention and treatment efforts

IMPLEMENTING THE SUPPORT FOR PATIENTS AND COMMUNITIES (SUPPORT) ACT

CMS is implementing nearly 50 provisions of the SUPPORT Act, enacted in 2018, that aim to increase options to treat beneficiaries with substance use disorders including opioid use disorder, ensure appropriate prescribing, improve the treatment of acute and chronic pain, heighten safety, and illuminate prescribing data.

A CLOSER LOOK: DETAILED ACTIVITIES ON THE 2020 ROADMAP

PREVENTION

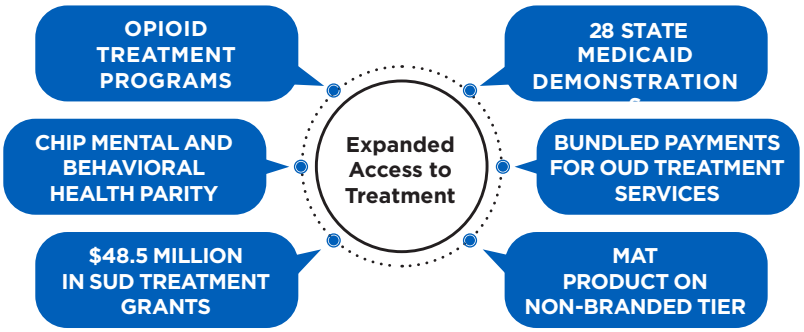
CMS has continued reducing inappropriate opioid prescribing by:

- Introducing new Medicare Part D opioid safety policies that include improved safety alerts at the pharmacy for Part D beneficiaries who are filling their initial opioid prescription or who are receiving high doses of prescription opioids, in addition to requiring pharmacies and prescribers to have tools to designate if a prescription is a partial fill.
- Outlining options and sharing best practices for state Medicaid agencies and other payers to expand access to non-opioid pain treatments and other tactics to help address pain and the opioid crisis.[9]
- In Medicare, supporting opioid alternatives offered by MA plans, Part D and Original Medicare, for example through new coverage of acupuncture to address lower back pain and educating providers on other non-opioid alternatives.
- Issuing guidance to states on drug utilization reviews to improve prescription safety in the Medicaid program.[10]

TREATMENT

CMS is pursuing solutions to eliminate treatment barriers for opioid use disorders across Medicare, Medicaid, and CHIP, including:

- Increasing access to MAT through providing coverage of comprehensive episodes of care for OUD treatment.
- Supporting the development of the OUD treatment workforce by issuing grants to states for capacity planning.
- Expanding access to SUD treatment in CHIP.

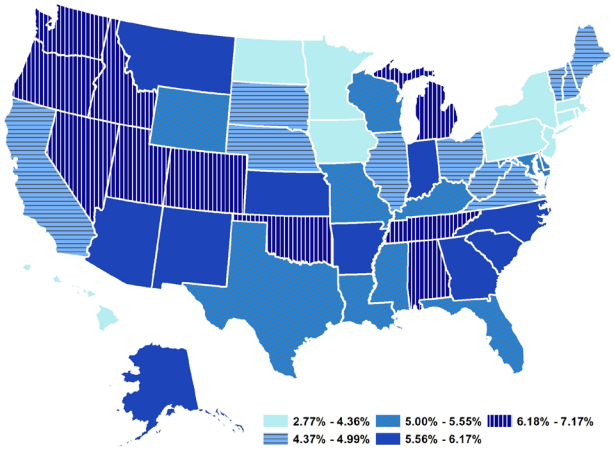


DATA & ANALYTIC **TOOLS**

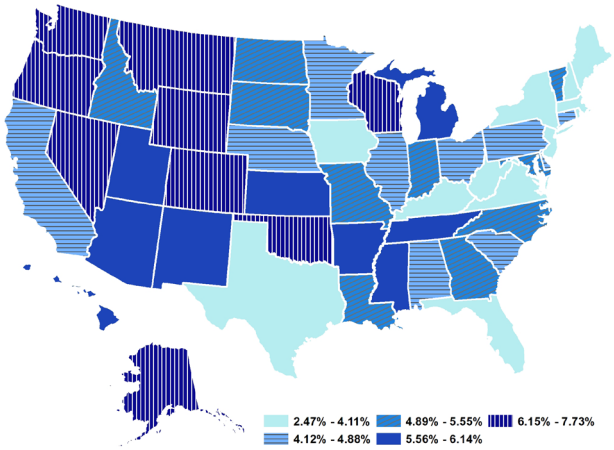
CMS will focus our data efforts and provide tools for states, plans and providers to:

- **Monitor** success of prevention measures related to reducing overuse and misuse of prescription opioids.
- **Improve** transparency tools and interoperability, and expand data tools like the "heat map" of prescribing rates in Medicare and Medicaid that help determine where to target safe prescribing efforts (see maps below).
- **Analyze** prescription opioid use patterns across CMS programs and in special populations such as individuals in rural areas, dually eligible for Medicare and Medicaid, and with certain health conditions.
- **Support** state Medicaid program capacity to track and report data.

2017 MEDICARE PRESCRIBING RATES [11]



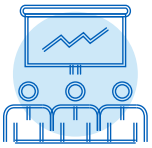
2017 MEDICAID PRESCRIBING RATES [12]



HIGHLIGHTING **INNOVATION**

MEDICAID DEMONSTRATION PROJECTS

CMS approved **28 Medicaid demonstrations to improve access to OUD treatment**, including flexibility to cover inpatient and residential treatment. We're already seeing results: In Virginia, the number of Medicaid beneficiaries with SUD receiving SUD services increased 104%, from 13,389 to 27,319. And Utah reported an increase in the expenditures for SUD-related services from December 2017 ($1.2 million) through November 2018 ($4.6 million).

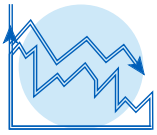


INCREASING SUD TREATMENT WORKFORCE

CMS announced $48.5 million in planning grant awards to 15 state Medicaid agencies to increase the treatment capacity of providers to furnish SUD treatment and recovery services. The planning grants are intended to increase the capacity of Medicaid providers to deliver SUD treatment or recovery services through: an ongoing assessment of the SUD treatment needs of the state; recruitment, training, and technical assistance for Medicaid providers that offer SUD treatment or recovery services; and improved reimbursement for and expansion of the number or treatment capacity of Medicaid providers.

PROMOTED ACCESS TO NON-OPIOID PAIN TREATMENTS

CMS released an informational bulletin[9] providing guidance to states aimed at reducing the use of opioids and promoting access to non-opioid options for chronic pain management, like the Oregon Health Plan initiative. Through this initiative, the state expanded Medicaid coverage for non-opioid treatment for pain to include chiropractic services, osteopathic manipulation, cognitive behavioral therapy, and physical therapy as potential alternatives, when appropriate, to surgeries, opioids, and epidural steroid injections.



ADVANCED ANALYTICS

CMS's Quality Improvement Organizations provided advanced data analytic support and clinical expertise to a network of 10 hospitals and partners across Colorado to change pain management practices and improve care. Over a 6-month timeframe, CMS data showed that these hospitals achieved a 36% reduction in the use of opioids—about 35,000 fewer administrations of opioids in the emergency department—and an increase in non-opioid pain medications by 31%.

INNOVATIVE MODELS

CMS entered into 18 cooperative agreements that include funding with state and local partners for two innovative opioid models focused on supporting advances in coordinated care for vulnerable populations, the Maternal Opioid Misuse (MOM)[13] and Integrated Care for Kids (InCK)[14] Models. The MOM Model supports the transformation in the care of pregnant women with an opioid use disorder. By merging clinical care and community services critical to health, well-being, and recovery, the model is expected to improve care quality and reduce costs for mothers and infants. InCK aims to improve the quality of care for at-risk children covered by Medicaid and CHIP through prevention, early identification, and coordinated care across behavioral, physical, and other pediatric providers. The pre-implementation periods for both MOM and InCK Models began January 2020.

SOURCES:

1 HHS: https://www.hhs.gov/opioids/sites/default/files/2019-11/Opioids%20Infographic_letterSizePDF_10-02-19.pdf

2 CDC: https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html

3 CDC: https://www.cdc.gov/drugoverdose/prescribing/guideline.html

4 SAMHSA: https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf

5 SAMHSA: https://www.samhsa.gov/sites/default/files/aatod_2018_final.pdf

6 SAMHSA: https://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat

7 CDC: https://www.cdc.gov/drugoverdose/pdf/Guidelines_At-A-Glance-508.pdf

8 GOVINFO: https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf

9. MEDICAID: https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib022219.pdf

10. MEDICAID: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib080519-1004.pdf

11 CMS: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap_Medicare_PartD

12. CMS: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap_Medicaid_State.html

13. CMS: https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model

14.CMS: https://innovation.cms.gov/innovation-models/integrated-care-for-kids-model

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Special Fraud Alert: Speaker Programs

November 16, 2020

I. Introduction

This Special Fraud Alert highlights the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. For purposes of this Special Fraud Alert, speaker programs are generally defined as company-sponsored events at which a physician or other health care professional (collectively, "HCP") makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company. The company generally pays the speaker HCP an honorarium, and often pays remuneration (for example, free meals) to the attendees. In the last three years, drug and device companies have reported paying nearly $2 billion to HCPs for speaker-related services.[1]

The Office of Inspector General (OIG) and Department of Justice (DOJ) have investigated and resolved numerous fraud cases involving allegations that remuneration offered and paid in connection with speaker programs violated the anti-kickback statute. The Federal government has pursued civil and criminal cases against companies and individual HCPs involving speaker programs. These cases alleged, for example, that drug and device companies:

- selected high-prescribing HCPs to be speakers and rewarded them with lucrative speaker deals (e.g., some HCPs received hundreds of thousands of dollars for speaking);[2]

[1] Drug and device companies are required to report certain payments made to HCPs to the Centers for Medicare & Medicaid Services (CMS). CMS makes this information publicly available on its Open Payments website. According to Open Payments, drug and device companies paid HCPs nearly $2 billion under the category "compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program" for years 2017, 2018, and 2019 combined. *Open Payments Complete 2017, 2018, and 2019 Program Year Datasets*, CMS, https://www.cms.gov/OpenPayments/Explore-the-Data/Data-Overview (*accessed* Sept. 9, 2020).

[2] Though not addressed in this Special Fraud Alert, remuneration paid by drug and device companies relating to the training of HCP speakers also may raise fraud and abuse risks.

- conditioned speaker remuneration on sales targets (e.g., required speaker HCPs to write a minimum number of prescriptions in order to receive the speaker honoraria);

- held speaker programs at entertainment venues or during recreational events or otherwise in a manner not conducive to an educational presentation (e.g., wineries, sports stadiums, fishing trips, golf clubs, and adult entertainment facilities);

- held programs at high-end restaurants where expensive meals and alcohol were served (e.g., in one case, the average food and alcohol cost per attendee was over $500); and

- invited an audience of HCP attendees who had previously attended the same program or HCPs' friends, significant others, or family members who did not have a legitimate business reason to attend the program.

Our enforcement experience demonstrates that some companies expend significant resources on speaker programs and that some HCPs receive substantial remuneration from companies. This Special Fraud Alert highlights some of the inherent fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration related to company-sponsored speaker programs.

II. The Anti-Kickback Statute

Congress enacted the anti-kickback statute, in part, to protect patients from referrals or recommendations by HCPs who may be influenced by inappropriate financial incentives. The anti-kickback statute makes it a criminal offense to knowingly and willfully solicit, receive, offer, or pay any remuneration to induce or reward, among other things, referrals for, or orders of, items or services reimbursable by a Federal health care program.[3] When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. For purposes of the anti-kickback statute, the offer, payment, solicitation, or receipt of "remuneration" includes the transfer of anything of value, directly or indirectly, overtly

[3] See section 1128B(b)(1)–(2) of the Social Security Act; 42 U.S.C. § 1320a-7b(b)(1)–(2). The anti-kickback statute applies broadly to remuneration to induce or reward referrals of patients as well as the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any item or service reimbursable by any Federal health care program. In this Special Fraud Alert, we use the term "referral" to include the full range of these types of activities (including ordering or prescribing items) that falls within the scope of the anti-kickback statute.

or covertly, in cash or in kind. By its terms, the statute ascribes criminal liability to all parties to an impermissible "kickback" transaction (i.e., those who solicit or receive prohibited remuneration as well as those who offer or pay the prohibited remuneration). Violation of the statute is a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Criminal conviction will also lead to mandatory exclusion from Federal health care programs, including Medicare and Medicaid.[4] OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs and impose civil money penalties for conduct prohibited by the anti-kickback statute.[5]

III. Fraud and Abuse Risks of Speaker Programs

Numerous investigations have involved allegations that drug and device companies organize and pay for speaker programs with the intent to induce HCPs to prescribe or order (or recommend the prescription or ordering of) the companies' products. Speaker programs typically involve an HCP who is not an employee of the company speaking in person to other HCPs about a company product or disease state using a presentation developed and approved by the company. According to a pharmaceutical industry trade group, HCPs "participate in company-sponsored speaker programs in order to help educate and inform other health care professionals about the benefits, risks, and appropriate uses of company medicines."[6]

OIG is skeptical about the educational value of such programs. Our investigations have revealed that, often, HCPs receive generous compensation to speak at programs offered under circumstances that are not conducive to learning or to speak to audience members who have no legitimate reason to attend. Such cases strongly suggest that one purpose of the remuneration to the HCP speaker and attendees is to induce or reward referrals. Furthermore, studies have shown that HCPs who receive remuneration from a company are more likely to prescribe or order that company's products.[7] This remuneration to

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[4] See 42 U.S.C. § 1320a-7(a).

[5] See 42 U.S.C. § 1320a-7(b)(7); § 1320a-7a(a)(7).

[6] *Code on Interactions with Health Care Professionals*, PhRMA, 7 (June 2020), available at https://phrma.org/Codes-and-guidelines/Code-on-Interactions-with-Health-Care-Professionals. A device industry trade group also addresses this topic and interactions with HCPs generally in its code of ethics. See *AdvaMed Code of Ethics*, AdvaMed (July 2020), available at https://www.advamed.org/resource-center/advamed-code-ethics-2020.

[7] Amarnath Annapureddy et al., *Association Between Industry Payments to Physicians and Device Selection in ICD Implantation*, 324 JAMA 17, 2020, at 1759, 1762–63; William Fleischman et al., *Association between payments from manufacturers of pharmaceuticals to physicians and regional prescribing: cross sectional ecological study*, 354 BMJ i4189, 2016, at 1, 4–7; James P. Orlowski & Leon Wateska, *The effects of pharmaceutical firm enticements on physician prescribing patterns. There's no such thing as a free lunch.*, 102 CHEST, 1992, 270.

HCPs may skew their clinical decision making in favor of their own and the company's financial interests, rather than the patient's best interests.

There are many other ways for HCPs to obtain information about drug and device products and disease states that do not involve remuneration to HCPs. HCPs can access the same or similar information provided in a speaker program using various online resources, the product's package insert, third-party educational conferences, medical journals, and more. The availability of this information through means that do not involve remuneration to HCPs further suggests that at least one purpose of remuneration associated with speaker programs is often to induce or reward referrals.

Parties involved in speaker programs may be subject to increased scrutiny. These include any drug or device company that organizes or pays remuneration associated with the program, any HCP who is paid to speak, and any HCP attendees who receive remuneration from the company (e.g., free food and drink). OIG has long expressed concerns over the practice of drug and device companies providing anything of value to HCPs in a position to make or influence referrals to such companies' products. In the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers,[8] OIG identified manufacturer compensation relationships with physicians connected directly or indirectly to marketing and sales activities, including speaking activities, as an area of potential risk under the anti-kickback statute. OIG noted that when a drug or device company engages in "entertainment, recreation, travel, meals or other benefits in association with information or marketing presentations," such arrangements may potentially implicate the anti-kickback statute.[9]

OIG also warned physicians that a consultant or speaking arrangement with a drug or device company could be an improper inducement "to prescribe or use [company] products on the basis of . . . loyalty to the company or to get more money from the company, rather than because it is the best treatment for the patient."[10] OIG recommended that physicians consider the propriety of any proposed relationship with a company and advised that if the basis for a physician's compensation "is your ability to

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[8] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003), available at https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf. The guidance is not limited to pharmaceutical manufacturers; it states, "the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by [F]ederal health care programs, such as medical devices and infant nutritional products." Id. at 23742, n.5.

[9] Id. at 23738.

[10] *A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse*, HHS-OIG, 22 (Nov. 2010), available at https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf; *OIG Compliance Program for Individual and Small Group Physician Practices*, 65 Fed. Reg. 59434 (Oct. 5, 2000), available at https://oig.hhs.gov/authorities/docs/physician.pdf.

prescribe a drug or use a medical device or refer your patients for particular services or supplies, the proposed consulting arrangement likely is one you should avoid as it could violate fraud and abuse laws."[11] Again, we note that HCPs could face liability under the anti-kickback statute for knowingly and willfully soliciting or receiving remuneration in connection with speaker programs in return for prescribing or ordering products reimbursable by a Federal health care program.

OIG recognizes that the lawfulness of any remunerative arrangement, including speaker program arrangements, under the anti-kickback statute depends on the facts and circumstances and intent of the parties. Such intent may be evidenced by the speaker program's characteristics and the actual conduct of the parties involved. Below we describe some characteristics, which, taken separately or together, potentially indicate a speaker program arrangement that could violate the anti-kickback statute. As previously stated, drug and device companies that host or pay for such speaker programs and HCPs who speak at or attend such programs could be liable under the anti-kickback statute for any prohibited remuneration. This list of suspect characteristics is illustrative, not exhaustive, and the presence or absence of any one of these factors is not determinative of whether a particular arrangement would be suspect under the anti-kickback statute.

- The company sponsors speaker programs where little or no substantive information is actually presented;

- Alcohol is available or a meal exceeding modest value is provided to the attendees of the program (the concern is heightened when the alcohol is free);

- The program is held at a location that is not conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues);

- The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information;

- There has been a significant period of time with no new medical or scientific information nor a new FDA-approved or cleared indication for the product;

[11] Id. at 23.

- HCPs attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic);

- Attendees include individuals who don't have a legitimate business reason to attend the program, including, for example, friends, significant others, or family members of the speaker or HCP attendee; employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information;

- The company's sales or marketing business units influence the selection of speakers or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (e.g., a return on investment analysis is considered in identifying participants);

- The company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the HCPs.

IV. Conclusion

OIG has significant concerns about companies offering or paying remuneration (and HCPs soliciting or receiving remuneration) in connection with speaker programs. Based on our investigations and enforcement actions, this remuneration is often offered or paid to induce (or solicited or received in return for) ordering or prescribing items paid for by Federal health care programs. If the requisite intent is present, both the company and the HCPs may be subject to criminal, civil, and administrative enforcement actions. This Special Fraud Alert is not intended to discourage meaningful HCP training and education. Rather, the purpose of this Special Fraud Alert is to highlight certain inherent risks of remuneration related to speaker programs. Drug and device companies and HCPs should consider the risks when assessing whether to offer, pay, solicit, or receive remuneration related to speaker programs.

We are issuing this alert during the pandemic emergency, which is necessarily curtailing many in-person activities. While companies may have decreased in-person speaker program-related remuneration to HCPs during the pandemic, risks remain whenever payments are offered or made to HCPs who generate Federal health care program

business for the company. The risks associated with speaker programs will become more pronounced if companies resume in-person speaker programs or increase speaker program-related remuneration to HCPs. Companies should assess the need for in-person programs given the risks associated with offering or paying related remuneration and consider alternative less-risky means for conveying information to HCPs. HCPs should likewise consider the risks of soliciting or receiving remuneration related to speaker programs given other available means to gather information relevant to providing appropriate treatment for patients. If a company or HCP has questions about a specific speaker program arrangement involving remuneration to referral sources, the OIG Advisory Opinion process remains available. Information about that process may be found at: https://oig.hhs.gov/faqs/advisory-opinions-faq.asp.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies

July 20, 2022

I. Introduction

The Office of Inspector General (OIG) has conducted dozens of investigations of fraud schemes involving companies that purported to provide telehealth, telemedicine, or telemarketing services (collectively, Telemedicine Companies) and exploited the growing acceptance and use of telehealth. For example, in some of these fraud schemes Telemedicine Companies intentionally paid physicians and nonphysician practitioners (collectively, Practitioners) kickbacks to generate orders or prescriptions for medically unnecessary durable medical equipment, genetic testing, wound care items, or prescription medications, resulting in submissions of fraudulent claims to Medicare, Medicaid, and other Federal health care programs. These fraud schemes vary in design and operation, and they have involved a wide range of different individuals and types of entities, including international and domestic telemarketing call centers, staffing companies, Practitioners, marketers, brokers, and others.

One common element of these schemes is the way Telemedicine Companies have used kickbacks to aggressively recruit and reward Practitioners to further the fraud schemes. Generally, the Telemedicine Companies arrange with Practitioners to order or prescribe medically unnecessary items and services for individuals (referred to here as "purported patients") who are solicited and recruited by Telemedicine Companies. In many of these arrangements, Telemedicine Companies pay Practitioners in exchange for ordering or prescribing items or services: (1) for purported patients with whom the Practitioners have limited, if any, interaction; and (2) without regard to medical necessity. Such payments are sometimes described as payment per review, audit, consult, or assessment of medical charts. Telemedicine Companies often tell Practitioners that they do not need to contact the purported patient or that they only need speak to the purported patient by telephone. In addition, Practitioners are not given an opportunity to review the purported patient's real medical records. Furthermore, the Telemedicine Company may direct Practitioners to order or prescribe a preselected item or service, regardless of medical necessity or clinical appropriateness. In many cases, the Telemedicine Company sells the order or prescription generated by Practitioners to other individuals or entities that then fraudulently bill for the unnecessary items and services.

These schemes raise fraud concerns because of the potential for considerable harm to Federal health care programs and their beneficiaries, which may include: (1) an inappropriate increase in

costs to Federal health care programs for medically unnecessary items and services and, in some instances, items and services a beneficiary never receives; (2) potential to harm beneficiaries by, for example, providing medically unnecessary care, items that could harm a patient, or improperly delaying needed care; and (3) corruption of medical decision-making.

OIG encourages Practitioners to exercise caution and use heightened scrutiny when entering into arrangements with Telemedicine Companies that have one or more of the suspect characteristics described below. This Special Fraud Alert provides information to help Practitioners identify potentially suspect arrangements with Telemedicine Companies.[1]

II. Multiple Federal Laws Implicated

The schemes described above may implicate multiple Federal laws, including the Federal anti-kickback statute. The Federal anti-kickback statute is a criminal law that prohibits knowingly and willfully soliciting or receiving (or offering or paying) any remuneration in return for (or to induce), among other things, referrals for, or orders of, items or services reimbursable by a Federal health care program.[2] One purpose of the Federal anti-kickback statute is to protect patients from improper medical referrals or recommendations by health care professionals and others who may be influenced by financial incentives. When a party knowingly and willfully pays remuneration to induce or reward referrals of items or services payable by a Federal health care program, the Federal anti-kickback statute is violated. By its terms, the statute ascribes liability to parties on both sides of an impermissible kickback transaction. Practitioner arrangements with Telemedicine Companies may also lead to criminal, civil, or administrative liability under other Federal laws including, for example, OIG's exclusion authority related to kickbacks,[3] the Civil Monetary Penalties Law provision for kickbacks,[4] the criminal health care

[1] OIG has previously addressed other potentially suspect arrangements involving Practitioners. See e.g., "OIG Special Fraud Alert: Laboratory Payments to Referring Physicians" (June 2014), https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf; "OIG Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services" (Jan. 1999), https://oig.hhs.gov/documents/special-fraud-alerts/872/dme.htm; and "OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services" (Oct. 1994), https://oig.hhs.gov/documents/physicians-resources/980/121994.pdf. All of OIG's Special Fraud Alerts are available at https://oig.hhs.gov/compliance/alerts.

[2] Section 1128B(b) of the Social Security Act (the Act). The Federal anti-kickback statute applies broadly to remuneration to induce or reward referrals of patients as well as the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any item or service reimbursable by any Federal health care program. In this Special Fraud Alert, we use the term "referral" to include the full range of activities (including ordering or prescribing items) that falls within the scope of the Federal anti-kickback statute. In addition, this Special Fraud Alert uses the term "kickback" to refer to any remuneration prohibited by the Federal anti-kickback statute.

[3] Section 1128(b)(7) of the Act.

[4] Section 1128A(a)(7) of the Act.

fraud statute,[5] and the False Claims Act.[6] Practitioners may be personally liable for these types of arrangements, including for submitting or causing the submission of claims if they are involved in ordering or prescribing medically unnecessary items or services.[7]

III. Recent Enforcement Experience

In recent years, OIG and the Department of Justice (DOJ) have investigated numerous criminal, civil, and administrative fraud cases involving kickbacks from Telemedicine Companies to Practitioners who inappropriately ordered or prescribed items or services reimbursable by Federal health care programs in exchange for remuneration. In those cases, Practitioners, Telemedicine Companies, and other participants in schemes have been held civilly, criminally, and administratively liable for:[8] (1) paying or receiving a payment in violation of the Federal anti-kickback statute, (2) causing a submission of claims in violation of the False Claims Act,[9] and/or (3) other Federal criminal laws.[10]

While the facts and circumstances of each case differed, often they involved at least one Practitioner ordering or prescribing items or services for purported patients they never examined or meaningfully assessed to determine the medical necessity of items or services ordered or prescribed. In addition, Telemedicine Companies commonly paid Practitioners a fee that correlated with the volume of federally reimbursable items or services ordered or prescribed by the Practitioners, which was intended to and did incentivize a Practitioner to order medically unnecessary items or services. These types of volume-based fees not only implicate and potentially violate the Federal anti-kickback statute, but they also may corrupt medical decision-making, drive inappropriate utilization, and result in patient harm.

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[5] 18 U.S.C. § 1347.

[6] 31 U.S.C. §§ 3729-33.

[7] We note that other persons may face liability for conduct that contributes to violations of these laws including pharmacies, durable medical equipment suppliers, laboratories, and other providers and suppliers that bill for items and services based on the fraudulent orders or prescriptions.

[8] For example, each violation of the Federal anti-kickback statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid.

[9] A claim that includes items or services resulting from a violation of the Federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

[10] See e.g., U.S. Attorney's Office for the Southern District of Georgia press release, "Georgia nurse practitioner convicted of health care fraud in complex telemedicine fraud scheme" (Feb. 2, 2022), https://www.justice.gov/usao-sdga/pr/georgia-nurse-practitioner-convicted-health-care-fraud-complex-telemedicine-fraud; U.S. Attorney's Office for the Western District of Michigan press release, "U.S. Attorney Announces Criminal And Civil Enforcement Actions Against Medical Practitioners For Roles In Telemedicine Fraud Schemes" (Aug. 24, 2021), https://www.justice.gov/usao-wdmi/pr/2021_0824_Happy_Clickers; U.S. Attorney's Office for the District of Montana press release, "Two Montana nurse practitioners admit telemedicine scheme to defraud Medicare of more than $18 million" (Apr. 21, 2021), https://www.justice.gov/usao-mt/pr/two-montana-nurse-practitioners-admit-telemedicine-scheme-defraud-medicare-more-18.

IV. Suspect Characteristics

Based on OIG's and DOJ's enforcement experience, we have developed the below list of suspect characteristics related to Practitioner arrangements with Telemedicine Companies which, taken together or separately, could suggest an arrangement that presents a heightened risk of fraud and abuse. This list is illustrative, not exhaustive, and the presence or absence of any one of these factors is not determinative of whether a particular arrangement with a Telemedicine Company would be grounds for legal sanctions.

- The purported patients for whom the Practitioner orders or prescribes items or services were identified or recruited by the Telemedicine Company, telemarketing company, sales agent, recruiter, call center, health fair, and/or through internet, television, or social media advertising for free or low out-of-pocket cost items or services.

- The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed.[11]

- The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed.

- The Telemedicine Company only furnishes items and services to Federal health care program beneficiaries and does not accept insurance from any other payor.

- The Telemedicine Company claims to only furnish items and services to individuals who are not Federal health care program beneficiaries but may in fact bill Federal health care programs.[12]

- The Telemedicine Company only furnishes one product or a single class of products (e.g., durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a Practitioner's treating options to a predetermined course of treatment.

[11] For example, we have seen instances in which a Telemedicine Company requires the Practitioner to use audio-only technology to facilitate engagement with purported patients, regardless of their preference, and does not provide the Practitioner with other telehealth modalities. Additionally, a Telemedicine Company may provide a Practitioner with purported "medical records" that reflect only cursory patient demographic information or a medical history that appears to be a template but does not provide sufficient clinical information to inform the Practitioner's medical decision-making.

[12] An attempt to carve out Federal health care program beneficiaries from arrangements with Telemedicine Companies may still result in criminal, civil, or administrative liability for a Practitioner's role in any resulting fraudulent activity that involves Federal health care program beneficiaries.

- The Telemedicine Company does not expect Practitioners (or another Practitioner) to follow up with purported patients nor does it provide Practitioners with the information required to follow up with purported patients (e.g., the Telemedicine Company does not require Practitioners to discuss genetic testing results with each purported patient).

Practitioners who enter into arrangements with Telemedicine Companies in which one or more of these suspect characteristics are present should exercise care and may face criminal, civil, or administrative liability depending on the facts and circumstances. This Special Fraud Alert is not intended to discourage legitimate telehealth arrangements.[13] For example, OIG is aware that many Practitioners have appropriately used telehealth services during the current public health emergency to provide medically necessary care to their patients. However, OIG encourages Practitioners to use heightened scrutiny, exercise caution, and consider the above list of suspect criteria prior to entering into arrangements with Telemedicine Companies. This Special Fraud Alert does not alter any person's obligations under any applicable statutes or regulations, including those governing the billing or submission of Federal health care program claims.

For more information on telehealth-related issues, please visit our website, which includes additional materials relating to the provision of telehealth. If you have information about Practitioners, Telemedicine Companies, or other individuals or entities engaging in any of the activities described above, please contact the OIG Hotline at https://oig.hhs.gov/fraud/report-fraud or by phone at 1-800-447-8477 (1-800-HHS-TIPS).

[13] As OIG has previously noted, "[f]or most, telehealth expansion is viewed positively, offering opportunities to increase access to services, decrease burdens for both patients and providers, and enable better care, including enhanced mental health care." See "Principal Deputy Inspector General Grimm on Telehealth" (Feb. 26, 2021), https://oig.hhs.gov/coronavirus/letter-grimm-02262021.asp.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability

June 9, 2015

Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide. Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business. OIG encourages physicians to carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them.

OIG recently reached settlements with 12 individual physicians who entered into questionable medical directorship and office staff arrangements. OIG alleged that the compensation paid to these physicians under the medical directorship arrangements constituted improper remuneration under the anti-kickback statute for a number of reasons, including that the payments took into account the physicians' volume or value of referrals and did not reflect fair market value for the services to be performed, and because the physicians did not actually provide the services called for under the agreements. OIG also alleged that some of the 12 physicians had entered into arrangements under which an affiliated health care entity paid the salaries of the physicians' front office staff. Because these arrangements relieved the physicians of a financial burden they otherwise would have incurred, OIG alleged that the salaries paid under these arrangements constituted improper remuneration to the physicians. OIG determined that the physicians were an integral part of the scheme and subject to liability under the Civil Monetary Penalties Law.

Those who commit fraud involving Federal health care programs are subject to possible criminal, civil, and administrative sanctions. For more information on physician relationships, see OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" available at http://oig.hhs.gov/authorities/docs/physician.pdf and OIG's "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse" available at http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf.

If you have information about physicians or other providers engaging in any of the activities described above, contact the OIG Hotline at https://forms.oig.hhs.gov/hotlineoperations/ or by phone at 1-800-447-8477 (1-800-HHS-TIPS).