



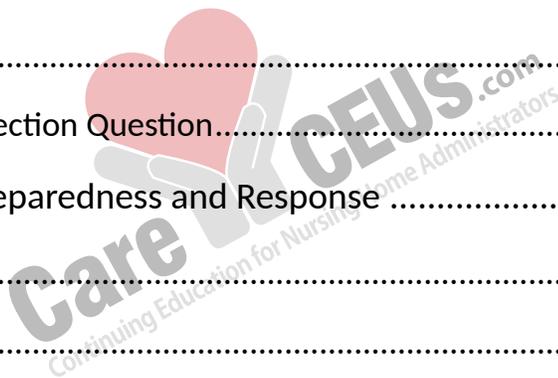
Improving The Organization



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Introduction

In the wake of the coronavirus disease 2019 (COVID-19) pandemic, health care organizations are looking to improve in order to meet the growing expectations of both government agencies, such as the U.S. Department of Health and Human Services, and potential residents. The question is, how can health care organizations improve? This course will answer that very question, while reviewing the key aspects of organizational improvement. This course will also highlight recommendations that may be used to improve resident care. The information found within this course may be used to develop training and educational offerings to health care professionals. The information found within this course may also be used to develop and update organizational policies and procedures.

Section 1: Mission, Vision, and Values Statements

Health care administrators of a nursing home review the results of a recent resident satisfaction survey. Some of the notes are positive, however the survey results deliver a clear message to the health care administrators. The health care organization needs to improve. Nursing home leaders take immediate action and put together a team of health care administrators and health care professionals, and task them with coming up with ideas to improve the organization. During the first team meeting, the health care administrators and health care professionals begin to brainstorm, and come up with ideas on how to improve their health care organization. They consider the residents, the residents' families, as well as the staff. The team also considers the overall vision and goals of the nursing home. The team makes progress, however, the fundamental question remains, how can health care organizations improve? Fortunately, for the health care team, and health care organizations across the country, there is a simple answer to the

seemingly complex question of organizational improvement. Health care organizations can improve by implementing the eight key aspects of organizational improvement. This section of the course will review the first key aspect of organizational improvement, which is to establish a mission, vision, and values for a health care organization. The information found within this section of the course was derived from materials provided by Berxi unless, otherwise, specified (Lica, 2022).

How can a health care organization establish a mission, vision, and values?

A health care organization can establish a mission, vision, and values by developing mission, vision, and values statements.

What are mission, vision, and values statements?

- **Mission statement** - a mission statement is an explanation that focuses on the present goal of an organization (i.e., what does the health care organization hope to accomplish).
- **Vision statement** - a vision statement is an explanation that focuses on where an organization will be in the future.
- **Values statement** - a values statement is a description of an organization's priorities and values.

What is an example of a mission statement?

The following is an example of a mission statement: it is our mission to provide residents and their families with superior care that is delivered with compassion and care.

What is an example of a vision statement?

The following is an example of a vision statement: we aspire to be one of the nation's leading health care facilities that provides safe, effective, and compassionate care.

What is an example of a values statement?

The following is an example of a values statement: we are dedicated to resident care, and we treat each resident with respect, dignity, and empathy.

Why are mission, vision, and values statements important?

Mission, vision, and values statements are important because they can help provide direction for a health care organization, as well as attract residents and health care professionals to the organization.

Mission, vision, and values statements are also important because they can help create a mission driven culture.

What is a mission driven culture?

A mission driven culture is one that provides clear intent (task, purpose, end state) and guidelines within which individuals or teams make well-informed and safety-

conscious decisions on the most effective way to approach a given situation (Federal Emergency Management Agency [FEMA], 2021).

Health care professionals should note that a mission driven culture can help improve health care outcomes.

How can health care organizations effectively develop mission, vision, and values statements?

Health care organizations can effectively develop mission, vision, and values statements, as well as a mission driven culture by considering the ethical principles of health care. Specific information regarding the ethical principles of health care may be found below.

- **Patient autonomy** - patient autonomy may refer to a patient's right to make decisions regarding his or her own personal health care, without the direct influence of a health care professional. Essentially, patient autonomy grants patients the sole right to make decisions regarding their health, health care, and personal well-being. Health care professionals must respect patient autonomy when caring for patients. Violations of patient autonomy may occur if a health care professional makes health care-related decisions for a patient, influences a patient's decisions, bullies a patient into making a decision, withholds relevant information from a patient in order to steer a patient into making a specific decision, provides a patient with biased information and/or education, fails to provide vital details to a patient, and/or simply does not give a patient an opportunity to make his or her own decision regarding the administration of health care (e.g., carries out a procedure without consent from a patient). Health care professionals may uphold patient autonomy by allowing patients to remain independent when making decisions about their health care. Health care professionals should

note that they are allowed to provide patients with unbiased information and education to help them make a decision regarding their own health care - however, a health care professional must not make the final decision for a patient. Health care professionals should also note that there may be health care situations where patient autonomy concepts may not necessarily apply, such as emergency situations where life-saving interventions are required.

- **Beneficence** - beneficence may refer to the obligation of the health care professional to act in the best interest of the patient. Health care professionals must adhere to the principle of beneficence when caring for patients. Examples of potential violations of beneficence may include the following: a health care professional does not act in the best interest of a patient, a health care professional puts his or her own interest before a patient's best interest, a health care professional does not consider the risks and benefits of a health care intervention before it is administered to a patient, a health care professional does not consider a patient's pain, physical, and/or mental suffering when administering health care, a health care professional does not consider a patient's risk of disability, diminished health, and/or death when administering health care, and a health care professional does not promote a patient's health for personal reasons (e.g., a health care professional encourages a patient to follow a therapeutic regimen that will, ultimately, jeopardize the patient's health, overall well-being, and quality of life). Health care professionals may uphold the ethic principle of beneficence by simply doing what is best for a patient's health.
- **Nonmaleficence** - nonmaleficence may refer to the obligation of the health care professional to act in a manner that does not cause harm to the individual patient; do no harm. Examples of potential violations of nonmaleficence may include the following: a health care professional

intentionally harms a patient, a health care professional gives a patient a medication knowing it will only harm the patient, a health care professional chooses interventions for a patient that will harm the patient, a health care professional does not follow safety precautions while administering care to a patient, and a health care professional does not follow organizational policies and procedures, which were put in place to safeguard patients' health. Health care professionals may uphold the ethic principle of nonmaleficence by simply acting in a manner that does not intentionally harm a patient (note: although beneficence and nonmaleficence are related, they are two separate and distinct ethic principles of health care).

- **Justice** - justice may refer to the fair and equitable distribution of health care resources to patients. Essentially, the ethic principle of justice stipulates that patients in similar situations should have access to the same health care or the same level of health care. An example of a potential violation of justice may include the following - a health care professional denies a patient health care due to the patient's socioeconomic status. Health care professionals can uphold the ethic principle of justice by administering health care in an unbiased manner.

How can health care organizations encourage health care professionals to commit to the culture created by mission, vision, and values statements?

- **Effective communication** - first and foremost, health care organizations should use effective communication to encourage health care professionals to commit to a desired culture. Specific information regarding effective communication may be found below.

- Communication may refer to the process of transmitting information and messages from one individual or party to another individual or party in order to obtain meaning and a common understanding.
- Effective communication occurs when information and messages are adequately transmitted, received, and understood.
- Organizational communication may refer to the process of sending and receiving information/messages among interrelated individuals within a given organization, such as a health care facility.
- Communication typically moves or flows, within an organization, in a vertical and/or a horizontal manner.
- **Vertical communication** - vertical communication, within the context of organizational communication, may refer to the flow of communication between individuals associated with the same organization who are on different levels of the organization's hierarchy. Vertical communication may flow in a downwards or upwards manner. Downward communication occurs when organizational leaders or managers share information with lower-level employees (e.g., a nurse manager gives a nurse instructions). Upward communication occurs when lower-level employees share information with organizational leaders or managers (e.g., a health care professional informs a health care administrator of a safety hazard). Health care professionals should also note that vertical communication is essential to creating and maintaining a shared understanding and culture between organizational administrators, leaders, and employees.

- **Horizontal communication** - horizontal communication may refer to the flow of communication between individuals and/or departments that are on the same level of a given organization (e.g., a health care administrator provides information to another health care administrator; an intensive care nurse provides another intensive care nurse with relevant patient information). Health care professionals should note that horizontal communication may be an essential element to establishing a desired culture within a given health care facility.
- Communication may also flow into and out of an organization. Health care professionals should ensure that the communication flowing out of their specific health care organization promotes the preferred culture (note: positive communication flowing out of a health care organization can help attract health care professionals and other potential employees that are open and willing to commit to an established culture; social media can help health care organizations deliver desired communication; the term social media may refer to any electronically driven application that enables individuals to create and share content for the purposes of virtual communication).
- **Encourage communication** - health care professionals should encourage communication when working to promote a specific culture. This may seem obvious, however, the simple truth of the matter is that, often, individuals do not encourage communication. With that said, health care professionals can encourage communication by remaining professional, poised, calm, collected, level headed, respectful, receptive, approachable, engaging, objective, and by limiting bias and judgment. Health care professionals should note that effective communication often begins with encouragement and receptiveness.

- **Utilize positive reinforcement** - health care professionals should utilize positive reinforcement when attempting to promote a specific culture. Positive reinforcement may refer to a communication exchange or response that encourages a constructive or beneficial action or behavior. In essence, positive reinforcement can be used by health care professionals to inspire or motivate individuals to repeat constructive, beneficial, and/or productive behavior, as well as support a specific culture. Examples of positive reinforcement include the following: simply saying thank you to an individual from the workforce, verbal praise, and recommending a peer or colleague for an intra-organizational employee recognition award.
- **Allow for and encourage mentoring programs** - a mentoring program may refer to any program that allows/encourages individuals with less work experience to work, interact, and engage with individuals with more work experience. Encouraging employees to take part in mentoring programs can help employees effectively communicate, relate to each other, and, ultimately, create opportunities to share a common culture.
- **Allow for and encourage team-building programs** - a team-building program may refer to any program designed to encourage cooperative group collaboration with various individuals throughout an organization. Much like with mentoring programs, team-building programs can allow individuals with less work experience to work, interact, and engage with individuals with more work experience. Furthermore, team-building programs can help health care professionals create professional bonds and relationships that can support an organization's culture. Examples of team-building programs include the following: education workshops, organizational retreats, and employee shadowing (note: the term employee shadowing may refer to any program that allows a health care professional

from one department to follow and observe a health care professional from another department in order to gain insight and perspective).

- **Allow for and encourage participation in employee functions, retreats, and group talk sessions** - health care professionals should engage in and encourage participation in employee functions, retreats, and group talk sessions (note: the term group talk session may refer to a small gathering of individuals who possess a common bond, and a willingness to discuss specific topics centered around positive notions, such as peer recognition and gratitude). Employee functions, retreats, and group talk sessions may provide opportunities for health care professionals to congregate and discuss work-related issues. They can also be an opportunity for health care professionals to socialize and recognize each other for their efforts and achievements. Such socialization can perpetuate motivation within a health care organization, as well as a common culture. Health care professionals should be encouraged to organize employee functions, retreats, and group talk sessions, when applicable (note: such events do not have to be extravagant in nature, they just have to present an opportunity for health care professionals to recognize each other for their self sacrifices, health care service, and dedication to patient care, as well as share a specific culture).

Section 1 Summary

A health care organization can establish a mission, vision, and values by developing mission, vision, and values statements. Health care organizations can effectively develop mission, vision, and values statements, as well as a mission driven culture by considering the ethical principles of health care, which include: patient autonomy, beneficence, nonmaleficence, and justice. Health care

organizations can encourage health care professionals to commit to a desired culture through effective communication, encouraging communication, utilizing positive reinforcement, as well as allowing for and encouraging mentoring programs, team-building programs, and employee functions, retreats, and group talk sessions.

Section 1 Key Concepts

- The first key aspect of organizational improvement is to establish a mission, vision, and values for a health care organization.
- Mission, vision, and values statements are important because they can help provide direction for a health care organization, as well as attract residents and health care professionals to the organization; mission, vision, and values statements are also important because they can create a mission driven culture.

Section 1 Key Terms

Mission statement - an explanation that focuses on the present goal of an organization

Vision statement - an explanation that focus on where an organization will be in the future

Values statement - a description of an organization's priorities and values

Mission driven culture - a culture that provides clear intent (task, purpose, end state) and guidelines within which individuals or teams make well-informed and safety-conscious decisions on the most effective way to approach a given situation (FEMA, 2021)

Patient autonomy - a patient's right to make decisions regarding his or her own personal health care, without the direct influence of a health care professional

Beneficence - the obligation of the health care professional to act in the best interest of the patient

Nonmaleficence - the obligation of the health care professional to act in a manner that does not cause harm to the individual patient; do no harm

Justice - the fair and equitable distribution of health care resources to patients

Communication - the process of transmitting information and messages from one individual or party to another individual or party in order to obtain meaning and a common understanding

Organizational communication - the process of sending and receiving information/ messages among interrelated individuals within a given organization, such as a health care facility

Vertical communication - the flow of communication between individuals associated with the same organization who are on different levels of the organization's hierarchy

Horizontal communication - the flow of communication between individuals and/ or departments that are on the same level of a given organization

Social media - any electronically driven application that enables individuals to create and share content for the purposes of virtual communication

Positive reinforcement - a communication exchange or response that encourages a constructive or beneficial action or behavior

Mentoring program - any program that allows/encourages individuals with less work experience to work, interact, and engage with individuals with more work experience

Team-building program - any program designed to encourage cooperative group collaboration with various individuals throughout an organization

Employee shadowing - any program that allows a health care professional from one department to follow and observe a health care professional from another department in order to gain insight and perspective

Group talk session - a small gathering of individuals who possess a common bond, and a willingness to discuss specific topics centered around positive notions, such as peer recognition and gratitude

Section 1 Personal Reflection Question

How can a mission driven culture improve a health care organization?

Section 2: SWOT Analysis

The second key aspect of organizational improvement is to identify organizational strengths, weaknesses, opportunities, and threats. A health care organization can identify potential strengths, weaknesses, opportunities, and threats by conducting a SWOT analysis. This section of the course will review information central to conducting an effective SWOT analysis. The information found within this section of the course was derived from materials provided by Practice Builders unless, otherwise, specified (Practice Builders, 2023).

What does SWOT stand for?

SWOT stands for Strengths, Weaknesses, Opportunities, and Threats.

What is a SWOT analysis?

A SWOT analysis may refer to the process of assessing an organization's strengths, weaknesses, opportunities, and threats.

What are the goals of a SWOT analysis?

- One of the main goals of a SWOT analysis is to help an organization become self aware so it can grow and thrive.
- Another main goal of a SWOT analysis is to help administrators and leaders within an organization make informed decisions that lead to positive outcomes.

How can a SWOT analysis help a health care organization improve?

- **Discover aspects of an organization that should be maintained** - first and foremost, by conducting a SWOT analysis and identifying the strengths of a health care organization, health care administrators and health care professionals can discover aspects of an organization that should be maintained in order to optimize patient care. For example, if an assisted living facility receives high resident satisfaction scores due to specific programs, then the assisted living facility should maintain identified programs to sustain resident satisfaction.

- **Discover aspects of an organization that should be improved** - on the other side of the coin, a SWOT analysis can reveal the weakness of a health care organization and the aspects of an organization that should be improved in order to optimize patient care. For example, if an assisted living facility receives low resident satisfaction scores due to specific programs, then the assisted living facility should improve upon, or even eliminate, identified programs to increase resident satisfaction.
- **Recognize opportunities** - a SWOT analysis can help health care organizations recognize opportunities for growth and expansion. For example, while conducting a SWOT analysis a health care organization may recognize that they may be able to expand through a diversified growth strategy (note: the term diversified growth strategy may refer to a method of organizational growth that is characterized by the acquisition of new capabilities that expand operations and services).
- **Identify obstacles** - a SWOT analysis can enable health care organizations to identify obstacles to patient care. For example, a SWOT analysis may reveal staffing as an obstacle to patient care. When a SWOT analysis reveals obstacles, health care organizations should work to remove such obstacles. For example, if staffing is an obstacle to patient care, then health care organizations should start to recruit health care professionals to fill staffing needs.
- **Identify external threats** - in addition to obstacles, a SWOT analysis can enable health care organizations to identify external threats. For example, a SWOT analysis may identify rising cases of coronavirus disease 2019 (COVID-19) within the surrounding community as an external threat to patient safety (note: coronavirus disease 2019 [COVID-19] may refer to a respiratory illness that can spread from person to person, which is caused

by a virus known as the severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]). Much like with obstacles, when a SWOT analysis reveals external threats to a health care organization, health care administrators and health care professionals should work to mitigate such threats. For example, if rising cases of COVID-19 are an external threat to a health care organization, then that health care organization may consider suggesting that health care professionals and visitors wear facemasks.

- **Identify opportunities to pivot** - the term pivot, when applied to health care organizations, may refer to the act of changing policies, procedures, protocols, and/or organizational goals and directives without negatively impacting patient care. At times health care organizations may need to pivot to improve the quality of patient care, as well as patient safety. A SWOT analysis can reveal opportunities to pivot by providing insight into what a health care organization needs to maintain or improve upon to optimize patient outcomes.
- **Analyze the implications of an organizational decision** - when a decision is made, within a health care organization, it has the potential to impact countless individuals including: staff, patients, and future patients. A SWOT analysis can help a health care organization analyze and work out the implications of a decision by providing insight into what may occur once a decision is made. For example, the administrators of a nursing home may elect to limit recreational therapy (note: recreational therapy, also known as therapeutic recreation, may refer to a systematic process that utilizes recreation and other activity-based interventions to address the assessed needs of individuals with illnesses and/or disabling conditions, as a means to psychological and physical health, recovery, and well-being) (American Therapeutic Recreation Association, 2023). Such a decision could negatively impact resident care, overall health, and quality of life. It could also put

increased stress on health care professionals who utilize recreational therapy to address the social, mental, and physical needs of residents. Through the process of conducting a SWOT analysis, health care administrators may identify the aforementioned effects of limiting recreational therapy before the decision is made, and thus, avoid making such a decision.

- **Manage contracted services** - contracted services may refer to services that are provided according to a written agreement between a health care organization and the individual or individuals providing the services; a health care contract may refer to a written agreement between an individual or entity and a health care organization. A SWOT analysis can help health care organizations manage contracted services by allowing health care administrators to determine the goals of each contract; ensure the terms of each contract meet specific goals; establish contract termination procedures; meet deadlines; and select a project manager, when needed.
- **Manage environmental services** - environmental services may refer to a department or unit within a health care facility that is responsible for cleaning, decontamination, disinfection, sterilization, housekeeping, laundry, and other related duties. Environmental services are essential to the day-to-day operation of a health care facility because they help prevent the transmission of infectious diseases (note: environmental services prevent the transmission of infectious diseases through cleaning, disinfection, and sterilization). A SWOT analysis can help health care organizations manage environmental services by allowing health care administrators to gain insight into how such services can better protect health care professionals and patients from health-care associated infections (note: the term health care associated infections may refer to

infections that affect patients while they are receiving care in a health care facility).

- **Prevent medical errors** - a SWOT analysis can help organizations prevent medical errors from occurring (note: the term medical error may refer to a preventable adverse effect of care that may or may not be evident or causes harm to a patient) (Joint Commission, 2023). Essentially, a SWOT analysis can help health care organizations determine if appropriate mechanisms are in place to prevent medical errors. Examples of such mechanisms include the following: health care professionals are using at least two patient identifiers when providing care, treatment, or services; a health care organization has written policies and procedures for managing the critical results of tests and diagnostic procedures; health care professionals immediately discard any medication or solution found unlabeled; leaders established alarm system safety as a health care facility priority; the health care organization works to improve compliance with hand hygiene guidelines (Joint Commission, 2023).
- **Prevent patient suicide** - much like with medical errors, a SWOT analysis can help health care organizations prevent patient suicides by allowing health care organizations to determine if appropriate mechanisms are in place to prevent the suicide of a patient (note: the suicide of a patient while in a staffed, round-the-clock care setting is a frequently reported type of sentinel event; the term sentinel event may refer to an unanticipated event in a health care setting that results in death or serious physical or psychological injury to a patient[s], not related to the natural course of the patient's illness). Such mechanisms may include the following: screening patients for suicidal ideation, when appropriate; developing policies and procedures addressing the care of patients identified as at risk for suicide; monitoring the implementation and effectiveness of policies and

procedures for screening, assessing, and managing patients at risk for suicide; taking action to improve compliance with related policies and procedures (Joint Commission, 2023).

- **Ensure health care organizations are adhering to relevant laws** - through the process of assessing strengths, weaknesses, opportunities, and threats, health care organizations can determine if they are adhering to relevant laws. For example, if a health care organization identifies that employee safety is a weakness, then that may mean the health care organization is not adhering to relevant employee safety laws such as those included in the Occupational Safety and Health Act of 1970 (OSH Act). The Occupational Safety and Health Act of 1970 (OSH Act) may refer to the group of labor laws that govern the federal law of occupational health and safety in the private sector and federal government in the U. S. Specific information regarding the OSH Act may be found below. The information found below was derived from materials provided by the U. S. Department of Labor (U. S. Department of Labor, 2023).
 - The OSH Act was passed to prevent workers from being killed or otherwise harmed at work.
 - The OSH Act requires employers to provide their employees with working conditions that are free of known dangers.
 - The OSH Act created the Occupational Safety and Health Administration (OSHA), which sets and enforces protective workplace safety and health standards.
 - The OSH Act gives workers the right to safe and healthful working conditions. It is the duty of employers to provide workplaces that are free of known dangers that could harm their employees. This law also

gives workers important rights to participate in activities to ensure their protection from job hazards.

- The OSH Act states that employers have the responsibility to provide a safe workplace. Employers must provide their employees with a workplace that does not have serious hazards and must follow all OSHA safety and health standards.
- Employers must inform workers about hazards through training, labels, alarms, color-coded systems, chemical information sheets, and other methods.
- Employers must train workers in a language and vocabulary they can understand.
- Employers must keep accurate records of work-related injuries and illnesses.
- Employers must perform tests in the workplace, such as air sampling, required by some OSHA standards.
- Employers must provide hearing exams or other medical tests required by OSHA standards.
- Employers must post OSHA citations and injury and illness data where workers can see them.
- Employers must notify OSHA within eight hours of a workplace fatality or within 24 hours of any work-related inpatient hospitalization, amputation, or loss of an eye.

- Employers must not retaliate against workers for using their rights under the law, including their right to report a work-related injury or illness.
- Employers must comply with the General Duty Clause of the OSH Act. This clause requires employers to keep their workplaces free of serious recognized hazards and is generally cited when no specific OSHA standard applies to the hazard.
- Employers must provide most protective equipment free of charge. Employers are responsible for knowing when protective equipment is needed. Examples of protective equipment include: respirators, goggles, and gloves.
- OSHA gives workers and their representatives the right to see information that employers collect on hazards in the workplace. Workers have the right to know what hazards are present in the workplace and how to protect themselves. Additionally, the Hazard Communication standard, known as the “right-to-know” standard, requires employers to inform and train workers about hazardous chemicals and substances in the workplace.
- Many OSHA standards require employers to run tests of the workplace environment to find out if their workers are being exposed to harmful levels of hazardous substances such as lead or asbestos, or high levels of noise or radiation. These types of tests are called exposure monitoring. OSHA gives workers the right to get the results of these tests.
- OSHA conducts on-site inspections of worksites to enforce the OSHA law that protects workers and their rights. On-site inspections can be

triggered by a worker complaint of a potential workplace hazard or violation.

- Workers and their representatives have the right to ask for an inspection without OSHA telling their employer who filed the complaint. It is a violation of the OSH Act for an employer to fire, demote, transfer or retaliate in any way against a worker for filing a complaint or using other OSHA rights.
- When the OSHA area director determines that there was a violation of OSHA standards, regulations, or other requirements, the area director issues a citation and notification of proposed penalty to an employer (typically following an inspection).
- A citation includes a description of the violation and the date by when the corrective actions must be taken. Depending on the situation, OSHA can classify a violation as serious, willful, or repeat. The employer can also be cited for failing to correct a violation for which it has already been cited. Employers must post a copy of a citation in the workplace where employees will see it.
- Workers and employers can contest citations once they are issued to the employer. Workers may only contest the amount of time the employer is given to correct the hazard. Workers or their representatives must file a notice of contest with the OSHA area office within 15 days of the issuance of a citation.
- Employers have the right to challenge whether there is a violation, how the violation is classified, the amount of any penalty, what the employer must do to correct the violation and how long they have to fix it. Workers or their representatives may participate in this appeals

process by electing “party status.” This is done by filing a written notice with the Occupational Safety and Health Review Commission (OSHRC).

- The OSHRC hears appeals of OSHA citations. They are an independent agency separate from the Department of Labor.
- The OSHA area director evaluates complaints from employees or their representatives according to the procedures defined in the OSHA Field Operations Manual. If the area director decides not to inspect the workplace, he or she will send a letter to the complainant explaining the decision and the reasons for it.
- OSHA will inform complainants that they have the right to request a review of the decision by the OSHA regional administrator. Similarly, in the event that OSHA decides not to issue a citation after an inspection, employees have a right to further clarification from the area director and an informal review by the regional administrator.
- The OSH Act prohibits employers from retaliating against their employees for using their rights under the OSH Act. These rights include filing an OSHA complaint, participating in an inspection or talking to the inspector, seeking access to employer exposure and injury records, raising a safety or health issue with the employer, or any other workers’ rights described above. Protection from retaliation means that an employer cannot punish workers by taking “adverse action,” such as firing or laying off.
- If an employee has been retaliated against for using their rights, they must file a complaint with OSHA within 30 calendar days from the date the retaliatory decision has been both made and communicated

to the employee (the worker). Following a complaint, OSHA will contact the complainant and conduct an interview to determine whether an investigation is necessary.

- If the evidence shows that the employee has been retaliated against for exercising safety and health rights, OSHA will ask the employer to restore that worker's job, earnings, and benefits. If the employer refuses, OSHA may take the employer to court.
- Employees may file a complaint with OSHA concerning a hazardous working condition at any time. However, an employee should not leave the worksite merely because he or she has filed a complaint. If the condition clearly presents a risk of death or serious physical harm, there is not sufficient time for OSHA to inspect, and, where possible, an employee has brought the condition to the attention of his or her employer, an employee may have a legal right to refuse to work in a situation in which you would be exposed to the hazard.
- If a worker, with no reasonable alternative, refuses in good faith to expose himself or herself to a dangerous condition, he or she would be protected from subsequent retaliation. The condition must be of such a nature that a reasonable person would conclude that there is a real danger of death or serious harm and that there is not enough time to contact OSHA and for OSHA to inspect. Where possible, the employee must have also sought from his employer, and been unable to obtain, a correction of the condition.
- Since passage of the OSH Act in 1970, Congress expanded OSHA's whistleblower protection authority to protect workers from retaliation under federal law. These laws protect employees who report violations of various workplace safety, airline, commercial

motor carrier, consumer product, environmental, financial reform, health care reform, nuclear, pipeline, public transportation agency, railroad, maritime and securities laws. Complaints must be reported to OSHA within set timeframes following the retaliatory action, as prescribed by each law.

- OSHA offers cooperative programs under which businesses, labor groups and other organizations can work cooperatively with OSHA; the OSHA Strategic Partnerships (OSP) provide the opportunity for OSHA to partner with employers, workers, professional or trade associations, labor organizations, and/or other interested stakeholders; through the Alliance Program, OSHA works with groups to develop compliance assistance tools and resources to share with workers and employers, and educate workers and employers about their rights and responsibilities.
- **Prevent lawsuits** - by helping to manage contracted services and environmental services, as well as helping to prevent medical errors and patient suicide, while ensuring health care organizations are adhering to relevant laws, conducting a SWOT analysis can prevent lawsuits against health care organizations.

How can health care professionals conduct a SWOT analysis?

- **Identify strengths** - first health care professionals should identify the strengths of a health care organization. To identify the strengths of a health care organization, health care professionals should attempt to answer the following types of questions: what does our health care organization do well; what makes our health care organization unique; what resources does our health care organization have; what are our assets. Examples of

potential strengths of a health care organization include the following: positive health care outcomes, high resident satisfaction scores, good location, personalized care, and a talented and dedicated health care professional staff.

- **Recognize weakness** - secondly, health care professionals should recognize the weakness of a health care organization. To identify the weaknesses of a health care organization, health care professionals should attempt to answer the following types of questions: what does our health care organization lack; what do other health care organizations do better; what resources does our health care organization lack. Examples of potential weaknesses of a health care organization include the following: poor health care outcomes, low resident satisfaction scores, budgetary concerns, and high staff turnover.
- **Discover opportunities** - next health care professionals should examine external factors to identify opportunities. To identify opportunities, health care professionals should attempt to answer the following types of questions: how can we expand; how can we grow; how can we increase resident satisfaction scores; what are our residents' needs; how can we better meet residents' needs; how can we attract needed health care professionals; how can we diversify staff; how can we get our message out to the public. Examples of potential opportunities for a health care organization include expanding to an underserved area.
- **Determine threats** - finally, health care professionals should continue to examine external factors to identify threats. To identify threats, health care professionals should attempt to answer the following types of questions: what is our competition; is our health care organization experiencing staff dissatisfaction; what is causing staff dissatisfaction; what is causing resident

dissatisfaction. Examples of potential threats to a health care organization include the following: other health care organizations, a negative public perception, and infectious diseases that could negatively impact resident care (e.g., increasing cases of COVID-19 within the surrounding community).

- Once health care professionals complete a SWOT analysis they should then develop strategies to maintain and reinforce strengths, improve upon weaknesses, capitalize on opportunities, and mitigate threats.

Section 2 Summary

A SWOT analysis can help a health care organization improve by revealing aspects of an organization that should be maintained; aspects of an organization that should be improved; opportunities; obstacles; external threats; opportunities to pivot; the implications of an organizational decision; effective methods to manage contracted services; effective methods to manage environmental services; prevent medical errors; prevent patient suicide; adhere to relevant laws; prevent lawsuits. Finally, once health care professionals complete a SWOT analysis they should then develop strategies to maintain and reinforce strengths, improve upon weaknesses, capitalize on opportunities, and mitigate threats.

Section 2 Key Concepts

- The second key aspect of organizational improvement is to identify organizational strengths, weaknesses, opportunities, and threats.
- **SWOT** stands for **S**trengths, **W**eaknesses, **O**pportunities, and **T**hreats.
- Health care professionals can conduct a SWOT analysis by identifying the strengths of a health care organization; recognizing the weakness of a

health care organization; examining external factors to identify opportunities; examining external factors to identify threats.

Section 2 Key Terms

SWOT analysis - a process of assessing an organization's strengths, weaknesses, opportunities, and threats

Diversified growth strategy - a method of organizational growth that is characterized by the acquisition of new capabilities that expand operations and services

Coronavirus disease 2019 (COVID-19) - a respiratory illness that can spread from person to person, which is caused by a virus known as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

Pivot (when applied to health care organizations) - the act of changing policies, procedures, protocols, and/or organizational goals and directives without negatively impacting patient care

Recreational therapy (also known as therapeutic recreation) - a systematic process that utilizes recreation and other activity-based interventions to address the assessed needs of individuals with illnesses and/or disabling conditions, as a means to psychological and physical health, recovery, and well-being (American Therapeutic Recreation Association, 2023)

Contracted services - services that are provided according to a written agreement between a health care organization and the individual or individuals providing the services

Health care contract - a written agreement between and individual or entity and a health care organization

Environmental services - a department or unit within a health care facility that is responsible for cleaning, decontamination, disinfection, sterilization, housekeeping, laundry, and other related duties

Health care associated infections - infections that affect patients while they are receiving care in a health care facility

Medical error - a preventable adverse effect of care that may or may not be evident or causes harm to a patient) (Joint Commission, 2023)

Sentinel event - an unanticipated event in a health care setting that results in death or serious physical or psychological injury to a patient(s), not related to the natural course of the patient's illness (Joint Commission, 2023)

Occupational Safety and Health Act of 1970 (OSH Act) - the group of labor laws that govern the federal law of occupational health and safety in the private sector and federal government in the U. S.

Section 2 Personal Reflection Question

How can health care professionals initiate a SWOT analysis for their specific health care organization?

Section 3: Employee Recruitment and Motivation

The third key aspect of organizational improvement is effective employee recruitment and motivation. This section of the course will review employee recruitment and motivation recommendations. The information found within this section of the course was derived from materials provided by the U.S. government unless, otherwise, specified (U.S. Department of Labor, 2023).

Employee Recruitment and Motivation Recommendations

- **Embrace the essential elements of employee recruitment** - employee recruitment may refer to the process of identifying, attracting, interviewing, selecting, hiring, and onboarding new employees (note: the term onboarding may refer to any actions used to integrate a new employee into an organization). The essential elements of employee recruitment include the following: assessing needs, developing a job description, developing an application process, promoting the open position(s), the application review process, the initial screening process, the interview process, extending an offer, and onboarding new employees. Specific information regarding each of the aforementioned essential elements of employee recruitment may be found below.

- **Assess needs** - first and foremost, health care organizations should assess their employment needs (e.g., determine if they need to fill part-time, full-time, or contract positions, as well as short-term or long-term positions). Health care professionals should note that working to assess employment needs can help focus and streamline the recruiting process.
- **Develop a job description** - job descriptions can be paramount to the application process (note: a job description may refer to an outline or an accounting of the general tasks, duties, and responsibilities of a specific position). Essentially, job descriptions attract an applicant to a specific position. If the job description is not well organized or written, then a potential applicant may not apply for the available position. Therefore, health care professionals should take the appropriate time to develop a well organized job description that is written in a concise, direct style and includes the following key points

or sections: job title, job purpose, job duties and responsibilities, educational qualifications, required qualifications, preferred qualifications, experience, and working conditions.

- **Develop an application process** - when developing an application process for a specific position, health care professionals should make the application process as simple and as straightforward as possible. Applying for a position within a health care organization should be a simple, straightforward process for an applicant. A potential applicant should be able to identify a position, within a health care organization, understand the position description, determine the qualifications for the position, and then apply (note: applicants are more likely to apply for positions with a simple and straightforward application process).
- **Promote the open position(s)** - once an application process is developed, health care organizations can begin promoting the open position or positions. Open positions may be promoted through external means (e.g., employment websites), internally via employee notification platforms, and/or simply on the health care organization's website (note: promoting an open position or positions through various means can attract a large and diverse talent pool; a large and diverse talent pool can be useful in identifying candidates for current and future open positions).
- **Application review process** - before employee recruitment begins, health care professionals should have an application review process in place to review potential candidates for available positions. The application review process should include mechanisms for collecting applications, identifying if applicants meet the minimum

qualifications for the open position or positions, and a means to deliver applications to those individuals conducting the initial screenings and/or interviews (note: the application review process should be conducted in a timely manner, and it should begin as soon as applications arrive from potential candidates).

- **Initial screening process** - once the application process identifies potential candidates for a position, the initial screening process should begin. Typically, the initial screening process consists of phone interviews that are used to determine if an applicant possesses the necessary qualifications to fill a position, and is interested in interviewing for the position, when deemed appropriate (note: an efficient initial screening process can help health care professionals narrow down the list of candidates for interviews, and save valuable time).
- **Interview process** - it has been argued that the interview process is one of the most important elements of employee recruitment. Essentially, the interview process provides a means for employers, existing staff, and potential managers to meet potential candidates to determine if they are indeed truly qualified for the available position, if they can meet the responsibilities of the available position, and if they are capable of integrating themselves into the culture of the organization. Due to the importance of the interview process, many different types of interviews may be used during the interview process to differentiate and select potential candidates for the open position or positions (e.g., phone interviews; video interviews; in-person interviews).

- **Extending an offer** - once a decision is made regarding a candidate and a specific position, an offer may be extended to a candidate. The offer made to a candidate should be extended in a timely manner after the interview process is complete or during the third/final in-person interview (note: offers made to candidates should reflect any terms discussed in the interview process).
- **Onboarding new employees** - once an offer is accepted by a candidate and the candidate fulfills any and all employment requirements, health care professionals should focus on the onboarding process (note: the onboarding process may include: employee introductions, an orientation program, organization education programs, initial scheduling, and training).
- **Utilize social media** - one of the biggest cultural trends impacting current employee recruitment is the use of social media. Since its initial inception, social media has impacted the greater cultural constructs it has been a part of, and, in more recent years, the use of social media impacted employee recruitment. In order to optimize employee recruitment, health care professionals should utilize social media in the recruitment process. Health care professionals can utilize social media to post organizational openings, provide existing employees with information regarding organizational openings, discover potential employee candidates, increase organizational awareness among potential employee candidates, save time in the recruiting process, and attract a diverse candidate pool.
- **Ensure effective employee staffing** - effective employee staffing can be vital to employee motivation, especially in the wake of the coronavirus disease 2019 (COVID-19) pandemic (note: effective employee staffing, in the modern health care system, occurs when all required schedules and open

shifts are filled with consideration for employee satisfaction; employee satisfaction may refer to an employee's perceived level of contentment related to his or her place of employment). That said, there are a variety of different strategies or models that may be used to effectively staff employees. One model, in particular, that is currently standing out among other staffing models as an effective means to staff employees and promote employee motivation is known as the collaborative staffing model. The collaborative staffing model may refer to an employee staffing model that encourages and allows health care managers and health care professionals to work together to create schedules and/or fill required open shifts across a health care organization.

- **Embrace integrity** - integrity may refer to the consistent inclusion of honesty, morals, and values into daily actions and behavior. Integrity can be vital to the process of understanding, leading, and motivating other individuals from the workforce. Essentially, integrity can help build trust and respect, which in turn can help health care professionals effectively understand, lead, and motivate individuals from the workforce. Examples of how health care professionals can incorporate and display integrity in the workplace may be found below.
 - **Embrace honesty** - honesty is often the foundation of integrity. Thus, when one is attempting to act with integrity, one first has to be honest with him or herself and others.
 - **Embrace shared morals and values** - much like with honesty, when one is attempting to act with integrity, one has to embrace shared morals and values.
 - **Embrace transparency** - transparency, within the context of health care, may refer to an open and honest method of transmitting

information regarding operating practices and patient care. Within a health care organization transparency can foster trust, honesty, effective communication, teamwork, responsibility, accountability, and, subsequently, motivation. Health care professionals can embrace transparency in health care organizations by the following means: utilize direct and honest communication; establish open door policies for health care managers; provide individuals from the workforce with organizational updates.

- **Consistently showing up to work on time** - consistently showing up to work on time may not be an action that comes to mind when considering integrity. However, consistently showing up to work on time can be a very simple and straightforward way to incorporate/ display integrity in the workplace. Essentially, consistently showing up to work on time sends the message that one respects other individuals' time, while consistently showing up late to work sends the message that one does not respect other individuals' time. Such a message can undermine a health care professional's ability to effectively understand, lead, and motivate other individuals. Thus, health care professionals should make every effort to show up to work on time.
- **Do not waste other individuals' time** - to build on the previous recommendation, health care professionals should not waste other individuals' time. Much like with the previous integrity recommendation, wasting other individuals' time sends the message that one does not respect other individuals' time; sending the message that one does not respect other individuals' time can undermine a health care professional's ability to effectively understand, lead, and motivate other individuals. Examples of how

one can waste other individuals' time include the following: excessive talking about personal matters that may be irrelevant to health care, making personal calls, sending personal text messages, engaging in personal social media interactions, taking excessively long breaks (e.g., taking a break which exceeds the allotted time), causing distractions, causing disorganization, running disorganized meetings, deliberately moving in a slow manner, failing to engage in relevant training, and refusing to follow specific instructions.

- **Follow a health care organization's policies and procedures** - following related health care organization policies and procedures can show others that one is attempting to follow directions, pursue education, and create commonality among peers and colleagues. Attempting to follow directions, pursue education, and create commonality among peers and colleagues can help health care professionals effectively understand, lead, and motivate individuals from the workforce.
- **Be professional** - lastly, acting in a professional manner can go a long way when attempting to incorporate/display integrity in the workplace. Examples of how a health care professional can act in a professional manner include the following: remain calm, especially in the face of a challenge or adversity; follow directions; listen to others; refrain from using excessive profanity and/or crude language; remain educated and up to date on relevant health care-related information; respect other individual's privacy; do not inject unnecessary personal information or "drama" into professional dynamics; refrain from injecting oneself into other individuals' personal "drama" or personal social dynamics; do not engage in personal social media interactions that may lead to conflict in the workplace; work to efficiently and

effectively resolve workplace grievances; follow health care-related laws and guidelines (e.g., the Health Insurance Portability and Accountability Act of 1996 [HIPAA]); follow related scopes of practice; adhere to relevant standards of practice (note: the term scope of practice may refer to a description of services qualified health care professionals are deemed competent to perform and permitted to undertake under the terms of their professional license; the term standards of practice may refer a statement of duties or specific guidelines for a health care professional).

- **Allow for flexible job options** - flexible job options (e.g., flexible schedules) can allow employees to find a professional option that best suits their needs, which in turn can promote a positive, comfortable work environment, which in turn can increase morale, foster effective communication, and maximize productivity and the professional impact of each individual. Health care professionals should note that job rigidity and a lack of flexible job options can have the opposite effect (e.g., decreased opportunities to effectively understand, lead, and motivate individuals from the workforce).
- **Allow for and encourage professional autonomy** - professional autonomy may refer to any allowance that enables an employee to complete a task with little to no interruption or interference. Professional autonomy is another example of a powerful tool that can motivate and ignite individuals' desire to self-start, work independently, take on responsibilities and tasks, complete tasks, accept accountability, communicate effectively, maximize efforts, and optimize patient care. When allowing for professional autonomy, health care professionals should consider the following elements of professional autonomy: give individuals space and freedom, professional trust, professional independence, professional accountability, the authority

to make decisions, effective communication, organization, support, and avoiding micromanagement. Specific information regarding the aforementioned elements of professional autonomy may be found below.

- **Give individuals space and freedom** - giving individuals space and freedom is absolutely essential to professional autonomy. It has been argued that, without giving individuals space and freedom, there can truly be no professional autonomy. Therefore, health care professionals should allow individuals from the workforce the space and freedom to work independently, at times, to complete tasks, collaborate with peers, and work to optimize patient care (note: giving individuals space and freedom often means allowing individuals to work with little to no interruption or interference from other individuals that may disrupt an individual's ability to complete a task or required duty).
- **Professional trust** - professional trust is also absolutely essential to professional autonomy. Health care administrators and health care managers must trust in their employees' abilities to complete tasks and required duties. Without professional trust there can be no professional autonomy. Health care professionals should note the following methods to effectively establish trust with health care administrators and health care managers: complete tasks when they are assigned, meet deadlines, consistently show up to work on time, assist peers and colleagues, remain honest, follow health care organization policies and procedures, work to improve patient safety, work to improve patient care, and act professionally.
- **Professional independence** - professional independence may refer to the ability of an individual to work safely and effectively on his or her

own with little to no direct supervision or management. Health care professionals should cultivate their professional independence if they would like to or prefer to work autonomously (note: health care administrators and health care managers are more likely to extend professional autonomy to health care professionals who exhibit professional independence).

- **Professional accountability** - professional accountability may refer to the act of taking responsibility for the failure or success of an action, project, or task taken or completed in a professional setting. If a health care professional would like to work autonomously then he or she should take professional accountability for his or her actions (note: professional accountability often requires commitment to professional oaths, codes, scopes of practice, and/or standards of practice).
- **The authority to make decisions** - often, the success of professional autonomy rests on an individual's authority to make his or her own decisions. If an individual is truly given professional autonomy he or she should possess, at least some, authority to make decisions (note: authority to make decisions can empower individuals to take on more responsibility, and grant them the professional confidence to accept and complete difficult professional challenges).
- **Effective communication** - effective communication is often the foundation for professional autonomy. Individuals from every level of a health care organization must be able to effectively communicate in order for professional autonomy to be effective. Health care administrators and health care managers must be able to communicate vital health care-related information to health care

professionals, and health care professionals must be able to effectively communicate vital health care-related information to health care administrators and health care managers (note: in order for communication to be effective, within the context of professional autonomy, health care administrators and health care professionals must remain approachable, open, and receptive to communication).

- **Organization** - health care professionals granted professional autonomy must be organized. Essentially, the individual health care professional given professional autonomy should be organized enough to efficiently and effectively complete assigned tasks, duties, and responsibilities within the given time frame. Health care professionals should note that time management is often essential to organization in a professional setting.
- **Support** - individual health care professionals granted professional autonomy may require support, at times, to efficiently and effectively complete assigned tasks, duties, and responsibilities. Support should be extended when required. Health care professionals should note that support may come in the form of assistance from other health care professionals, health care-related resources (e.g., meeting space and/or personal computers), and effective intra-organizational communication.
- **Avoid micromanagement** - finally, micromanagement should be avoided. Micromanagement, within the context of a professional organization, may refer to a management style that exhibits excessive control over employees and their professional actions. Professional autonomy can motivate and ignite individuals' desire to self-start, work independently, take on responsibilities and tasks, complete

tasks, accept accountability, communicate effectively, maximize efforts, and optimize patient care, while micromanagement can have the opposite effects; micromanagement can professionally suffocate individuals, and potentially decrease individuals' desire to self-start, work independently, take on responsibilities and tasks, complete tasks, accept accountability, communicate effectively, maximize efforts, and optimize patient care (note: micromanagement often decrease, stifles, suppress, and/or extinguishes motivation).

- **Provide positive feedback** - positive feedback may refer to a form of communication that recognizes an individual's success, achievements, and/or hard work. Positive feedback often motivates individuals to do their best. Therefore, health care professionals should provide positive feedback to motivate individuals from the workforce. Health care professionals should note the following examples of positive feedback: "excellent work today;" "you did a great job helping patients today;" "I appreciate all your hard work;" "your effort is really making a difference;" "your effort is helping to improve patient care."
- **Set goals** - setting goals can be a powerful motivational tool in health care settings. Essentially, goals can give individuals direction, let individuals know what needs to be done, and provide individuals with information on what is required. When setting goals, health care professionals should consider the following elements of goal setting: identify the intent or purpose of the goal; determine if the goal is a short-term or long-term goal; determine the time-line for the goal; develop a plan to meet the goal; inform individuals about the goal and related concepts; ensure individuals have what they require to accomplish the goal; follow up with individuals to assess progress; make required adjustments to the goal, as needed; recognize the goal when achieved; express gratitude to those individuals who helped

achieve the goal. When individuals from the workforce are working to achieve desired goals, health care professionals should provide positive feedback and positive reinforcement to focus and further motivate individuals to maximize their efforts to accomplish the desired goal.

- **Initiate employee incentive programs** - employee incentive programs can be powerful workforce motivational tools. Essentially, employee incentive programs can drive individuals to go above and beyond the minimum necessary effort to complete their employee-related requirements and functions. By providing individuals from the workforce with incentives, health care organizations can maximize the effort of their workforce. Examples of employee incentive programs include the following: financial bonuses, tuition reimbursement, and professional development programs.
- **Work to achieve employee satisfaction** - it has been argued that employee satisfaction is one of the major driving forces behind employee motivation. Thus, health care professionals should work to achieve employee satisfaction among a health care organization's workforce. Health care professionals can work to achieve employee satisfaction by incorporating many or all of the aforementioned recommendations into the cultural, executive, and directional structure of their health care organization.

Section 3 Summary

Health care organizations should work to effectively recruit and motivate employees. Such efforts can optimize the safe and effective administration of care to residents in need. Finally, health care organizations should follow relevant recommendations to maximize employee recruitment and motivation.

Section 3 Key Concepts

- The third key aspect of organizational improvement is effective employee recruitment and motivation.

Section 3 Key Terms

Employee recruitment - the process of identifying, attracting, interviewing, selecting, hiring, and onboarding new employees

Onboarding - any actions used to integrate a new employee into an organization

Job description - an outline or an accounting of the general tasks, duties, and responsibilities of a specific position

Employee satisfaction - an employee's perceived level of contentment related to his or her place of employment

Collaborative staffing model - an employee staffing model that encourages and allows health care managers and health care professionals to work together to create schedules and/or fill required open shifts across a health care organization

Integrity - the consistent inclusion of honesty, morals, and values into daily actions and behavior

Transparency (within the context of health care) - an open and honest method of transmitting information regarding operating practices and patient care

Scope of practice - a description of services qualified health care professionals are deemed competent to perform and permitted to undertake under the terms of their professional license

Standards of practice - a statement of duties or specific guidelines for a health care professional

Professional autonomy - any allowance that enables an employee to complete a task with little to no interruption or interference

Professional independence - the ability of an individual to work safely and effectively on his or her own with little to no direct supervision or management

Professional accountability - the act of taking responsibility for the failure or success of an action, project, or task taken or completed in a professional setting

Micromanagement (within the context of a professional organization) - a management style that exhibits excessive control over employees and their professional actions

Positive feedback (with the context of communication) - a form of communication that recognizes an individual's success, achievements, and/or hard work

Section 3 Personal Reflection Question

How can health care professionals use the above recommendations to effectively improve their health care organization?

Section 4: Health Care Marketing and Advertising Laws

It is often argued that health care marketing and advertising are essential to the success of a health care organization. It is also argued that health care organizations need marketing and advertising to get their message out to potential residents. Unfortunately, many health care organizations fail to develop

effective marketing and advertising campaigns that both attract potential residents and adhere to relevant laws. With that in mind, the fourth key aspect of organizational improvement is to develop marketing and advertising campaigns that adhere to relevant laws. This section of the course will review such laws.

Laws that Apply to Health Care Marketing and Advertising

- **Truth in Health care Marketing Act of 2017** - the Truth in Health care Marketing Act of 2017 may refer to a group of U.S. laws that were enacted to protect consumers from deceptive and potentially misleading marketing practices by any business in the health care industry. Specific information regarding the Truth in Health Care Marketing Act of 2017 may be found below. The information found below was derived from materials provided by the U.S. government (GovInfo, 2023).
 - The Truth in Health Care Marketing Act of 2017 ensures that patients receive accurate health care information by prohibiting misleading and deceptive advertising or representation in the provision of health care services, to require the identification of the license of health care professionals, and for other purposes.
 - The Truth in Health Care Marketing Act of 2017 indicates that many types of health care professionals including physicians, technicians, nurses, physician assistants, and other allied practitioners are engaged in providing services in health care settings, and all of these individuals play an important and distinct role in the health care delivery system; the exchange of information between patients and their health care professionals is critical to helping patients understand their health care choices; consumers are often unaware of the differences in, and seek more information about, the

qualifications, training, and education of their health care professionals; evidence exists of patient confusion resulting from ambiguous health care nomenclature and related advertisements and marketing products; and nationwide surveys revealed the depth of confusion regarding the education, skills, and training of health care professionals and indicated strong support for increasing clarity in the advertising and marketing claims of health care professionals.

- The Truth in Health Care Marketing Act of 2017 prohibits any person from making any deceptive or misleading statement, or engaging in any deceptive or misleading act, that misrepresents whether such person holds a State health care license; or misrepresents such person's education, training, degree, license, or clinical expertise.
- The Truth in Health Care Marketing Act of 2017 requires that any person who is advertising health care services provided by such person, shall disclose in such advertisement the applicable license under which such person is authorized to provide such services.
- A violation shall be treated as an unfair or deceptive act or practice prescribed under Section 5 of the Federal Trade Commission Act (15 U.S.C. 45). The Federal Trade Commission shall enforce these laws in the same manner, by the same means, and with the same jurisdiction as though all applicable terms and provisions of the Federal Trade Commission Act were incorporated.
- **Physician Self-Referral Law** - the Physician Self-Referral Law, otherwise referred to as Stark law, may refer to the U.S. law that prohibits physicians from referring patients to receive designated health services (DHS) payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship. Specific information

regarding the Physician Self-Referral Law may be found below. The information found below was derived from materials provided by the U.S. Centers for Medicare and Medicaid Services (U.S. Centers for Medicare and Medicaid Services, 2023).

- When enacted in 1989, Section 1877 of the Social Security Act (the Act) applied only to physician referrals for clinical laboratory services; in 1993 and 1994, Congress expanded the prohibition to additional designated health services (DHS) and applied certain aspects of the physician self-referral law to the Medicaid program; in 1997, Congress added a provision permitting the Secretary to issue written advisory opinions concerning whether a referral relating to DHS (other than clinical laboratory services) is prohibited under section 1877 of the Act; in 2003 Congress authorized the Secretary to promulgate an exception to the physician self-referral prohibition for certain arrangements in which the physician receives non-monetary remuneration that is necessary and used solely to receive and transmit electronic prescription information and established a temporary moratorium on physician referrals to certain specialty hospitals in which the referring physician has an ownership or investment interest.
- The Physician Self-Referral law establishes the following items or services as DHS: clinical laboratory services; physical therapy services; occupational therapy services; outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home

health services; outpatient prescription drugs; inpatient and outpatient hospital services.

- The Physician Self-Referral law prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
- The Physician Self-Referral law prohibits an entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.
- The Physician Self-Referral law establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.
- **Anti-Kickback Statute (AKS)** - the Anti-Kickback Statute (AKS) may refer to a U.S. 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 federal health care programs. Specific information regarding the AKS may be found below. The information found below was derived from materials provided by the U.S. Department of Health and Human Services (U.S. Department of Health and Human Services, 2023).
 - The AKS 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 federal health care programs (e.g., drugs, supplies, or health care

services for Medicare or Medicaid patients); health care administrators should note that remuneration includes anything of value and can take many forms besides cash, such as: free rent, expensive hotel stays, meals, and excessive compensation for medical directorships or consultancies.

- The AKS covers the payers of kickbacks, those who offer or pay remuneration, as well as the recipients of kickbacks, and those who solicit or receive remuneration (note: the term kickback may refer to compensation for facilitating a transaction or service).
- The kickback prohibition applies to all sources of referrals, including patients.
- Criminal penalties and administrative sanctions for violating the AKS include: fines, jail terms, and exclusion from participation in federal health care programs; physicians who pay or accept kickbacks also face penalties of up to \$50,000 per kickback plus three times the amount of the remuneration.
- Health care administrators should note that 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.
- Health care administrators should note that 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.

- **Federal Trade Commission Act Section 5: Unfair or Deceptive Acts or Practices** - Section 5 of the Federal Trade Commission Act (FTC Act) (15 USC 45) are a group of laws that prohibit unfair or deceptive acts or practices in or affecting commerce. Specific information regarding the FTC Act may be found below. The information found below was derived from materials provided by the Federal Trade Commission (Federal Trade Commission, 2023).
 - The Federal Trade Commission Act is the primary statute of the Commission. Under the Act, as amended, the Commission is empowered, among other things, to prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; seek monetary redress and other relief for conduct injurious to consumers; prescribe rules defining with specificity acts or practices that are unfair or deceptive, and establishing requirements designed to prevent such acts or practices; gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce; and make reports and legislative recommendations to Congress and the public.
 - The prohibition applies to all persons engaged in commerce.
 - An act or practice is unfair when it causes or is likely to cause substantial injury to consumers; cannot be reasonably avoided by consumers; and is not outweighed by countervailing benefits to consumers or to competition.

- Public policy, as established by statute, regulation, or judicial decisions, may be considered with all other evidence in determining whether an act or practice is unfair.
- An act or practice is deceptive when a representation, omission, or practice misleads or is likely to mislead the consumer; a consumer's interpretation of the representation, omission, or practice is considered reasonable under the circumstances; and the misleading representation, omission, or practice is material.
- Claims must be substantiated, especially when they concern health, safety, or performance (note: the type of evidence may depend on the product, the claims, and what experts believe necessary; e.g., if the ad specifies a certain level of support for a claim - "tests show X" - it must have at least that level of support).
- Sellers are responsible for claims they make about their products and services. Third parties - such as advertising agencies or website designers and catalog marketers - also may be liable for making or disseminating deceptive representations if they participate in the preparation or distribution of the advertising, or know about the deceptive claims.
- Advertising agencies or website designers are responsible for reviewing the information used to substantiate ad claims; they may not simply rely on an advertiser's assurance that the claims are substantiated (note: in determining whether an ad agency should be held liable, the FTC looks at the extent of the agency's participation in the preparation of the challenged ad, and whether the agency knew or should have known that the ad included false or deceptive claims).

- Disclaimers and disclosures must be clear and conspicuous; consumers must be able to notice, read or hear, and understand the information (note: a disclaimer or disclosure alone usually is not enough to remedy a false or deceptive claim).
- Demonstrations must show how the product will perform under normal use.
- Refunds must be made to dissatisfied consumers - if you promised to make them.
- Health care professionals should note that some acts or practices may violate both Section 5 of the FTC Act and other federal or state laws; other acts or practices may violate only the FTC Act while fully complying with other consumer protection laws and regulations.
- **Guides Concerning the Use of Endorsements and Testimonials in Advertising** - Guides Concerning the Use of Endorsements and Testimonials in Advertising represent administrative interpretations of laws enforced by the Federal Trade Commission for the guidance of the public in conducting its affairs in conformity with legal requirements. Specific information regarding the Guides Concerning the Use of Endorsements and Testimonials in Advertising may be found below. The information found below was derived from materials provided by the U.S. government (Code of Federal Regulations, 2023).
 - The Guides address the application of Section 5 of the FTC Act to the use of endorsements and testimonials in advertising. The Guides provide the basis for voluntary compliance with the law by advertisers and endorsers. Practices inconsistent with these Guides may result in corrective action by the Commission under Section 5 if,

after investigation, the Commission has reason to believe that the practices fall within the scope of conduct declared unlawful by the statute. The Guides set forth the general principles that the Commission will use in evaluating endorsements and testimonials, together with examples illustrating the application of those principles. The Guides may not cover every possible use of endorsements in advertising. Whether a particular endorsement or testimonial is deceptive will depend on the specific factual circumstances of the advertisement at issue.

- Under the Guides an endorsement means any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.
- The Commission treats endorsements and testimonials identically.
- Endorsements must reflect the honest opinions, findings, beliefs, or experience of the endorser. Furthermore, an endorsement may not convey any express or implied representation that would be deceptive if made directly by the advertiser.
- The endorsement message need not be phrased in the exact words of the endorser, unless the advertisement affirmatively so represents. However, the endorsement may not be presented out of context or reworded so as to distort in any way the endorser's opinion or experience with the product. An advertiser may use an endorsement

of an expert or celebrity only so long as it has good reason to believe that the endorser continues to subscribe to the views presented. An advertiser may satisfy this obligation by securing the endorser's views at reasonable intervals where reasonableness will be determined by such factors as new information on the performance or effectiveness of the product, a material alteration in the product, changes in the performance of competitors' products, and the advertiser's contract commitments.

- Advertisers are subject to liability for false or unsubstantiated statements made through endorsements, or for failing to disclose material connections between themselves and their endorsers (note: endorsers also may be liable for statements made in the course of their endorsements).
- An advertisement employing endorsements by one or more consumers about the performance of an advertised product or service will be interpreted as representing that the product or service is effective for the purpose depicted in the advertisement. Therefore, the advertiser must possess and rely upon adequate substantiation, including, when appropriate, competent and reliable scientific evidence, to support such claims made through endorsements in the same manner the advertiser would be required to do if it had made the representation directly (i.e., without using endorsements) (note: consumer endorsements themselves are not competent and reliable scientific evidence).
- An advertisement containing an endorsement relating the experience of one or more consumers on a central or key attribute of the product or service also will likely be interpreted as representing that the

endorser's experience is representative of what consumers will generally achieve with the advertised product or service in actual, albeit variable, conditions of use. Therefore, an advertiser should possess and rely upon adequate substantiation for this representation. If the advertiser does not have substantiation that the endorser's experience is representative of what consumers will generally achieve, the advertisement should clearly and conspicuously disclose the generally expected performance in the depicted circumstances, and the advertiser must possess and rely on adequate substantiation for that representation.

- Advertisements presenting endorsements by what are represented, directly or by implication, to be “actual consumers” should utilize actual consumers in both the audio and video, or clearly and conspicuously disclose that the persons in such advertisements are not actual consumers of the advertised product.
- Whenever an advertisement represents, directly or by implication, that the endorser is an expert with respect to the endorsement message, then the endorser's qualifications must in fact give the endorser the expertise that he or she is represented as possessing with respect to the endorsement.
- The expert may, in endorsing a product, take into account factors not within his or her expertise (e.g., matters of taste or price), the endorsement must be supported by an actual exercise of that expertise in evaluating product features or characteristics with respect to which he or she is expert and which are relevant to an ordinary consumer's use of or experience with the product and are available to the ordinary consumer. This evaluation must have

included an examination or testing of the product at least as extensive as someone with the same degree of expertise would normally need to conduct in order to support the conclusions presented in the endorsement. To the extent that the advertisement implies that the endorsement was based upon a comparison, such comparison must have been included in the expert's evaluation; and as a result of such comparison, the expert must have concluded that, with respect to those features on which he or she is expert and which are relevant and available to an ordinary consumer, the endorsed product is at least equal overall to the competitors' products; where the net impression created by the endorsement is that the advertised product is superior to other products with respect to any such feature or features, then the expert must in fact have found such superiority.

- Endorsements by organizations, especially expert ones, are viewed as representing the judgment of a group whose collective experience exceeds that of any individual member, and whose judgments are generally free of the sort of subjective factors that vary from individual to individual. Therefore, an organization's endorsement must be reached by a process sufficient to ensure that the endorsement fairly reflects the collective judgment of the organization. Moreover, if an organization is represented as being expert, then, in conjunction with a proper exercise of its expertise in evaluating the product under (expert endorsements), it must utilize an expert or experts recognized as such by the organization or standards previously adopted by the organization and suitable for judging the relevant merits of such products.
- When there exists a connection between the endorser and the seller of the advertised product that might materially affect the weight or

credibility of the endorsement (i.e., the connection is not reasonably expected by the audience), such connection must be fully disclosed. For example, when an endorser who appears in a television commercial is neither represented in the advertisement as an expert nor is known to a significant portion of the viewing public, then the advertiser should clearly and conspicuously disclose either the payment or promise of compensation prior to and in exchange for the endorsement or the fact that the endorser knew or had reason to know or to believe that if the endorsement favored the advertised product some benefit, such as an appearance on television, would be extended to the endorser.

- **Business Opportunity Rule** - the Business Opportunity Rule may refer to a law that requires business opportunity sellers to give prospective buyers specific information to help them evaluate a business opportunity. Specific information regarding the Business Opportunity Rule may be found below. The information found below was derived from materials provided by the U.S. government (Code of Federal Regulations, 2023).
 - In connection with the offer for sale, sale, or promotion of a business opportunity, it is a violation of the Business Opportunity Rule and an unfair or deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act ("FTC Act") for any seller to fail to furnish a prospective purchaser with the required material information in writing at least seven calendar days before the time that the prospective purchaser: signs any contract in connection with the business opportunity sale; or makes a payment or provides other consideration to the seller, directly or indirectly through a third party.

- In connection with the offer for sale, sale, or promotion of a business opportunity, it is a violation of this Rule and an unfair or deceptive act or practice in violation of Section 5 of the FTC Act, for any seller to fail to disclose to a prospective purchaser material information in a single written document and using an identified language.
- If any of the following persons has been the subject of any civil or criminal action for misrepresentation, fraud, securities law violations, or unfair or deceptive practices, including violations of any FTC Rule, within the 10 years immediately preceding the date that the business opportunity was offered per Section 5; if so, the individual should disclose all such actions in an attachment to the disclosure document; individuals should state the full caption of each action (names of the principal parties, case number, full name of court, and filing date); for each action, the seller may also provide a brief accurate statement not to exceed 100 words that describes the action.
- The seller should identify offers for a refund or the right to cancel the purchase.
- The seller should identify refunds that are not provided.
- Individuals should state the name, state, and telephone number of all purchasers who purchased the business opportunity within the last three years; if more than 10 purchasers purchased the business opportunity within the last three years, the seller may limit the disclosure by stating the name, state, and telephone number of at least the 10 purchasers within the past three years who are located nearest to the prospective purchaser's location; alternatively, a seller

may furnish a prospective buyer with a list disclosing all purchasers nationwide within the last three years.

- The seller should attach a duplicate copy of the disclosure document to be signed and dated by the purchaser; the seller may inform the prospective purchaser how to return the signed receipt (e.g., by sending to a street address, email address, or facsimile telephone number).
- In connection with the offer for sale, sale, or promotion of a business opportunity, it is a violation of the Business Opportunity Rule and an unfair or deceptive act or practice in violation of Section 5 of the FTC Act, for the seller to make any earnings claim to a prospective purchaser, unless the seller has a reasonable basis for its claim at the time the claim is made; has in its possession written materials that substantiate its claim at the time the claim is made; makes the written substantiation available upon request to the prospective purchaser and to the FTC; and furnishes to the prospective purchaser an earnings claim statement (note: the earnings claim statement shall be a single written document).
- Individuals should not disseminate industry financial, earnings, or performance information unless the seller has written substantiation demonstrating that the information reflects, or does not exceed, the typical or ordinary financial, earnings, or performance experience of purchasers of the business opportunity being offered for sale.
- Individuals should notify any prospective purchaser in writing of any material changes affecting the relevance or reliability of the information contained in an earnings claim statement before the prospective purchaser signs any contract or makes a payment or

provides other consideration to the seller, directly or indirectly, through a third party.

- If the seller conducts the offer for sale, sale, or promotion of a business opportunity in Spanish, the seller must provide the required disclosure document.
- If the seller conducts the offer for sale, sale, or promotion of a business opportunity in a language other than English or Spanish, the seller must provide the required disclosure document.
- In connection with the offer for sale, sale, or promotion of a business opportunity, it is a violation and an unfair or deceptive act or practice in violation of Section 5 of the FTC Act for any seller, directly or indirectly through a third party, to: disclaim, or require a prospective purchaser to waive reliance on, any statement made in any document or attachment that is required or permitted to be disclosed under the Business Opportunity Rule; make any claim or representation, orally, visually, or in writing, that is inconsistent with or contradicts the information required to be disclosed; include in any disclosure document or earnings claim statement any materials or information other than what is explicitly required or permitted by the Business Opportunity Rule; misrepresent the amount of sales, or gross or net income or profits a prospective purchaser may earn or that prior purchasers earned; fail to make available to prospective purchasers, and to the FTC upon request, written substantiation for the seller's earnings claims; misrepresent how or when commissions, bonuses, incentives, premiums, or other payments from the seller to the purchaser will be calculated or distributed; misrepresent the cost, or the performance, efficacy, nature, or central characteristics of the

business opportunity or the goods or services offered to a prospective purchaser; misrepresent any material aspect of any assistance offered to a prospective purchaser; misrepresent the likelihood that a seller, locator, or lead generator will find locations, outlets, accounts, or customers for the purchaser; misrepresent any term or condition of the seller's refund or cancellation policies; fail to provide a refund or cancellation when the purchaser has satisfied the terms and conditions; misrepresent a business opportunity as an employment opportunity; misrepresent the terms of any territorial exclusivity or territorial protection offered to a prospective purchase; assign to any purchaser a purported exclusive territory that, in fact, encompasses the same or overlapping areas already assigned to another purchaser; misrepresent that any person, trademark or service mark holder, or governmental entity, directly or indirectly benefits from, sponsors, participates in, endorses, approves, authorizes, or is otherwise associated with the sale of the business opportunity or the goods or services sold through the business opportunity; fail to disclose, with respect to any person identified as a purchaser or operator of a business opportunity offered by the seller.

- To prevent the unfair and deceptive acts or practices specified in the Business Opportunity Rule, business opportunity sellers and their principals must prepare, retain, and make available for inspection by FTC officials copies of the following documents for a period of three years: each materially different version of all documents required by the Business Opportunity Rule; each purchaser's disclosure receipt; each executed written contract with a purchaser; and all substantiation upon which the seller relies for each earnings claim from the time each such claim is made.

- **Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Social Media** - the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may refer to federal laws that provide provisions for safeguarding medical information. Specific information regarding HIPAA, and the application of HIPAA to marketing, advertising, and the use of social media may be found below. The information found below was derived from materials provided by the U.S. Department of Health and Human Services unless, otherwise, specified (U.S. Department of Health and Human Services, 2022).
 - The Standards for Privacy of Individually Identifiable Health Information, otherwise referred to as the Privacy Rule, establishes a set of national standards for the protection of certain health information.
 - The Privacy Rule standards address the use and disclosure of individuals' health information, which is referred to as "protected health information" by organizations subject to the Privacy Rule. Organizations subject to the Privacy Rule are referred to as "covered entities." The Privacy Rule also sets standards for individuals' privacy rights to understand and control how their health information is used.
 - One of the major goals of the Privacy Rule is to assure that individuals' health information is adequately protected while allowing the flow of health information needed to provide and promote high quality health care. Another major goal of the Privacy Rule is to protect the public's health and well being.
 - The Privacy Rule applies to the following entities:

- Health plans - a health plan may refer to any plan which covers the cost of health care. Health plans that may be affected by the stipulations of the Privacy Rule include: health, dental, vision, and prescription drug insurers, health maintenance organizations (HMOs), Medicare, Medicaid, Medicare+Choice and Medicare supplement insurers, and long-term care insurers (excluding nursing home fixed-indemnity policies). Additional health plans that may be affected by the stipulations of the Privacy Rule include: employer-sponsored group health plans, government and church-sponsored health plans, and multiemployer health plans.
- Health care providers - essentially, every health care provider, regardless of size, who electronically transmits health information in connection with certain transactions may be considered a covered entity.
- Health care clearinghouses - a health care clearinghouse may refer to any entity that processes nonstandard information from another entity into a standard format. Examples of health care clearinghouses include: billing services, repricing companies, and community health management information systems.
- Business associate - a business associate may refer to a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or to, a covered entity that involve the use or disclosure of individually identifiable health information.

- The Privacy Rule safeguards protected health information (PHI). PHI may refer to any information about health status, provision of health care, or payment for health care that is created or collected by a covered entity; individually identifiable health information. In essence, the Privacy Rule protects all individually identifiable health information held or transmitted by a covered entity or its business associate(s), in any form or media, whether electronic, paper, or oral.
- Individually identifiable health information is information, including demographic data, that relates to the following: an individual's past, present or future physical or mental health or condition, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual (i.e., individually identifiable health information is information that may be used to identify an individual and their relationship to the health care system). Health care professionals should also note that examples of individually identifiable health information includes patients' names, birth dates, home addresses, and Social Security Numbers (note: the Privacy Rule excludes from protected health information employment records that a covered entity maintains in its capacity as an employer and certain other records indicated by law).
- The Privacy Rule indicates that there are no restrictions on the use or disclosure of de-identified health information. De-identified health information may refer to information that neither identifies nor provides a reasonable basis to identify an individual (i.e., information that cannot, necessarily, link an individual to the health care system). Health care professionals should note the following two ways

information may be de-identified: a formal determination by a qualified statistician may de-identify information; the removal of specified identifiers of the individual and of the individual's relatives, household members, and employers is completed, and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.

- A major purpose of the Privacy Rule is to define and limit the circumstances in which an individual's protected health information may be used or disclosed by covered entities.
- A covered entity may not use or disclose protected health information, except as the Privacy Rule permits or requires; or as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing. Fundamentally, the Privacy Rule determines how PHI may be used and/or disclosed to protect individuals' privacy.
- A covered entity may use and disclose protected health information for its own treatment, payment, and health care operations activities.
- Treatment may refer to the provision, coordination, or management of health care and related services for an individual/patient by one or more health care professionals, including consultation between health care professionals regarding a patient and referral of a patient by one health care professional to another.
- Payment encompasses activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish or obtain reimbursement for health care delivered to a patient and activities of a health care provider to

obtain payment or be reimbursed for the provision of health care to a patient.

- Health care operations may include any of the following activities: quality assessment and improvement activities, including case management and care coordination; competency assurance activities, including health care provider or health plan performance evaluation, credentialing, and accreditation; conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; specified insurance functions, such as underwriting, risk rating, and reinsuring risk; business planning, development, management, and administration; and business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity.
- The Privacy Rule indicates the following: informal permission, regarding the use of PHI, may be obtained by asking an individual outright, or by circumstances that clearly give an individual the opportunity to agree, acquiesce, or object; when an individual is incapacitated (e.g., in an emergency situation) or not available, covered entities generally may make such uses and disclosures, if in the exercise of their professional judgment, the use or disclosure is determined to be in the best interests of an individual.
- The Privacy Rule does not require that every risk of an incidental use or disclosure of PHI be eliminated.
- Covered entities may use and disclose PHI without individual authorization as required by law.

- Covered entities may disclose PHI to public health authorities authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability and to public health or other government authorities authorized to receive reports of child abuse and neglect.
- Covered entities may disclose PHI to entities subject to the United States Food and Drug Administration's (FDA) regulations regarding FDA regulated products or activities for purposes such as adverse event reporting, tracking of products, product recalls, and post-marketing surveillance.
- Covered entities may disclose PHI to individuals who may have contracted or been exposed to a communicable disease when notification is authorized by law.
- Covered entities may disclose PHI to employers, regarding employees, when requested by employers, for information concerning a work-related illness or injury or workplace related medical surveillance, because such information is needed by the employer to comply with organizations such as the Occupational Safety and Health Administration (OSHA).
- In certain circumstances, covered entities may disclose PHI to appropriate government authorities regarding victims of abuse, neglect, or domestic violence.
- Covered entities may use or disclose PHI to facilitate the donation and transplantation of cadaveric organs, eyes, and/or tissue.

- Covered entities may disclose PHI that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat (including the target of the threat).
- An authorization is not required to use or disclose protected health information for certain essential government functions.
- A covered entity must obtain an individual's written authorization for any use or disclosure of PHI that is not for treatment, payment or health care operations or otherwise permitted or required by the Privacy Rule.
- The Privacy Rule indicates that most uses and disclosures of psychotherapy notes for treatment, payment, and health care operations purposes require an authorization.
- A covered entity must obtain an individual's authorization to use or disclose psychotherapy notes with the following exceptions - the covered entity who originated the notes may use them for treatment; a covered entity may use or disclose, without an individual's authorization, the psychotherapy notes, for its own training, and to defend itself in legal proceedings brought by an individual, for governmental investigations to determine the covered entity's compliance with the Privacy Rules, to avert a serious and imminent threat to public health or safety, to a health oversight agency for lawful oversight of the originator of the psychotherapy notes, for the lawful activities of a coroner or medical examiner or as required by law.

- A central aspect of the Privacy Rule is the principle of “minimum necessary” use and disclosure. A covered entity must make reasonable efforts to use, disclose, and request only the minimum amount of PHI needed to accomplish the intended purpose of the use, disclosure, or request. Essentially, the minimum necessary principle/rule can help prevent the disclosure of any unnecessary PHI. Health care professionals should always keep the minimum necessary principle/rule in mind when disclosing PHI.
- A covered entity must establish and implement policies and procedures (which may be standard protocols) for routine, recurring disclosures, or requests for disclosures, that limits the protected health information disclosed to that which is the minimum amount reasonably necessary to achieve the purpose of the disclosure.
- A covered entity, with certain exceptions, must provide a notice of its privacy practices.
- A covered health care provider with a direct treatment relationship with individuals must make a good faith effort to obtain written acknowledgement from patients of receipt of the privacy practices notice.
- Individuals have a right to an accounting of the disclosures of their protected health information by a covered entity or the covered entity’s business associates.
- Individuals have the right to request that a covered entity restrict use or disclosure of PHI for treatment, payment or health care operations, disclosure to persons involved in the individual’s health care or payment for health care, or disclosure to notify family

members or others about the individual's general condition, location, or death.

- A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of PHI in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure.
- The Privacy Rule requires a covered entity to treat a personal representative the same as the individual, with respect to uses and disclosures of the individual's protected health information, as well as the individual's rights under the Privacy Rule. A personal representative may refer to any individual legally authorized to make health care decisions on an individual's behalf or to act for a deceased individual or the estate.
- Typically, parents are the personal representatives for their minor children (note: the term minor child may refer to any individual under a specific age, typically under the age of 18). Therefore, in most cases, parents can exercise individual rights, such as access to medical records, on behalf of their minor children.
- Health care professionals should note the following: generally, state laws that are contrary to the Privacy Rule are preempted by the federal requirements, therefore federal requirements will apply.
- The HIPAA Privacy Rule gives individuals important controls over whether and how their protected health information is used and disclosed for marketing purposes. With limited exceptions, the Rule requires an individual's written authorization before a use or

disclosure of his or her protected health information can be made for marketing; as not to interfere with core health care functions, the Rule distinguishes marketing communications from those communications about goods and services that are essential for quality health care.

- The Privacy Rule addresses the use and disclosure of protected health information for marketing purposes by: defining what is “marketing” under the Rule; excepting from that definition certain treatment or health care operations activities; requiring individual authorization for all uses or disclosures of protected health information for marketing purposes with limited exceptions.
- The Privacy Rule defines marketing as communication about a product or service that encourages recipients of the communication to purchase or use the product or service (note: if the communication is “marketing,” then the communication can occur only if the covered entity first obtains an individual’s authorization).
- Examples of marketing communications requiring prior authorization include the following: a communication from a health care facility informing former patients about a cardiac facility, that is not part of the health care facility; a communication from a health insurer promoting a home and casualty insurance product offered by the same company.
- Marketing also means: an arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages

recipients of the communication to purchase or use that product or service. This part of the definition of marketing has no exceptions. The individual must authorize these marketing communications before they can occur; a covered entity may not sell protected health information to a business associate or any other third party for that party's own purposes.

- Covered entities may not sell lists of patients or enrollees to third parties without obtaining authorization from each person on the list. For example, it is marketing when: a health plan sells a list of its members to a company that sells blood glucose monitors, which intends to send the plan's members brochures on the benefits of purchasing and using the monitors; a drug manufacturer receives a list of patients from a covered health care professional and provides remuneration, then uses that list to send discount coupons for a new anti-depressant medication directly to the patients.
- The Privacy Rule identifies exceptions to the definition of marketing under the following three categories:
 1. A communication is not "marketing" if it is made to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care professional network or health plan network; health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits (note: this exception to the marketing definition permits communications by a covered entity about its own

products or services; for example, under this exception, it is not “marketing” when a health care facility uses its patient list to announce the arrival of a new specialty group [e.g., orthopedic] or the acquisition of new equipment [e.g., x-ray machine or magnetic resonance image machine] through a general mailing or publication; a health plan sends a mailing to subscribers approaching Medicare eligible age with materials describing its Medicare supplemental plan and an application form).

2. A communication is not marketing if it is made for treatment of the individual. For example, under this exception, it is not marketing when: a health care professional mails prescription refill reminders to patients, or contracts with a mail house to do so; a primary care physician refers an individual to a specialist for a follow-up test or provides free samples of a prescription drug to a patient.
3. A communication is not “marketing” if it is made for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care professionals, or settings of care to the individual. For example, under this exception, it is not marketing when: a health care professional shares a patient’s medical record with several behavior management programs to determine which program best suits the ongoing needs of the individual patient; a social worker shares medical record information with various nursing homes in the course of recommending that the patient be transferred from a hospital bed to a nursing home.

- For any of the three aforementioned exceptions to the definition of marketing, the activity must otherwise be permissible under the Privacy Rule, and a covered entity may use a business associate to make the communication; as with any disclosure to a business associate, the covered entity must obtain the business associate's agreement to use the protected health information only for the communication activities of the covered entity.
- Any communication that meets the definition of marketing is not permitted, unless the covered entity obtains an individual's authorization. If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.
- A communication does not require an authorization, even if it is marketing, if it is in the form of a face-to-face communication made by a covered entity to an individual; or a promotional gift of nominal value provided by the covered entity. For example, no prior authorization is necessary when: an insurance agent sells a health insurance policy in person to a customer and proceeds to also market a casualty and life insurance policy as well.
- Business associates cannot use protected health information for its own marketing purposes.
- Under the HIPAA Privacy Rule, a covered entity can share protected health information with a telemarketer only if the covered entity has either obtained the individual's prior written authorization to do so, or has entered into a business associate relationship with the telemarketer for the purpose of making a communication that is not

marketing, such as to inform individuals about the covered entity's own goods or services.

- Communications about government and government-sponsored programs do not fall within the definition of marketing.
- The Privacy Rule makes it clear that nothing in the marketing provisions of the Privacy Rule are to be construed as amending, modifying, or changing any rule or requirement related to any other Federal or State statutes or regulations, including specifically anti-kickback, fraud and abuse, or self-referral statutes or regulations, or to authorize or permit any activity or transaction currently proscribed by such statutes and regulations.
- Health care organizations may use social media for the purposes of advertising and marketing. Posting individually identifiable health information on social media without the written authorization from an individual is a HIPAA violation (note: an authorization form has to inform an individual what the disclosure is for and explain that the individual has the right to revoke the authorization; the individual should also be given the option of stipulating a time period after which the disclosure must end) (HIPAA Journal, 2023).
- Posting patient information on social media is a HIPAA violation without patient's authorization because it discloses individually identifiable health information to the public that could be used to commit fraud or identity theft (HIPAA Journal, 2023).
- Social media increases the risk for HIPAA violations because social media channels make it easy for users to take a photo and upload it with the tap of a screen; this increases the risk for HIPAA violations

because members of a covered entity's workforce may take a photo of an individual and post it on the Internet within seconds; if the photo reveals a PHI identifier and health information it is a violation of HIPAA unless the written authorization of the individual was obtained in advance (HIPAA Journal, 2023).

- HIPAA social media rules apply to all accounts - not just corporate accounts; it is important to be aware that images posted on private social media accounts without patient consent are in violation of HIPAA laws, because the individual not only posted electronic protected health information (ePHI) impermissibly, he or she also obtained the image from a corporate source that lacked the protections of the HIPAA Security Rule (HIPAA Journal, 2023).
- Covered entities may be fined for violations of HIPAA on social media because in most cases unauthorized disclosures of ePHI on social media are impermissible disclosures, which is a breach of the Privacy Rule (HIPAA Journal, 2023).
- Apply the "When in Doubt Rule" to health-related information and social media. The When in Doubt Rule may be applied to health-related information and social media as follows: if a health care professional has any doubt whether he or she should use specific health-related information on social media, then the health care professional should not use the specific health-related information on social media; when in doubt, do not use health-related information on any form of social media.
- Health care professionals should not use health-related information about rare diseases or rare injuries on social media. Essentially, health-related information about rare diseases or injuries could link a

specific individual to the health care system, even if the health-related details do not include any individually identifiable health information. For example, a third party could observe health-related information about a rare disease on social media, and then through the process of elimination, the third party could use the information to identify a patient.

- Health care organizations should develop a HIPAA compliant social media policy. A HIPAA compliant social media policy is a policy that stipulates the circumstances under which it is allowed to post any information on social media (note: social media posts can never be fully retracted, therefore, it is a best practice to prohibit any post containing individually identifiable health information and enforce sanctions on any member of the workforce that breaches this policy) (HIPAA Journal, 2023).
- The penalty for a social media HIPAA violation depends on who is responsible for an impermissible disclosure of PHI and what the consequences are (HIPAA Journal, 2023).
- Health care organizations should monitor related social media accounts - if a health care organization has a social media account(s), it should be monitored for potential HIPAA violations.
- Health care organizations should ensure they have a means to save information used on their social media accounts - the ability to save information used on health care organizations' social media accounts could prove to be invaluable if any potential HIPAA violations arise.
- Health care organizations should encourage health care professionals to report any potential HIPAA violations - if a health care professional

observes a potential HIPAA violation, he or she should consider reporting the potential HIPAA violation to their health care organization.

- Health care organizations should have internal channels for HIPAA violation reporting - it is not enough for a health care organization to encourage the reporting of potential HIPAA violations, a health care organization should have established, internal channels or networks for such reporting. Furthermore, health care organizations should make sure individuals are aware of such networks to encourage HIPAA reporting. Moreover, health care organizations should ensure reporting networks work to efficiently and effectively investigate and resolve any potential HIPAA violation. Health care professionals should be aware of their health care organizations' means for HIPAA violation reporting.
- All employees should be trained on HIPAA social media rules as part of their security awareness training; all members of the workforce should be aware of the organization's policies relating to social media whether they have access to ePHI or not (HIPAA Journal, 2023).
- Facebook is not HIPAA compliant; social media has some mechanisms to control unauthorized access to accounts, Meta will not sign a Business Associate Agreement with Covered Entities; however, under Facebook's terms for the Workplace by Facebook service, Meta prohibits the use of the service to submit any patient, medical, or other protected health information regulated by HIPAA or any similar federal or state laws, rules, or regulations (HIPAA Journal, 2023).
- - Health care professionals should note that Covered Entities and Business Associates can share personal health information on social

media sites provided they have the patient's authorization to do so; employees of Covered Entities and Business Associates are advised not to share personal health information on social media sites unless they have a valid reason for doing so and the patient's authorization was acquired by their employer (HIPAA Journal, 2023).

Section 4 Summary

Health care marketing and advertising are essential to the success of a health care organization. Health care organizations should develop effective marketing and advertising campaigns that both attract potential residents and adhere to relevant laws. Health care professionals should note that failing to adhere to relevant laws can jeopardize the sustainability of a health care organization.

Section 4 Key Concepts

- The fourth key aspect of organizational improvement is to develop marketing and advertising campaigns that adhere to relevant laws.
- Laws that apply to health care marketing and advertising include the following: Truth in Health Care Marketing Act of 2017, Physician Self-Referral Law, Anti-Kickback Statute (AKS), Federal Trade Commission Act Section 5: Unfair or Deceptive Acts or Practices, Guides Concerning the Use of Endorsements and Testimonials in Advertising, Business Opportunity Rule, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Section 4 Key Terms

Truth in Healthcare Marketing Act of 2017 - a group of U.S. laws that were enacted to protect consumers from deceptive and potentially misleading marketing practices by any business in the health care industry

Physician Self-Referral Law (otherwise referred to as Stark law) - the U.S. law that prohibits physicians from referring patients to receive designated health services (DHSs) payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship

Anti-Kickback Statute (AKS) - a U.S. 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 federal health care programs

Kickback - compensation for facilitating a transaction or service

Federal Trade Commission Act Section 5: Unfair or Deceptive Acts or Practices - a group of laws that prohibit unfair or deceptive acts or practices in or affecting commerce

Guides Concerning the Use of Endorsements and Testimonials - administrative interpretations of laws enforced by the Federal Trade Commission for the guidance of the public in conducting its affairs in conformity with legal requirements

Endorsement - any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views

expressed by that party are identical to those of the sponsoring advertiser (Code of Federal Regulations, 2023)

Business Opportunity Rule - laws that require business opportunity sellers to give prospective buyers specific information to help them evaluate a business opportunity

Health Insurance Portability and Accountability Act of 1996 (HIPAA) - federal laws that provide provisions for safeguarding medical information

Health plan - any plan that covers the cost of health care (U.S. Department of Health and Human Services, 2022)

Health care clearinghouse - any entity that processes nonstandard information from another entity into a standard format (U.S. Department of Health and Human Services, 2022)

Business associate - a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or to, a covered entity that involve the use or disclosure of individually identifiable health information (U.S. Department of Health and Human Services, 2022)

Protected health information (PHI) - any information about health status, provision of health care, or payment for health care that is created or collected by a covered entity; individually identifiable health information (U.S. Department of Health and Human Services, 2022)

De-identified health information - information that neither identifies nor provides a reasonable basis to identify an individual (U.S. Department of Health and Human Services, 2022)

Treatment - the provision, coordination, or management of health care and related services for an individual/patient by one or more health care professionals, including consultation between health care professionals regarding a patient and referral of a patient by one health care professional to another (U.S. Department of Health and Human Services, 2022)

Personal representative - any individual legally authorized to make health care decisions on an individual's behalf or to act for a deceased individual or the estate (U.S. Department of Health and Human Services, 2022)

Minor child - any individual under a specific age, typically under the age of 18 (U.S. Department of Health and Human Services, 2022)

Marketing (within the context of the Privacy Rule) - communication about a product or service that encourages recipients of the communication to purchase or use the product or service; an arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service (U.S. Department of Health and Human Services, 2022)

HIPAA compliant social media policy - a policy that stipulates the circumstances under which it is allowed to post any information on social media (HIPAA Journal, 2023)

Section 4 Personal Reflection Question

How can health care organizations ensure that their marketing and advertising campaigns adhere to relevant laws?

Section 5: Infection Prevention

The fifth key aspect of organizational improvement is maximizing infection prevention, which is especially important in the current health care climate. This section of the course will highlight recommendations that may be used to prevent infections.

***Clostridioides Difficile* Infection (CDI) Prevention**

Health care organizations should work to prevent *Clostridioides Difficile* infection (CDI). Specific information and recommendations regarding *Clostridioides Difficile* infection (CDI) prevention may be found below. The information found below was derived from materials provided by the Centers for Disease Control and Prevention (CDC) (Centers for Disease Control and Prevention [CDC], 2021; CDC 2022).

- *Clostridioides difficile*, also known as *C. diff.*, is a bacterium that causes diarrhea and colitis (note: colitis may refer to inflammation of the colon); most cases of *C. diff.* infection occur while taking antibiotics or not long after taking antibiotics; *C. diff.* is shed in feces; any surface, device, or material that becomes contaminated with feces could serve as a reservoir for *C. diff.* spores; *C. diff.* spores can also be transferred to patients via the hands of health care professionals who touched a contaminated surface or item; *C. diff.* can be life-threatening, especially in older adult populations.
- Create protocols to facilitate rapid isolation of patients with suspected or confirmed CDI.

- Patients with diarrhea should be isolated while evaluation for the cause is ongoing.
- Health care professionals should ensure rapid evaluation for suspected patients.
- Place symptomatic patients on contact precautions, in a single-patient room with a dedicated toilet.
- If single-patient rooms are not available, room patients with confirmed CDI together.
- For patients with confirmed CDI, maintain contact precautions for at least 48 hours after diarrhea is resolved, or longer.
- Use dedicated patient-care equipment.
- Implement daily patient bathing or showering with soap and water.
- When transferring patients, notify receiving wards or facilities about the patient's CDI status so contact precautions are maintained in the patient's new location.
- Assess for appropriateness of testing; health care professionals should consider other infectious or non-infectious causes of diarrhea before testing for CDI.
- Utilize molecular tests, when applicable. FDA-approved PCR assays, which test for the genes encoding toxin, are same-day tests that are highly sensitive and specific for the presence of a toxin-producing *C. diff.* organism. Molecular assays can be positive for *C. diff.* in individuals who are asymptomatic and do not have infection. When using multi-pathogen

(multiplex) molecular methods, the results should be read with caution as the pre-test probability of *C. diff.* infection might be less.

- Utilize antigen detection, when applicable. These are rapid tests (<1 hour) that detect the presence of *C. diff.*, such as antigen glutamate dehydrogenase (GDH); because results of antigen testing alone are nonspecific, antigen assays may be employed in combination with tests for toxin detection, PCR, or toxigenic culture in two-step testing algorithms.
- Utilize toxin testing, when applicable. Tissue culture cytotoxicity assay detects toxin B only. This assay requires technical expertise to perform, is costly, and requires 24 to 48 hours for a final result. It does provide specific and sensitive results for CDI. While it served as a historical gold standard for diagnosing clinically significant disease caused by *C. diff.*, it is recognized as less sensitive than PCR or toxigenic culture for detecting the organism in patients with diarrhea. Enzyme immunoassay detects toxin A, toxin B, or both A and B. Due to concerns over toxin A-negative, B-positive strains causing disease, most laboratories employ a toxin B-only or A and B assay. Because these are same-day assays that are relatively inexpensive and easy to perform, they are popular with clinical laboratories. However, there are increasing concerns about their relative insensitivity (less than tissue culture cytotoxicity and much less than PCR or toxigenic culture) (note: *C. diff.* toxin is very unstable; the toxin degrades at room temperature and might be undetectable within two hours after collection of a stool specimen; false-negative results occur when specimens are not promptly tested or kept refrigerated until testing can be done).
- Utilize stool cultures, when applicable. Results of toxigenic cultures do serve as a gold standard against which other test modalities are compared in clinical trials; however, it is the one most often associated with false-

positive results due to the presence of nontoxigenic *C. diff.* strains; results of stool cultures are typically available in 48 to 96 hours.

- If a patient is still symptomatic, discontinue laxatives and wait for at least 48 hours before testing.
- Once a patient has a positive CDI test do not repeat testing to detect cure; tests may remain positive for ≥ 6 weeks.
- Implement laboratory procedures to ensure testing of only appropriate specimens (e.g., unformed stool) for *C. difficile* or its toxins.
- Create daily and terminal cleaning protocols and checklists for patient-care areas and equipment.
- Perform daily cleaning of CDI patient rooms using a *C. difficile* sporicidal agent.
- Clean and disinfect the patient-care environment (including the immediate vicinity around a CDI patient and high touch surfaces) at least once a day, including toilets.
- Perform terminal cleaning after CDI patient transfer/discharge with a *C. difficile* sporicidal agent.
- Clean additional areas that are contaminated during transient visits by patients with suspected or confirmed CDI with a *C. difficile* sporicidal agent.
- Incorporate reduction of CDI into the facility health care-associated infection prevention program, including but not limited to the design, implementation, evaluation, and feedback of intervention result.

- Include a multidisciplinary workgroup, including physicians, nursing, and environmental services to identify and implement strategies and to use data for action.
- Monitor health care facility CDI rates, and target units with highest incidence of CDI for evaluation and intervention.
- Review health care facility-onset CDI cases to help identify potential gaps and opportunities for improvement (note: the review should focus on opportunities for improvement across each strategy; utilize findings to engage relevant care teams and staff in gap remediation and performance improvement as soon after the CDI case as possible).
- Educate and train health care professionals on prevention practices for CDI.
- Provide CDI rates and other performance improvement measures to senior leadership, clinical providers, laboratory personnel, environmental services, and other stakeholders.
- Notify appropriate individuals and facility departments about changes in the incidence (or frequency), complications (including recurrences), or severity of CDI.
- Assess the appropriateness of prescribing antibiotics that pose the highest risk for CDI, especially fluoroquinolones, carbapenems, and 3rd and 4th generation cephalosporins.
- Develop facility-specific treatment recommendations for common infections that include first- and second-line antibiotics.
- Evaluate antibiotic treatment of conditions that commonly lead to high-risk antibiotic use, such as asymptomatic bacteriuria and common infections

such as urinary tract infection and community-acquired pneumonia, to minimize the use of high-risk antibiotics.

- Ensure that patients receive the shortest effective duration of antibiotic therapy.

Influenza Prevention

Along with CDI, health care organizations should work to prevent influenza. Specific information and recommendations regarding influenza prevention may be found below. The information found below was derived from materials provided by the CDC (CDC, 2021; CDC 2022).

- Influenza viruses are thought to spread from person to person primarily through large-particle droplet transmission (e.g., when an infected person coughs or sneezes near a susceptible person); influenza, otherwise known as the flu, is a respiratory infection caused by influenza viruses; transmission via large-particle droplets requires close contact between source and recipient persons, because droplets generally travel only short distances (approximately six feet or less) through the air; indirect contact transmission via hand transfer of influenza virus from virus-contaminated surfaces or objects to mucosal surfaces of the face (e.g., nose, mouth) may also occur; airborne transmission via small particle aerosols in the vicinity of the infectious individual may also occur; however, the relative contribution of the different modes of influenza transmission is unclear; airborne transmission over longer distances, such as from one patient room to another has not been documented and is thought not to occur; all respiratory secretions and bodily fluids, including diarrheal stools, of patients with influenza are considered to be potentially infectious; however, the risk may vary by strain.

- Preventing transmission of influenza virus and other infectious agents within health care settings requires a multi-faceted approach; the transmission of influenza virus can occur among health care professionals, patients, and visitors; in addition, health care professionals may acquire influenza from persons in their household or community.
- Annual vaccination is the most important measure to prevent seasonal influenza infection (note: vaccination may refer to the act of introducing a vaccine into the body to produce immunity to a specific disease; immunity may refer to protection from an infectious disease; if an individual is immune to a specific disease, he or she may be exposed to the disease without becoming infected). Achieving high influenza vaccination rates of health care professionals and patients is a critical step in preventing health care transmission of influenza from health care professionals to patients and from patients to health care professionals. According to current national guidelines, unless contraindicated, vaccinate all people aged six months and older, including health care professionals and residents of long-term care facilities.
- Vaccines work (i.e., provide protection against infectious agents) by introducing an infectious agent into the human body via injection, oral administration, or nasal administration; the term infectious agent may refer to an organism that is capable of producing an infection or infectious disease; infectious agents include: bacteria, fungi, viruses, and parasites; once an infectious agent, such as a virus, is introduced into the human body, via a vaccine, the human body's immune system responds, and, ultimately, builds protection against the infectious agent and related infection. In other words, vaccines work by giving the human body's immune system the tools and ability necessary to prevent infection from infectious agents, such as a virus.

- Systematic strategies employed by health care organizations to improve health care professional vaccination rates include the following: providing incentives, providing vaccines at no cost to health care professionals, improving access (e.g., offering vaccination at work and during work hours), requiring personnel to sign declination forms to acknowledge that they were educated about the benefits and risks of vaccination, and mandating influenza vaccination for all health care professionals without contraindication. Many of these approaches were shown to increase vaccination rates; tracking influenza vaccination coverage among health care professionals can be an important component of a systematic approach to protecting patients and health care professionals.
- Vaccination should be offered in September or October; however, vaccination should continue throughout the season as long as influenza viruses are circulating.
- Vaccination during July and August is not recommended for most older adults over the age of 65 (note: the term older adult may refer to an individual 65 years or older).
- Individuals in isolation for COVID-19 or in quarantine for known or suspected exposures should not be vaccinated if vaccination will pose an exposure risk to others in the vaccination setting.
- For individuals who are moderately or severely ill with COVID-19, vaccination should be deferred until they recover.
- For individuals who are mildly ill or asymptomatic, deferral might be considered to avoid confusing COVID-19 illness symptoms with post vaccination reactions.

- The Vaccine Adverse Event Reporting System (VAERS) is the national vaccine safety monitoring system co-managed by the CDC and the FDA, which serves as an early warning system to detect possible safety problems with U.S. vaccines; health care professionals should report to VAERS any adverse event listed by the vaccine manufacturer as a contraindication to further doses of vaccine and adverse events.
- Health care organizations may consider offering various influenza vaccines to patients. Health care professionals should be familiar with the various influenza vaccines. Specific information regarding influenza vaccines may be found below.

Afluria Quadrivalent Influenza Vaccine

Vaccine notes - Afluria Quadrivalent is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Afluria Quadrivalent is approved for use in individuals six months of age and older. The recommended dose for Afluria Quadrivalent is 0.5 mL. Individuals nine years and older should receive one dose. Afluria Quadrivalent is a suspension for injection supplied in the following three presentations: 0.25 mL pre-filled syringe (single dose); 0.5 mL pre-filled syringe (single dose); 5 mL multi-dose vial (0.25 mL or 0.5 mL). Health care professionals should store Afluria Quadrivalent refrigerated at 2 - 8°C (36 - 46°F) (note: do not freeze). The most common adverse reactions associated with Afluria Quadrivalent include: injection-site pain, myalgia, and headache.

Safety notes - contraindications associated with Afluria Quadrivalent include the following: severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine. Warnings and precautions associated with Afluria Quadrivalent

include the following: appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Considerations for special patient populations - observe older adults after administration.

Fluad (Influenza Vaccine, Adjuvanted)

Vaccine notes - Fluad is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. Fluad is approved for use in persons 65 years of age and older. Fluad should be administered as a single 0.5 mL dose via intramuscular injection. Fluad is an injectable emulsion supplied in 0.5 mL single-dose, pre-filled syringes. Fluad should be refrigerated at 2°C to 8°C (36°F to 46°F) (note: protect from light; do not freeze). The most common adverse reactions associated with Fluad include: injection-site pain, fatigue, myalgia, and headache.

Safety notes - contraindications associated with Fluad include the following: severe allergic reaction to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine. Warnings and precautions associated with Fluad include the following: if Guillain-Barré Syndrome (GBS) occurred within six weeks of previous influenza vaccination, the decision to give Fluad should be based on careful consideration of the potential benefits and risks.

Considerations for special patient populations - Fluad is not approved for use in persons < 65 years of age.

FluMist Quadrivalent (Influenza Vaccine Live, Intranasal)

Vaccine notes - FluMist is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluMist Quadrivalent is approved for use in persons two through 49 years of age. FluMist is for intranasal administration. The recommended dose of FluMist is 0.2 mL. Individuals two years through eight years of age may receive one or two doses separated by one month. Individuals nine years through 49 years of age should receive one dose. Each FluMist 0.2mL dose is a suspension supplied in a single-dose, pre-filled intranasal sprayer. Health care professionals should store FluMist refrigerated at 2 - 8°C (36 - 46°F) (note: do not freeze). The most common adverse reactions associated with FluMist include runny nose and nasal congestion.

Safety notes - contraindications associated with FluMist include the following: severe allergic reaction (e.g., anaphylaxis) to any component of FluMist Quadrivalent, including egg protein, or after a previous dose of any influenza vaccine; concomitant aspirin therapy in children and adolescents. Warnings and precautions associated with FluMist include the following: if Guillain-Barré syndrome occurred within six weeks of any prior influenza vaccination, the decision to give FluMist Quadrivalent should be based on careful consideration of the potential benefits and risks.

Considerations for special patient populations - FluMist Quadrivalent is not approved for use in persons 65 years of age and older.

- Health care organizations should effectively store vaccines. Effective vaccine storage occurs when vaccines are adequately stored and maintained in a manner which maintains their potency and ability to provide protection against infections and/or diseases. It is the responsibility of all health care professionals, who handle vaccines or administer vaccines, to ensure

effective vaccine storage. Vaccines should continue to be stored at recommended temperatures immediately upon receipt and until use; vaccines licensed for refrigerator storage should be stored at 2°C - 8°C (36°F - 46°F). Damage to a vaccine exposed to temperatures outside of the recommended range might not be apparent visually; vaccines that were stored at inappropriate temperatures should not be administered unless public health authorities or the manufacturer determines it is safe and effective; vaccines exposed to inappropriate temperatures that are inadvertently administered to patients should generally be repeated; inactivated vaccines should generally be repeated as soon as possible; live vaccines should be repeated after a 28-day interval from the invalid dose to reduce the risk for interference from interferon on the subsequent dose.

- Health care professionals may use any influenza vaccine appropriate for age and health status annually. If a patient has an egg allergy, with symptoms limited to hives only, health care professionals may use any influenza vaccine appropriate for age and health status annually; if a patient has an egg allergy, with symptoms other than hives (e.g., angioedema; respiratory distress), health care professionals should administer vaccine in a medical setting under supervision of health care professionals who can recognize and manage severe allergic reactions.
- After a vaccine is administered to a patient, health care professionals should monitor the patient for vaccine related adverse reactions. When monitoring a patient for vaccine related adverse reactions, health care professionals should pay particular attention to the signs and symptoms of an allergic reaction (e.g., local or generalized hives or angioedema; hypotension; and shock). Health care professionals should also pay particular attention to the more specific signs and symptoms of anaphylaxis, which include the following: sensation of throat closing or tightness; stridor (i.e., high-pitched

sound while breathing); hoarseness; respiratory distress (e.g., shortness of breath or wheezing); coughing; trouble swallowing/drooling; nasal congestion; rhinorrhea; sneezing; nausea; vomiting; diarrhea; abdominal pain; cramps; dizziness; fainting; tachycardia (i.e., abnormally fast heart rate); hypotension (i.e., abnormally low blood pressure); weak pulse, cyanosis (i.e., bluish discoloration); pallor; flushing; generalized hives; widespread redness; itching; conjunctivitis; swelling of the eyes, lips, tongue, mouth, face, or extremities; agitation; convulsions; acute change in mental status; sense of impending doom (i.e., a feeling that something bad is about to happen); sudden increase in secretions (from eyes, nose, or mouth); urinary incontinence. Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system [e.g., hypotension respiratory distress, or significant swelling of the tongue or lips]). Symptoms of anaphylaxis often occur within 15 - 30 minutes of vaccination; however, it may take several hours for symptoms to appear; early signs of anaphylaxis can resemble a mild allergic reaction; symptoms of anaphylaxis might be more difficult to recognize in people with communication difficulties, such as long-term care facility residents with cognitive impairment, those with neurologic disease, or those taking medications that can cause sedation. When monitoring patients for vaccine related adverse reactions (e.g., an allergic reaction), health care professionals should keep the following emergency equipment and medications in close proximity: epinephrine (e.g., prefilled syringe, autoinjector), H1 antihistamine (e.g., diphenhydramine, cetirizine), blood pressure monitor, timing device to assess pulse, pulse oximeter, oxygen, bronchodilator (e.g., albuterol), H2 antihistamine (e.g., famotidine, cimetidine), intravenous fluids, intubation

kit, and adult-sized pocket mask with one-way valve (i.e., cardiopulmonary resuscitation [CPR] mask).

- If a patient has an acute allergic reaction to a vaccine (e.g., anaphylaxis), health care professionals should immediately work to treat and manage such a reaction. Immediate-immunoglobulin E (IgE)-mediated (type 1) immune reactions (e.g., anaphylaxis) usually occur within minutes of vaccine administration. Immediate acute allergic reaction recognition and initiation of treatment are required to prevent possible progression to respiratory failure or cardiovascular collapse. For respiratory or cardiovascular symptoms, or other signs or symptoms of anaphylaxis, immediate intramuscular epinephrine is the treatment of choice; antihistamines (e.g., diphenhydramine; cetirizine) may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis; caution should be used if oral medications are administered to people with impending airway obstruction; if hypotension is present, the patient should be placed in a recumbent position with the legs elevated; maintenance of the airway, oxygen administration, and intravenous normal saline might be necessary; after the patient is stabilized, health care professionals should make arrangements for immediate transfer to an emergency health care facility for additional evaluation and treatment, when applicable; anaphylaxis may recur after patients begin to recover, monitoring in a health care facility for several hours is advised, even after complete resolution of signs and symptoms.
- Health care organizations should take steps to minimize potential exposures. A range of administrative policies and practices can be used to minimize influenza exposures before arrival, upon arrival, and throughout the duration of the stay within a health care facility. Measures include screening and triage of symptomatic patients and implementation of

respiratory hygiene and cough etiquette. Respiratory hygiene and cough etiquette are measures designed to minimize potential exposures of all respiratory pathogens, including influenza virus, in health care settings and should be adhered to by everyone including: health care professionals, patients, and visitors.

- During periods of increased influenza activity, health care organizations should take steps to minimize visits by individuals with suspected or confirmed influenza.
- Upon entry and during a visit to a health care facility, health care organizations should take steps to ensure all individuals with symptoms of a respiratory infection adhere to respiratory hygiene, cough etiquette, and hand hygiene procedures throughout the duration of the visit. Such steps may include posting visual alerts (e.g., signs, posters) at the entrance and in strategic places (e.g., waiting areas, elevators, cafeterias) to provide health care professionals and patients with instructions (in appropriate languages) about respiratory hygiene and cough etiquette, especially during periods when influenza virus is circulating in the community; providing supplies to perform hand hygiene to all individuals upon arrival to a health care facility (e.g., at entrances of facility, waiting rooms, at patient check-in) and throughout the entire duration of the visit to the health care setting; providing facemasks to patients with signs and symptoms of respiratory infection (note: hand hygiene may refer to the process of cleaning hands in order to prevent contamination and/or infections); provide space and encourage individuals with symptoms of respiratory infections to sit as far away from others as possible.
- Health care professionals and other staff with potential respiratory infections should be instructed to not to report to work, or if at work, to

stop patient-care activities, don a facemask, and promptly notify their supervisor and infection control personnel/occupational health before leaving work; reminded that adherence to respiratory hygiene and cough etiquette after returning to work is always important (note: if symptoms such as cough and sneezing are still present, health care professionals should wear a facemask during patient-care activities; the importance of performing frequent hand hygiene [especially before and after each patient contact and contact with respiratory secretions] should be reinforced; excluded from work until at least 24 hours after they no longer have a fever (without the use of fever-reducing medicines such as acetaminophen) (note: those with ongoing respiratory symptoms should be considered for evaluation by occupational health to determine appropriateness of contact with patients); considered for temporary reassignment or exclusion from work for seven days from symptom onset or until the resolution of symptoms, whichever is longer, if returning to care for patients in a protective environment.

- Health care professionals with influenza or many other infections may not have fever or may have fever alone as an initial symptom or sign. Therefore, it can be difficult to distinguish influenza from many other causes, especially early in a person's illness; health care professionals with fever alone should follow workplace policy for health care professionals with fever until a more specific cause of fever is identified or until fever resolves.
- Health care professionals who develop acute respiratory symptoms without fever may still have influenza infection and should be: considered for evaluation by occupational health to determine appropriateness of contact with patients (note: health care professionals suspected of having influenza may benefit from influenza antiviral treatment); reminded that adherence to respiratory hygiene and cough etiquette after returning to work is always

important (note: if symptoms such as cough and sneezing are still present, health care professionals should wear a facemask during patient care activities; the importance of performing frequent hand hygiene [especially before and after each patient contact] should be reinforced).

- Health care organizations should develop sick leave policies for health care professionals that are non-punitive, flexible, and consistent with public health guidance to allow and encourage health care professionals with suspected or confirmed influenza to avoid coming to work. Such policies and procedures should include the exclusion of health care professionals who develop a fever and respiratory symptoms from work for at least 24 hours after they no longer have a fever, without the use of fever-reducing medicines (note: all employees who are not directly employed by the health care facility but provide essential daily services, should be aware of the sick leave policies).
- Employee health services should establish procedures for tracking absences; reviewing job tasks and ensuring that personnel known to be at higher risk for exposure to those with suspected or confirmed influenza are given priority for vaccination; ensuring that employees have prompt access, including via telephone to medical consultation and, if necessary, early treatment; and promptly identifying individuals with possible influenza.
- Health care professionals should self-assess for symptoms of febrile respiratory illness; in most cases, decisions about work restrictions and assignments for personnel with respiratory illness should be guided by clinical signs and symptoms rather than by laboratory testing for influenza because laboratory testing may result in delays in diagnosis, false negative test results, or both.

- During the care of any patient, all health care professionals in every health care setting should adhere to standard precautions, which are the foundation for preventing transmission of infectious agents in all health care settings (note: standard precautions assume that every individual is potentially infected or colonized with a pathogen that could be transmitted in the health care facility). Elements of standard precautions that apply to patients with respiratory infections, including those caused by the influenza virus, may be found below.

- **Hand hygiene** - health care professionals should perform hand hygiene frequently, including before and after all patient contact, contact with potentially infectious material, and before putting on and upon the removal of personal protective equipment (PPE), including gloves. Hand hygiene in health care settings can be performed by washing with soap and water or using alcohol-based hand rubs (note: health care professionals should use soap and water, not alcohol-based hand rubs, if hands are visibly soiled; health care facilities should ensure that supplies for performing hand hygiene are available).
- **Personal protective equipment (PPE)** - personal protective equipment (PPE) may refer to equipment designed to protect, shield, and minimize exposure to hazards that may cause serious injury, illness, and/or disease (e.g., masks, gloves, gowns). Health care professionals should wear facemasks, when applicable. Health care professionals should wear gloves for any contact with potentially infectious material (note: remove gloves after contact, followed by hand hygiene; do not wear the same pair of gloves for the care of more than one patient; do not wash gloves for the purpose of reuse). Health care professionals should wear gowns for any patient-care

activity when contact with blood, body fluids, secretions (including respiratory), or excretions is anticipated (note: remove gown and perform hand hygiene before leaving the patient's environment; do not wear the same gown for the care of more than one patient).

- Droplet precautions should be implemented for patients with suspected or confirmed influenza for seven days after illness onset or until 24 hours after the resolution of fever and respiratory symptoms, whichever is longer, while a patient is in a health care facility; in some cases, health care facilities may choose to apply droplet precautions for longer periods based on clinical judgment.
- Place patients with suspected or confirmed influenza in a private room or area. When a single patient room is not available, consultation with infection control personnel is recommended to assess the risks associated with other patient placement options.
- Health care professionals should don a facemask when entering the room of a patient with suspected or confirmed influenza; remove the facemask when leaving the patient's room, dispose of the facemask in a waste container, and perform hand hygiene.
- If health care facilities and organizations opt to provide employees with alternative personal protective equipment, this equipment should provide the same protection of the nose and mouth from splashes and sprays provided by facemasks (e.g., face shields and N95 respirators or powered air purifying respirators).
- If a patient under droplet precautions requires movement or transport outside of the room: the patient should wear a facemask, if possible, and follow respiratory hygiene and cough etiquette and hand hygiene;

communicate information about patients with suspected, probable, or confirmed influenza to appropriate personnel before transferring them to other departments in the health care facility or to other facilities.

- Patients under droplet precautions should be discharged from medical care when clinically appropriate, not based on the period of potential virus shedding or recommended duration of droplet precautions; before discharge, communicate the patient's diagnosis and current precautions with post-care providers (e.g., long-term care facilities) as well as transporting personnel.
- Use caution when performing aerosol-generating procedures. Some procedures performed on patients with suspected or confirmed influenza infection may be more likely to generate higher concentrations of infectious respiratory aerosols than coughing, sneezing, talking, or breathing. These procedures potentially put health care professionals at an increased risk for influenza exposure. Although there is limited data available on influenza transmission related to such aerosols, many authorities recommend that additional precautions be used when such procedures are performed. These include some procedures that are usually planned ahead of time, such as bronchoscopy, sputum induction, elective intubation and extubation, and autopsies; and some procedures that often occur in unplanned, emergent settings and can be life-saving, such as cardiopulmonary resuscitation, emergent intubation and open suctioning of airways; a combination of measures should be used to reduce exposures from these aerosol-generating procedures when performed on patients with suspected or confirmed influenza. However, it is appropriate to take feasibility into account, especially in challenging emergent situations, where timeliness in performing a procedure can be critical to achieving a positive patient outcome.

- Precautions for aerosol-generating procedures include: only performing procedures on patients with suspected or confirmed influenza if they are medically necessary and cannot be postponed; limiting the number of health care professionals present during the procedure to only those essential for patient care and support; health care professionals should adhere to standard precautions, including wearing gloves, a gown, and either a face shield that fully covers the front and sides of the face or goggles; health care professionals should wear respiratory protection equivalent to a fitted N95 filtering facepiece respirator or equivalent N95 respirator (e.g., powered air purifying respirator, elastomeric) during aerosol-generating procedures) (note: when respiratory protection is required in an occupational setting, respirators must be used in the context of a comprehensive respiratory protection program that includes fit-testing and training); unprotected health care professionals should not be allowed in a room where an aerosol-generating procedure was conducted until sufficient time has elapsed to remove potentially infectious particles; conduct environmental surface cleaning following procedures.
- Manage visitor access and movement within the health care facility.
- Limit visitors for patients in isolation for influenza to individuals who are necessary for the patient's emotional well-being and care; visitors who were in contact with the patient are a possible source of influenza for other health care professionals, patients, and visitors.
- For persons with acute respiratory symptoms, health care facilities should develop visitor restriction policies that consider location of the patient being visited and circumstances, such as end-of-life situations, where exemptions to the restriction may be considered at the discretion of the

facility; all visitors should follow respiratory hygiene and cough etiquette precautions.

- Visits to patients in isolation for influenza should be scheduled and controlled to allow for: screening visitors for symptoms of acute respiratory illness before entering the health care facility; facilities should provide instruction, before visitors enter patients' rooms, on hand hygiene, limiting surfaces touched, and the use of PPE according to current facility policy while in the patient's room; visitors should not be present during aerosol-generating procedures; visitors should be instructed to limit their movement within the facility; if consistent with facility policy, visitors can be advised to contact their health care professional for information about influenza vaccination.
- Monitor influenza activity. Health care facilities should establish mechanisms and policies by which health care professionals are promptly alerted about increased influenza activity in the community or if an outbreak occurs within the facility and when collection of clinical specimens for viral culture may help to inform public health efforts; close communication and collaboration with local and state health authorities is recommended; policies should include designations of specific persons within the health care facility who are responsible for communication with public health officials and dissemination of information to health care professionals.
- Implement environmental infection control. Standard cleaning and disinfection procedures (e.g., using cleaners and water to preclean surfaces prior to applying disinfectants to frequently touched surfaces or objects for indicated contact times) are adequate for influenza virus environmental control in all settings within the health care facility, including those patient-

care areas in which aerosol-generating procedures are performed; management of laundry, food service utensils, and medical waste should also be performed in accordance with standard procedures; laundry and food service utensils should first be cleaned, then sanitized as appropriate; some medical waste may be designated as regulated or biohazardous waste and require special handling and disposal methods approved by the State authorities.

- Implement engineering controls. Consider designing and installing engineering controls to reduce or eliminate exposures by shielding health care professionals and other patients from infected individuals (e.g., installing physical barriers such as partitions in triage areas or curtains that are drawn between patients in shared areas). Engineering controls may also be important to reduce exposures related to specific procedures such as using closed suctioning systems for airways suction in intubated patients; another important engineering control is ensuring that appropriate air-handling systems are installed and maintained in health care facilities.
- Health care administrators should ensure that all health care professionals receive job- or task-specific education and training on preventing transmission of infectious agents, including influenza, associated with health care during orientation to the health care facility. The information should be updated periodically during ongoing education and training programs. Competency should be documented initially and repeatedly, as appropriate, for the specific staff positions. A system should be in place to ensure that health care professionals employed by outside employers meet education and training requirements through programs offered by the outside employer or by participation in the health care facility's program.

- Key aspects of influenza and its prevention that should be emphasized to all health care professionals.
- Health care professionals should be made aware that, if they have conditions that place them at higher risk of complications, they should inform their health care provider immediately if they become ill with an influenza-like illness so they can receive early treatment if indicated.
- Health care professionals at high risk for complications from influenza infection include: persons 65 years old and older, persons with chronic diseases such as asthma, heart disease, diabetes, diseases that suppress the immune system, certain other chronic medical conditions, and morbid obesity. Vaccination and early treatment with antiviral medications are very important for health care professionals at higher risk for influenza complications because they can decrease the risk of hospitalizations and deaths; health care professionals at higher risk for complications should check with their health care provider if they become ill so that they can receive early treatment.
- Some health care professionals may identify themselves as being at higher risk of complications, and express concerns about their risks; such concerns should be discussed and the importance of careful adherence to relevant guidelines should be emphasized; work accommodations to avoid potentially high-risk exposure scenarios, such as performing or assisting with aerosol-generating procedures on patients with suspected or confirmed influenza, may be considered in some settings, particularly for health care professionals with more severe or unstable underlying disease.
- Administer antiviral treatment and chemoprophylaxis, when applicable (note: both health care professionals and patients should be reminded that persons treated with influenza antiviral medications continue to shed

influenza virus while on treatment; thus, hand hygiene, respiratory hygiene and cough etiquette practices should continue while on treatment).

COVID-19 Prevention and Control

Additionally, health care organizations should work to prevent COVID-19. Specific information and recommendations regarding COVID-19 prevention may be found below. The information found below was derived from materials provided by the CDC (CDC, 2022; CDC 2023).

- Encourage everyone to remain up to date with all recommended COVID-19 vaccine doses.
- Health care professionals, patients, and visitors should be offered resources and counseled about the importance of receiving a COVID-19 vaccine.
- Establish a process to identify and manage individuals with suspected or confirmed SARS-CoV-2 infection.
- Ensure everyone is aware of recommended infection prevention and control practices in the health care facility.
- Post visual alerts (e.g., signs, posters) at the entrance and in strategic places (e.g., waiting areas, elevators, cafeterias). These alerts should include instructions about current infection prevention and control recommendations (e.g., when to use source control and perform hand hygiene) (note: dating visual alerts can help ensure people know that they reflect current recommendations; the term source control may refer to the use of respirators or well-fitting facemasks or cloth masks to cover an individual's mouth and nose to prevent spread of respiratory secretions when he or she is breathing, talking, sneezing, or coughing).

- Establish a process to make everyone entering the facility aware of recommended actions to prevent transmission to others if they have any of the following three criteria: a positive viral test for SARS-CoV-2; symptoms of COVID-19; close contact with someone with SARS-CoV-2 infection (for patients and visitors).
- Visitors with confirmed SARS-CoV-2 infection or compatible symptoms should defer non-urgent in-person visitation until they meet the health care criteria to end isolation; this time period is longer than what is recommended in the community; for visitors who had close contact with someone with SARS-CoV-2 infection or were in other situations that put them at higher risk for transmission, it is safest to defer non-urgent in-person visitation until 10 days after their close contact.
- Source control is recommended for individuals in health care settings who: have suspected or confirmed SARS-CoV-2 infection or other respiratory infection (e.g., those with runny nose, cough, sneeze); or had close contact or a higher-risk exposure with someone with SARS-CoV-2 infection, for 10 days after their exposure.
- As SARS-CoV-2 transmission in the community increases, the potential for encountering asymptomatic or pre-symptomatic patients with SARS-CoV-2 infection also likely increases. Therefore, health care facilities should consider implementing broader use of respirators and eye protection by health care professionals during patient care encounters.
- Optimize the use of engineering controls to reduce or eliminate exposures by shielding health care professionals and patients from infected individuals (e.g., physical barriers at reception/triage locations and dedicated pathways to guide symptomatic patients through waiting rooms and triage areas).

- Take measures to limit crowding in communal spaces.
- Explore options, in consultation with health care facility engineers, to improve ventilation delivery and indoor air quality in patient rooms and all shared spaces.
- Anyone with even mild symptoms of COVID-19, regardless of vaccination status, should receive a viral test for SARS-CoV-2 as soon as possible.
- Asymptomatic patients with close contact with someone with SARS-CoV-2 infection should have a series of three viral tests for SARS-CoV-2 infection. Testing is recommended immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be on day one (where day of exposure is day 0), day three, and day five.
- Due to challenges in interpreting the result, testing is generally not recommended for asymptomatic people who recovered from SARS-CoV-2 infection in the prior 30 days. Testing should be considered for those who recovered in the prior 31 - 90 days; however, an antigen test instead of a nucleic acid amplification test (NAAT) is recommended because some people may remain NAAT positive but not be infectious during this period.
- The yield of screening testing for identifying asymptomatic infection is likely lower when performed on those in areas with lower levels of SARS-CoV-2 community transmission. However, these results might continue to be useful in some situations (e.g., when performing higher-risk procedures or for health care professionals caring for patients who are moderately to severely immunocompromised) to inform the type of infection control precautions used (e.g., room assignment/cohorting, or PPE used) and

prevent unprotected exposures. If implementing a screening testing program, testing decisions should not be based on the vaccination status of the individual being screened; to provide the greatest assurance that someone does not have SARS-CoV-2 infection, if using an antigen test instead of a NAAT, health care facilities should use three tests, spaced 48 hours apart.

- Performance of pre-procedure or pre-admission testing is at the discretion of the health care facility.
- Performance of expanded screening testing of asymptomatic health care professionals without known exposures is at the discretion of the health care facility.
- Health care facilities should have a plan for how SARS-CoV-2 exposures in a health care facility will be investigated and managed and how contact tracing will be performed.
- If health care-associated transmission is suspected or identified, health care facilities may consider expanded testing of health care professionals and patients as determined by the distribution and number of cases throughout the facility and ability to identify close contacts. For example, in an outpatient dialysis facility with an open treatment area, testing should ideally include all patients and health care professionals. Depending on testing resources available or the likelihood of health care-associated transmission, facilities may elect to initially expand testing only to health care professionals and patients on the affected units or departments, or a particular treatment schedule or shift, as opposed to the entire facility. If an expanded testing approach is taken and testing identifies additional infections, testing should be expanded more broadly. If possible, testing

should be repeated every 3 - 7 days until no new cases are identified for at least 14 days.

- Health care facilities responding to SARS-CoV-2 transmission within the health care facility should always notify and follow the recommendations of public health authorities.
- The decision to discontinue empiric Transmission-Based Precautions by excluding the diagnosis of current SARS-CoV-2 infection for a patient with symptoms of COVID-19 can be made based upon having negative results from at least one viral test.
- In general, asymptomatic patients do not require empiric use of Transmission-Based Precautions while being evaluated for SARS-CoV-2 following close contact with someone with SARS-CoV-2 infection. These patients should still wear source control and those who have not recovered from SARS-CoV-2 infection in the prior 30 days should be tested.
- Patients can be removed from Transmission-Based Precautions after day seven following the exposure (count the day of exposure as day zero) if they do not develop symptoms and all viral testing as described for asymptomatic individuals following close contact is negative.
- If viral testing is not performed, patients can be removed from Transmission-Based Precautions after day 10 following the exposure (count the day of exposure as day zero) if they do not develop symptoms.
- Place a patient with suspected or confirmed SARS-CoV-2 infection in a single-person room; the door should be kept closed (if safe to do so); ideally, the patient should have a dedicated bathroom.

- If cohorting, only patients with the same respiratory pathogen should be housed in the same room.
- Health care facilities may consider designating entire units within the facility, with dedicated health care professionals, to care for patients with SARS-CoV-2 infection when the number of patients with SARS-CoV-2 infection is high; dedicated means that health care professionals are assigned to care only for these patients during their shifts).
- Communicate information about patients with suspected or confirmed SARS-CoV-2 infection to appropriate personnel before transferring them to other departments in the facility and to other health care facilities.
- Health care professionals who enter the room of a patient with suspected or confirmed SARS-CoV-2 infection should adhere to Standard Precautions and use a NIOSH approved particulate respirator with N95 filters or higher, gown, gloves, and eye protection (i.e., goggles or a face shield that covers the front and sides of the face).
- Respirators should be used in the context of a comprehensive respiratory protection program, which includes medical evaluations, fit testing and training in accordance with the Occupational Safety and Health Administration's (OSHA) Respiratory Protection standard.
- Procedures that could generate infectious aerosols should be performed cautiously and avoided if appropriate alternatives exist.
- For the safety of the visitor, in general, patients should be encouraged to limit in-person visitation while they are infectious; however, health care facilities should adhere to local, territorial, tribal, state, and federal regulations related to visitation.

- Counsel patients and their visitor(s) about the risks of an in-person visit.
- Encourage the use of alternative mechanisms for patient and visitor interactions such as video-call applications on cell phones or tablets, when appropriate.
- Health care facilities should provide instruction, before visitors enter the patient's room, on hand hygiene, limiting surfaces touched, and the use of PPE according to current facility policy.
- Visitors should be instructed to only visit the patient room; they should minimize their time spent in other locations in the health care facility.
- Dedicated medical equipment should be used when caring for a patient with suspected or confirmed SARS-CoV-2 infection; all non-dedicated, non-disposable medical equipment used for that patient should be cleaned and disinfected according to manufacturer's instructions and facility policies before use on another patient.
- Routine cleaning and disinfection procedures (e.g., using cleaners and water to pre-clean surfaces prior to applying an EPA-registered, hospital-grade disinfectant to frequently touched surfaces or objects for appropriate contact times as indicated on the product's label) are appropriate for SARS-CoV-2 in health care settings, including patient-care areas.
- Management of laundry, food service utensils, and medical waste should be performed in accordance with routine procedures.
- Assign one or more individual with training in infection prevention and control to provide on-site management of the infection prevention and control program; this should be a full-time role for at least one person in facilities that have more than 100 residents or that provide on-site

ventilator or hemodialysis services; smaller facilities should consider staffing the infection prevention and control program based on the resident population and facility service needs.

- Admission testing is at the discretion of the health care facility; residents who leave the facility for 24 hours or longer should generally be managed as an admission.
- Empiric use of Transmission-Based Precautions is generally not necessary for admissions or for residents who leave the facility for less than 24 hours (e.g., for medical appointments, community outings).
- When performing an outbreak response to a known case, health care facilities should defer to the recommendations of the jurisdiction's public health authority.
- A single new case of SARS-CoV-2 infection in any health care professional or resident should be evaluated to determine if others in the facility were exposed.
- The approach to an outbreak investigation could involve either contact tracing or a broad-based approach; however, a broad-based (e.g., unit, floor, or other specific area(s) of the facility) approach is preferred if all potential contacts cannot be identified or managed with contact tracing or if contact tracing fails to halt transmission.
- Perform testing for all residents and health care professionals identified as close contacts or on the affected unit(s) if using a broad-based approach, regardless of vaccination status.
- In the event of ongoing transmission within a health care facility that is not controlled with initial interventions, strong consideration should be given to

use of Empiric use of Transmission-Based Precautions for residents and work restriction of health care professionals with higher-risk exposures; in addition, there might be other circumstances for which the jurisdiction's public authority recommends these and additional precautions.

- If additional cases are not identified during contact tracing or the broad-based testing, further testing is not indicated; empiric use of Transmission-Based Precautions for residents and work restriction for health care professionals who met criteria can be discontinued.
- If additional cases are identified, strong consideration should be given to shifting to the broad-based approach if not already being performed and implementing quarantine for residents in affected areas of the facility. As part of the broad-based approach, testing should continue on affected unit(s) or facility-wide every three to seven days until there are no new cases for 14 days.
- Evidence suggests that during the COVID-19 pandemic one of the strongest indicators of increasing cases in nursing homes was increasing community incidence. If a jurisdiction still has access to SARS-CoV-2-community incidence, using these data to guide local recommendations at the levels previously described (community incidence \geq 100/100,000) should be considered.
- Maintaining appropriate staffing in health care facilities is essential to providing a safe work environment for health care professionals and safe patient care; if community transmission levels rise, staffing shortages could occur due to health care professionals illness or the need to care for family members at home; health care facilities must be prepared for potential staffing shortages and have plans and processes in place to mitigate these shortages; such plans and processes should include communicating with

health care professionals about actions the facility is taking to address shortages, maintaining patient and health care professionals safety, and providing resources to assist health care professionals with anxiety and stress.

- Health care organizations should understand their normal staffing needs and the minimum number of staff needed to provide a safe work environment and safe patient care under normal circumstances; health care organizations should also understand the local epidemiology of COVID-19-related indicators (e.g., community transmission levels).
- Communicate with local health care coalitions and federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) to identify additional health care professionals (e.g., hiring additional health care professionals, recruiting retired health care professionals, using students or volunteers), when needed.
- When staffing shortages are anticipated, health care facilities and employers, in collaboration with human resources and occupational health services, should use contingency capacity strategies to plan and prepare for mitigating this problem.
- When required, adjust staff schedules, hiring additional health care professionals, and rotating health care professionals to positions that support patient care activities.
- Cancel all non-essential procedures and visits; shift health care professionals who work in these areas to support other patient care activities in the health care facility; facilities will need to ensure these health care professionals have received appropriate orientation and training to work in the areas that are new to them.

- Attempt to address social factors that might prevent health care professionals from reporting to work, such as need for transportation or housing that allows for physical distancing, particularly if health care professionals live with individuals with underlying medical conditions or older adults.
- Consider that social factors disproportionately affect persons from some racial and ethnic groups, who are also disproportionately affected by COVID-19 (e.g., African Americans, Hispanics, Latinos, American Indians, and Alaska Natives).
- Identify additional health care professionals to work in the facility; be aware of state-specific emergency waivers or changes to licensure requirements or renewals for select categories of health care professionals.
- As appropriate, request that health care professionals postpone elective time off from work; however, there should be consideration for the mental health benefits of time off and that care-taking responsibilities may differ substantially among staff.
- Allow health care professionals with SARS-CoV-2 infection who are well enough and willing to work to return to work as follows: at least five days passed since symptoms first appeared (day zero), and; at least 24 hours passed since the last fever without the use of fever-reducing medications, and symptoms (e.g., cough, shortness of breath) improved.
- Health care facilities may choose to confirm resolution of infection with a negative nucleic acid amplification test (NAAT) or a series of two negative antigen tests taken 48 hours apart.

- Some individuals may be beyond the period of expected infectiousness but remain NAAT positive for an extended period; antigen tests typically have a more rapid turnaround time but are often less sensitive than NAAT; antigen testing is preferred if testing asymptomatic health care professionals who recovered from SARS-CoV-2 infection in the prior 90 days.
- Considerations for determining which health care professionals should be prioritized to return to work include: the type of health care professional shortages that need to be addressed; the types of symptoms they are experiencing (e.g., persistent fever, cough); their degree of interaction with patients and other health care professionals in the facility (e.g., are they working in telemedicine services, providing direct patient care, or working in a satellite unit reprocessing medical equipment); the type of patients they care for (e.g., consider patient care only with patients known or suspected to have SARS-CoV-2 infection rather than patients who are immunocompromised).
- Health care professionals that return to work should self-monitor for symptoms and seek reevaluation from occupational health if symptoms reoccur or worsen.
- When staffing shortages occur, health care facilities and employers (in collaboration with human resources and occupational health services) may need to implement crisis capacity strategies to continue to provide patient care.
- Health care organizations should implement regional plans to transfer patients with COVID-19 to designated health care facilities, or alternate care sites with adequate staffing.

- If shortages continue despite other mitigation strategies, as a last resort consider allowing health care professionals to work even if they have suspected or confirmed SARS-CoV-2 infection, if they are well enough and willing to work, even if they do not meet all the contingency return to work criteria.
- If health care professionals are requested to work before meeting all criteria, they should be restricted from contact with patients who are moderately to severely immunocompromised (e.g., transplant patients, hematology-oncology patients) and health care facilities should consider prioritizing their duties.
- When required, health care organizations should allow health care professionals with suspected or confirmed SARS-CoV-2 infection to perform job duties where they do not interact with others, such as in telemedicine services.
- Health care organizations should only allow health care professionals with confirmed SARS-CoV-2 infection to provide direct care only for patients with confirmed SARS-CoV-2 infection, preferably in a cohort setting.

Containment of Novel or Targeted Multidrug-Resistant Organisms (MDROs)

Finally, health care organizations should work to prevent infections from novel or targeted multidrug-resistant organisms (MDROs). Specific information and recommendations regarding MDRO infection prevention may be found below. The information found below was derived from materials provided by the CDC (CDC, 2023).

Tier 1 Organisms

- The Tier 1 category includes organisms or resistance mechanisms that have never (or very rarely) been identified in the U. S. and for which experience in the U. S. is extremely limited. The objective of Tier 1 organism investigations is to identify all cases and prevent further transmission. Examples of Tier 1 organisms and mechanisms include the initial identifications of *Candida auris* and *mcr-1-carrying* Enterobacterales in the U.S.
- Upon identification of the organism or mechanism in a laboratory, the laboratory or health care facility should promptly notify the patient's primary health care provider, health care professionals caring for the resident, infection control department, and other health care staff per facility policies. Health care facilities (or clinical laboratories) should notify local and state public health departments promptly (within 24 hours), even if the organism/mechanism is not included in reporting mandates; state or local public health departments should notify federal public health authorities.
- Implement Contact Precautions for the index patient until the health department and health care facility can assess the risk for transmission; health care facilities should ensure adequate supplies are available to implement these measures and communicate any anticipated supply shortages to the public health authority (note: the term index patient may refer to an individual affected with the first known case of an infectious disease or genetically transmitted condition).
- Prioritize the index patient for a rapid infection control assessment to identify and address any potential gaps.

- Notify the patient about the results and infection control measures being implemented.
- If the MDRO was present on admission, notify the transferring facility so an appropriate investigation can occur.
- Due to the limited information regarding transmissibility and duration of colonization for most Tier 1 organisms, consider periodic testing (e.g., monthly) of the index patient and/or others found to be colonized, in consultation with public health; the goal of this type of testing is to inform public health understanding of the organism/mechanism and ongoing risk for transmission.
- There is often a lag time between specimen collection and identification of a novel organism or mechanism; therefore, retesting of the index patient should be performed if more than a month elapsed since collection of the specimen that yielded the Tier 1 organism.
- Discontinuing Transmission-based Precautions is not routinely recommended for patients infected or colonized with Tier 1 organisms; decisions about discontinuing Transmission-based Precautions should be made in consultation with public health authorities.
- Review the patient's health care exposures from at least 30 days prior to the initial positive specimen collection up to the present day.
- Prioritize collecting information about the index patient's health care facility admissions, admission/discharge dates, care location(s) within a facility, presence and duration of roommates, types of care received (e.g., respiratory therapy, wound care, hemodialysis), laboratory culture and screening results for the organism of interest, timing of health care facility

implementation of Transmission-based Precautions (if any), and history of travel and/or health care outside the U.S. in the prior 12 months.

- Additional epidemiological case level data such as chronic medical conditions, recent antimicrobial exposure, and detailed information about medical procedures may be gathered after the initial health care investigation begins.
- If information is available about the time that the organism was most likely acquired then consider this period the risk period for transmission for investigation.
- If the suspected time of acquisition is longer than 30 days prior to identification of the Tier 1 organism, review all health care exposures since the time of suspected acquisition, with particular focus on settings with high acuity and long lengths of stay.
- Screen patients who shared a room or bathroom with the index patient even if they were discharged from the facility to another health care facility or a private residence.
- If screening resources are limited, prioritize screening for patients who overlapped with the index case on the same unit or floor for three or more days or with characteristics that increase their risk of MDRO acquisition (e.g., presence of invasive medical devices and lines, bedbound, etc.), and those currently in health care settings with high-acuity patients and longer lengths of stay.
- Perform additional, wider point prevalence surveys if there is evidence or suspicion of ongoing transmission, such as clinical isolates from multiple patients or if screening identifies new cases.

- If contacts moved units or health care facilities are identified as cases, then contacts on the units or floors where they were admitted should also be screened to identify transmission.
- On units with suspected or confirmed transmission, periodic (e.g., every two weeks) point prevalence surveys are generally recommended until transmission is controlled; control of transmission may be demonstrated with two consecutive point prevalence surveys without new MDRO cases or, in health care facilities with high colonization pressure (i.e., > 30%), substantially decreased transmission.
- Screen health care professionals with extensive index patient contact (e.g., high-contact patient care activities such as bathing, toileting, wound care, or providing care to the patient for an extended period of time) if the risk of health care professional colonization following contact with a patient colonized or infected with the novel organism/mechanism is not known or if epidemiology suggests that the organism may have spread to patients from colonized or infected health care professionals or from colonized or infected patients to health care professionals.
- Engage clinical microbiology laboratories that serve health care facilities where the index patient received care in the previous 30 days (or in the period since suspected acquisition, if longer than 30 days) for prospective and retrospective surveillance to identify organisms with similar resistance profiles from clinical cultures.
- Environmental cultures can help clarify the role of the environment in transmission of a novel MDRO and may also help identify environmental reservoirs leading to ongoing transmission (note: environmental sampling plans should be developed in consultation with public health and environmental microbiology experts).

- Health care organizations should educate and inform the health care professionals and index patient's visitors about the organism and precautions to prevent transmission; conduct ongoing adherence monitoring of infection control practices and provide feedback to health care professionals; flag affected patients' medical records to initiate appropriate infection control precautions upon readmission.

Tier 2 Organisms

- Tier 2 organisms include MDROs that are primarily associated with health care settings and are not commonly identified in the region. In most of the U.S., carbapenem-resistant Enterobacterales (CRE) and carbapenem-resistant *Acinetobacter* spp. with OXA-48 or metallo- β -lactamase carbapenemases (e.g., New Delhi Metallo- β -lactamase [NDM], Verona-integron-mediated carbapenemase [VIM], and imipemenemase [IMP]), carbapenemase-producing *Pseudomonas* spp., and *Candida auris* meet the Tier 2 criteria. In many areas of the United States, carbapenem-resistant Enterobacterales producing *Klebsiella pneumoniae* carbapenemase (KPC-CRE) and *C. auris* also meet the Tier 2 criteria because they are not commonly identified.
- The objective of Tier 2 investigations should be to identify the extent of spread and implement measures to prevent further transmission in affected facilities and in the region.
- Initial response measures are intended to facilitate prompt implementation of appropriate infection prevention and control (IPC) measures (e.g., Contact Precautions if not already implemented for another indication) for the index patient, at the health care facility where he or she is currently admitted, to prevent transmission.

- Upon identification of the organism or mechanism in a laboratory, the laboratory or health care facility should promptly notify the patient's primary health care professional, health care professionals caring for the patient, infection control department, and other health care staff per facility policies (note: local and state public health departments should also be notified even if the organism does not fall under local reporting mandates).
- Health departments and health care facilities should ensure implementation of appropriate infection control measures (e.g., Contact Precautions), which may vary depending on the health care setting, and adequate supplies to implement these measures.
- Prioritize the facility for a rapid infection control assessment to identify and address any potential gaps in IPC.
- Notify the patient and family about related results and infection control measures.
- If the MDRO was present on admission, notification of the transferring facility should occur so appropriate review can occur at that facility.
- Review the patient's health care exposures from approximately 30 days prior to the initial positive culture up to the present.
- Prioritize collecting information about the index patient's admission/discharge dates, care location(s) within a health care facility, presence and duration of roommates, types of care received (e.g., respiratory therapy, wound care, hemodialysis), laboratory culture and screening results for organism of interest, timing of health care facility implementation of Transmission-based Precautions (if any), and history of travel and/or health care outside the U.S. in the prior 12 months.

- Additional epidemiological case-level data such as chronic medical conditions, recent antimicrobial exposure, and detailed information about medical procedures may be gathered after the initial health care investigation commences, to avoid delays in assessing for and preventing spread of infectious agents.
- If information is available about the time that the organism was most likely acquired, then health care professionals should consider this period the risk period for transmission for investigation; if this period is longer than 30 days, review the entire period from the time of suspected acquisition for health care exposures.
- Screen roommates and patients who shared a bathroom with the index patient; screen these contacts even if they were discharged from the facility to another inpatient setting.
- Broader screening using point prevalence surveys is preferred.
- Consider flagging charts of contacts who were discharged, to facilitate preemptive Contact Precautions and admission screening if they are readmitted in the next six months.
- Wider point prevalence surveys are indicated if there is evidence or suspicion for ongoing transmission.
- If new cases are identified, periodic (e.g., every two weeks) point prevalence surveys are recommended until transmission is controlled; control is generally defined as two consecutive point prevalence surveys with no new MDRO cases identified, or, in facilities with high colonization pressure (i.e., > 30%), substantially decreased transmission.

- In health care facilities with high colonization pressure, consider continuing point prevalence surveys at increasing intervals (e.g., monthly and then quarterly) after transmission is controlled, to ensure transmission remains low.
- If high levels of transmission persist across multiple point prevalence surveys in long-term care settings, consider increasing the interval between surveys (e.g., performing every four to six weeks) or temporarily pausing them while reassessing infection control and implementing interventions.
- If screening is paused or performed with reduced frequency, implement measures such as admission screening from facilities with ongoing transmission or preemptive Contact Precautions and/or admission screening at receiving facilities to prevent new outbreaks.
- Admission screening can help distinguish importation from ongoing transmission within a health care facility, such as in situations where the Tier 2 organism or mechanism is believed to be present at other facilities in the region.
- Prioritize admission screening in settings with good adherence to recommended infection control practices, due to higher likelihood that identification on admission will reduce intra-facility transmission (note: public health laboratory-supported admission screening may be available for a limited time period).
- In the absence of known or suspected transmission from health care professionals or other strong epidemiologic links, health care professionals screening is not recommended.

- Engage clinical microbiology laboratories that serve health care facilities identified in the health care investigation (or in the period since suspected acquisition) for prospective and retrospective surveillance to identify organisms with similar resistance profiles from clinical cultures.
- Laboratories should perform prospective surveillance for at least three months after identification of the index patient or, if transmission is identified through surveillance or screening, three months after the last case is identified.
- Most public health responses to Tier 2 organisms and mechanisms will not require environmental cultures; however, in some situations, environmental cultures may help identify environmental reservoirs or evaluate the effectiveness of cleaning and disinfection.
- Environmental cultures are recommended only if transmission is identified or suspected and there is epidemiologic evidence implicating an environmental reservoir in ongoing transmission.
- Health care organizations should educate and inform the health care professionals and visitors for the index patient about the organism and precautions indicated to prevent transmission; conduct ongoing adherence monitoring of infection control practices and provide feedback to health care professionals; flag affected patients' medical records to initiate appropriate infection control precautions.
- Health departments or other experts may conduct on-site IPC assessments at all health care facilities identified in the health care investigation.

- Health care facilities and health departments should ensure the index patient's MDRO status and required infection control precautions are communicated at transfer to higher or lower levels of care.
- In general, screening individuals with a history of colonization or infection with a targeted MDRO with the aim of discontinuing Transmission-based Precautions is not recommended.

Tier 3 Organisms

- Tier 3 MDROs are identified more frequently across a region than Tier 2 MDROs and are typically in stages of advanced spread but are not considered to be endemic. These organisms might be endemic in other areas of the United States. Examples include KPC-CRE, *Acinetobacter baumannii* with plasmid-mediated oxacillinases with carbapenemase activity that are more commonly identified (e.g., OXA-23, OXA-24/40), and *C. auris* in regions of the U. S. where these organisms are more regularly identified but are not endemic.
- The objective of Tier 3 investigations is to identify patients with targeted MDROs and find and address gaps in detection or infection control that could facilitate transmission.
- Initial response measures are intended to facilitate prompt implementation of appropriate infection prevention and control (IPC) measures (e.g., Contact Precautions if not already in place for another indication) for the index patient at the health care facility where he or she is currently admitted, to prevent transmission.
- Upon identification of the organism or mechanism in a laboratory, the laboratory or health care facility should promptly notify the patient's

primary health care professional, patient care personnel, and other health care staff per facility policies (note: depending on local regulations, state or local health departments might need to be notified).

- Health departments and health care facilities should ensure implementation of appropriate infection control measures (e.g., Contact Precautions, Enhanced Barrier Precautions), which may vary depending on the health care setting.
- The patient and his or her family should be notified about the results and infection control measures.
- Review the patient's health care exposures prior to the positive culture to present, including overnight stays in health care settings; investigations for Tier 3 organisms are generally limited to the current admission; however, if the admission immediately prior was within 30 days of specimen collection and occurred at a health care facility where the organism has never or rarely been identified, health departments should consider expanding the investigation to include this facility, especially if the patient was admitted to a unit with high-acuity and/or long lengths of stay.
- Health department recommendations for patient screening in response to identification of a Tier 3 organism should be tailored to the local epidemiology, laboratory capacity, and ongoing prevention activities and objectives in the jurisdiction; recommendations therefore may differ in intensity from the measures described.
- Prioritize broader screening, such as a unit or facility-wide point prevalence survey.

- If new cases are identified on screening, consult with public health regarding follow-up screening.
- After the initial response, additional screening may be indicated for a facility experiencing an acute outbreak or pronounced increase in prevalence of a Tier 3 organism.
- If an acute outbreak is suspected, periodic point prevalence surveys can serve as an infection control intervention and inform the epidemiologic investigation; these should generally have clear goals and a defined endpoint, such as reduced transmission with demonstrated IPC improvement.
- Rescreening patients known to have the novel or targeted MDRO that is the focus of the investigation is not recommended.
- In the absence of known or suspected transmission from health care professionals or other strong epidemiologic links, health care professional screening is not recommended.
- Screening household contacts is generally not recommended for Tier 3 organisms; however, consider screening household contacts who have frequent inpatient health care exposure and had extensive contact with the index patient to determine if Transmission-Based Precautions are necessary for subsequent admissions.
- Clinical laboratories that perform cultures from health care facilities identified in the health care investigation should report any organisms with similar resistance profiles from clinical cultures to public health and follow public health guidance regarding forwarding isolates for appropriate testing

at a public health laboratory to investigate whether they match the organism of interest.

- Environmental cultures are generally not recommended unless transmission is identified or suspected and there is epidemiologic evidence implicating an environmental reservoir in ongoing transmission.
- Health care facilities, particularly long-term care facilities, should ideally receive regular (e.g., at least yearly) infection control assessments using a standardized assessment tool and with observations of infection control practices and recommendations to address observed gaps (note: repeat on-site assessments might be needed to ensure that infection control gaps are fully addressed).
- Health care facilities and health departments should ensure the index patient's MDRO status and required infection control precautions are communicated at transfer to higher or lower levels of care.

Tier 4 Organisms

- Endemic (Tier 4) organisms are endemic in a region but can be less common in other areas of the United States. These are MDROs that were targeted by public health for their clinical significance and potential to spread rapidly (e.g., to other regions where they are less common). In some areas of the U.S., KPC-CRE, *Candida auris*, and *Acinetobacter baumannii* with certain plasmid-mediated oxacillinases with carbapenemase activity (e.g., OXA-23-like, OXA-24/40-like) are endemic.
- For Endemic (Tier 4) organisms, health departments and health care facilities should ensure that health care facilities and health care professionals promptly receive testing results, to facilitate implementation

of appropriate infection prevention and control measures for the affected patient; confirm measures are in place to ensure adherence to infection control and communication of patient MDRO status at transfer; prioritize prevention measures described in the Public Health Strategies to Prevent the spread of MDROs over a public health response to single cases, as is done for organisms in Tiers 1 - 3; remain vigilant for outbreaks and changes in regional epidemiology that may suggest additional measures (e.g., enhanced screening, expansion of prevention activities) are needed.

Section 5 Summary

In the current health care climate, it is absolutely essential that health care organizations maximize infection prevention. Health care facilities should follow recommendations provided by organizations such as the CDC to help prevent infections. Health care organizations should develop and/or update organizational policies and procedures to reflect such recommendations.

Section 5 Key Concepts

- The fifth key aspect of organizational improvement is maximizing infection prevention.
- Create protocols to facilitate rapid isolation of patients with suspected or confirmed CDI.
- Educate and train health care professionals on prevention practices for CDI.
- Preventing the transmission of influenza virus and other infectious agents within health care settings requires a multi-faceted approach.

- Annual vaccination is the most important measure to prevent seasonal influenza infection.
- Influenza vaccination should be offered in September or October; however, vaccination should continue throughout the season as long as influenza viruses are circulating.
- Health care professionals and other staff with potential respiratory infections should be instructed not to report to work, or if at work, to stop patient-care activities, don a facemask, and promptly notify their supervisor and infection control personnel/occupational health before leaving work.
- Health care organizations should develop sick leave policies for health care professionals that are non-punitive, flexible, and consistent with public health guidance to allow and encourage health care professionals with suspected or confirmed influenza to avoid coming to work.
- Health care organizations should establish a process to make everyone entering the facility aware of recommended actions to prevent transmission to others if they have any of the following three criteria: a positive viral test for SARS-CoV-2; symptoms of COVID-19; close contact with someone with SARS-CoV-2 infection.
- Anyone with even mild symptoms of COVID-19, regardless of vaccination status, should receive a viral test for SARS-CoV-2 as soon as possible.
- When performing an outbreak response to a known case, health care facilities should defer to the recommendations of the jurisdiction's public health authority.

- Maintaining appropriate staffing in health care facilities is essential to providing a safe work environment for health care professionals and safe patient care.
- Health care organizations can enhance resident safety by following the CDC's guidelines for containing novel or targeted multidrug-resistant organisms (MDROs).

Section 5 Key Terms

Clostridioides difficile (also known as *C. diff.*) - a bacterium that causes diarrhea and colitis

Colitis - inflammation of the colon

Influenza (otherwise known as the flu) - a respiratory infection caused by influenza viruses

Vaccination - the act of introducing a vaccine into the body to produce immunity to a specific disease

Immunity - protection from an infectious disease

Older adult - an individual 65 years or older

Infectious agent - an organism that is capable of producing an infection or infectious disease

Hand hygiene - the process of cleaning hands in order to prevent contamination and/or infections

Personal protective equipment (PPE) - equipment designed to protect, shield, and minimize exposure to hazards that may cause serious injury, illness, and/or disease

Source control - the use of respirators or well-fitting facemasks or cloth masks to cover an individual's mouth and nose to prevent the spread of respiratory secretions when he or she is breathing, talking, sneezing, or coughing

Dedicated (within the context of infection control) - health care professionals are assigned to care only for specific patients during their shifts

Index patient - an individual affected with the first known case of an infectious disease or genetically transmitted condition

Control (within the context of MDRO prevention) - two consecutive point prevalence surveys without new MDRO cases, or, in facilities with high colonization pressure, substantially decreased transmission

Section 5 Personal Reflection Question

How can health care professionals ensure infection prevention recommendations are followed within their health care organization?

Section 6: Infection Treatment

Infection treatment is often critical to effective resident care. Therefore, the sixth key aspect of organizational improvement is optimizing infection treatment. This section of the course will review recommendations that may be used to optimize infection treatment.

Antibiotic Stewardship

Health care organizations can optimize infection treatment through an antibiotic stewardship. Specific information and recommendations regarding antibiotic stewardships may be found below. The information found below was derived from materials provided by the CDC (CDC, 2021).

- The term antibiotic stewardship may refer to a set of commitments and actions designed to maximize the treatment of infections while reducing the adverse events associated with antibiotic use.
- The CDC recommends that all nursing homes and other health care facilities take steps to improve antibiotic prescribing practices and reduce inappropriate use.
- Antibiotics are among the most frequently prescribed medications in nursing homes, with up to 70% of residents in a nursing home receiving one or more courses of systemic antibiotics in a year.
- Evidence suggests that 40 - 75% of antibiotics prescribed in nursing homes may be unnecessary or inappropriate.
- Adverse effects from antibiotic overuse are significant for older adults receiving care in nursing homes and/or other health care facilities; such adverse effects include the following: risk of serious diarrheal infections from *Clostridium difficile*, increased adverse drug events and drug interactions, and colonization and/or infection with antibiotic-resistant organisms.
- Antibiotic stewardships require leadership commitment. Health care facility leadership, including both owners and administrators, can demonstrate commitment to antibiotic stewardship by writing statements in support of

improving antibiotic use to be shared with staff, residents, and families; including stewardship-related duties in position descriptions for the medical director, clinical nurse leads, and consultant pharmacists within the health care facility; communicating with nursing staff and prescribing health care professionals the facility's expectations about use of antibiotics; and the monitoring and enforcement of stewardship policies.

- Nursing homes and other health care facilities should identify individuals accountable for antibiotic stewardship activities.
- Medical directors should set standards for antibiotic prescribing practices for all health care professionals credentialed to deliver care in a health care facility and be accountable for overseeing adherence (note: to be effective in this role, the medical director should review antibiotic use data and ensure best practices are followed in the medical care of residents in the health care facility).
- Health care organizations should empower the director of nursing to set the practice standards for assessing, monitoring, and communicating changes in a resident's condition by front-line nursing staff; nurses and nurse aides often play a key role in the decision-making process for starting an antibiotic; the knowledge, perceptions, and attitudes among nursing staff of the role of antibiotics in the care of residents can significantly influence how information is communicated to other health care professionals who are deciding whether to initiate antibiotic therapy; therefore, the importance of an antibiotic stewardship is conveyed by the expectations set by nursing leadership in the health care facility.
- Engage pharmacists in supporting antibiotic stewardship oversight through quality assurance activities, such as medication regimen review and reporting of antibiotic use data.

- Infection prevention coordinators have key expertise and data to inform strategies to improve antibiotic use, which includes: tracking of antibiotic starts, monitoring adherence to evidence-based published criteria during the evaluation and management of treated infections, and reviewing antibiotic resistance patterns in a health care facility to understand which infections are caused by resistant organisms; infection prevention coordinators can monitor and support antibiotic stewardship activities.
- Contracted services can help health care organizations fill clinical gaps (note: contracted services may refer to services that are provided according to a written agreement between a health care organization and the individual or individuals providing the services; a health care contract may refer to a written agreement between an individual or entity and a health care organization). For example, a nursing home may contract laboratory services. Nursing homes and other health care facilities contracting laboratory services can request reports and services to support antibiotic stewardship activities. Examples of laboratory support for an antibiotic stewardship include: developing a process for alerting the facility if certain antibiotic-resistant organisms are identified, providing education for staff on the differences in diagnostic tests available for detecting various infectious pathogens (e.g., EIA toxin test vs. nucleic amplification tests for *C. difficile*), and creating a summary report of antibiotic susceptibility patterns from organisms isolated in cultures; such reports, also known as antibiograms, help inform empiric antibiotic selection (i.e., before culture results are available) and monitor for new or worsening antibiotic resistance.
- Health care organizations may benefit from the educational support and resources on antibiotic stewardship and infection prevention which are provided by the Healthcare-Associated Infection (HAI) Prevention programs at state and local health departments.

- Health care organizations should establish access to individuals with antibiotic expertise to implement antibiotic stewardship activities; receiving support from infectious disease consultants and consultant pharmacists with training in antibiotic stewardship can help a nursing home reduce antibiotic use and experience lower rates of positive *C. difficile* tests; additionally, health care organizations should consider partnering with antibiotic stewardship program leads at the hospitals within referral networks.
- Health care professionals participating in antibiotic stewardships should evaluate reported penicillin allergies. Specific information regarding evaluating reported penicillin allergies may be found below.
 - Approximately 10% of all U.S. patients report having an allergic reaction to a penicillin class antibiotic in their past; however, many patients who report penicillin allergies do not have true IgE-mediated reactions; when evaluated, fewer than 1% of the population are truly allergic to penicillins.
 - Broad-spectrum antibiotics are often used as an alternative to penicillins; the use of broad-spectrum antibiotics in patients labeled “penicillin-allergic” is associated with higher health care costs, increased risk for antibiotic resistance, and suboptimal antibiotic therapy; therefore, correctly identifying those who are not truly penicillin-allergic can decrease unnecessary use of broad-spectrum antibiotics.
 - Before prescribing broad-spectrum antibiotics to a resident thought to be penicillin-allergic, health care professionals should evaluate the resident for a true penicillin allergy (IgE-mediated) by conducting a

history and physical, and, when appropriate, a skin test and challenge dose.

- To effectively evaluate a resident for a true penicillin allergy, health care professionals should ask the resident the following types of questions during a history and physical examination: what kind of reaction occurred when you took penicillin; how long ago did the reaction occur; how was the reaction managed or treated; what was the outcome.
- Characteristics of an IgE-mediated (Type 1) reaction include the following: reactions occur immediately or usually within one hour, hives, angioedema, wheezing, shortness of breath, and anaphylaxis (note: hives may refer to pink/red raised areas of skin that are intensely itchy; angioedema may refer to localized edema without hives affecting the abdomen, face, extremities, genitalia, oropharynx, or larynx; anaphylaxis may refer to a life-threatening allergic reaction).
- Signs and symptoms of anaphylaxis include the following: hives, flushing, itching, angioedema, cough, nasal congestion, shortness of breath, chest tightness, wheeze, sensation of throat closure or choking, change in voice-quality, hypotension, faintness, tachycardia, bradycardia, tunnel vision, chest pain, sense of impending doom, loss of consciousness, nausea, vomiting, abdominal cramping, and diarrhea.
- Based on the resident's history and physical exam, additional tests may be needed to confirm a penicillin allergy.

- Penicillin skin testing and challenge doses are reliable and useful methods for evaluating an IgE-mediated penicillin allergy.
- A positive skin test result means the resident is likely to have a penicillin allergy; if negative, the skin test is usually followed by an oral penicillin class challenge (e.g., with amoxicillin) to safely rule out an IgE-mediated penicillin allergy.
- A direct oral challenge without prior skin testing may also be performed in selected patients, which can rule out a penicillin allergy.
- Nursing homes and other health care facilities should implement prescribing policies and change practices to improve antibiotic use; the introduction of new policies and procedures which address antibiotic use should be done in a step-wise fashion so health care professionals become familiar with and not overwhelmed by new changes in practice; interventions should be prioritized based on the needs of the health care facility; outcomes from successful interventions should be shared with nursing staff and other health care professionals. Examples of prescribing policies and procedures that may be used to improve antibiotic use may be found below.
 - **Documentation of dose, duration, and indication** - specify the dose (including route), duration (i.e., start date, end date, and planned days of therapy), and indication, which includes both rationale (i.e., prophylaxis vs. therapeutic) and treatment site (i.e., urinary tract), for every course of antibiotics; documenting and making this information accessible (e.g., verifying indication and planned duration can help ensure that antibiotics are modified as needed based on additional laboratory and clinical data and/or discontinued in a timely manner).

- **Establish best practices for use of microbiology testing** - inappropriate use of microbiology tests in nursing homes and other health care facilities may drive unnecessary antibiotic treatment; health care professionals should review the current protocols and laboratory testing practices to ensure that laboratory tests are used appropriately; identifying and reducing inappropriate use of laboratory testing may be a high-yield effort for improving antibiotic use and reducing other management costs.
- **Develop health care facility-specific treatment recommendations** - health care facility-specific treatment recommendations, based on national guidelines and local susceptibilities can optimize antibiotic selection and duration, especially for common indications for antibiotic use like pneumonia, urinary tract infection, and skin and soft tissue infections.
- **Review** - health care professionals should review the antibiotic agents available in their health care facility including an inventory of drugs accessible during off hours (e.g., emergency kit or overnight box) to ensure availability is not a barrier to use of preferred agents.
- **Algorithms** - develop and implement algorithms for the assessment of residents suspected of having an infection using evidence-based guidance.
- **Utilize a communication tool for residents suspected of having an infection** - because health care professionals are not always available on-site, a significant amount of management of residents is mediated via phone interactions; health care professionals must rely on the assessment and information conveyed to them by the front-line nursing staff to make diagnostic and treatment decisions; barriers to

effective phone interactions between health care professionals, such as inadequate preparation or feeling rushed on the phone may impact the quality of information exchange. Therefore, health care organizations should implement structured communication tools to guide health care professional interactions. Communication tools used to facilitate information when a resident is suspected of having an infection should include key pieces of the clinical history including the following: new symptoms, new complaints, physical exam findings, and other relevant information.

- **Develop and disseminate a facility-specific report of antibiotic susceptibility to health care professionals** - health care facilities should work with consultant laboratories to create a facility-specific summary of antibiotic susceptibility patterns from the organisms commonly isolated in microbiology cultures. For example, an antibiogram. Antibiograms may refer to tables developed by a microbiology laboratory showing the percent susceptibility for a panel of common bacteria tested against a panel of common antibiotics. Health care facilities' laboratories may have to tailor the antibiogram based on the facility's diagnostic testing practices. For example, a nursing home antibiogram may only include organisms causing urinary tract infection if urine cultures are the most frequent test sent to the laboratory. Antibiograms may be updated every 12 to 24 months, based on the number of cultures submitted by a facility (note: summaries of susceptibility patterns should be disseminated to health care professionals as an educational tool and to guide management decisions).
- **Perform antibiotic "time outs"** - an antibiotic time out is a formal process designed to prompt a reassessment of the ongoing need for

and choice of an antibiotic once data, such as: the clinical response, additional diagnostic information, and alternate explanations for the status change which prompted the antibiotic start. Health care facilities should have a process in place for a review of antibiotics by the clinical team two to three days after antibiotics are initiated to answer the following essential questions: does this resident have a bacterial infection that will respond to antibiotics; if so, is the resident on the most appropriate antibiotic(s), dose, and route of administration; can the spectrum of the antibiotic be narrowed or the duration of therapy shortened (i.e., de-escalation); would the resident benefit from additional infectious disease/antibiotic expertise to ensure optimal treatment of the suspected or confirmed infection.

- **Reduce prolonged antibiotic treatment courses for common infections** - due to the growing body of evidence that short courses of antibiotics are effective for common infections, interventions designed to decrease antibiotic duration among residents may reduce the complications and adverse events associated with antibiotic exposure.
- **Conduct a review of antibiotic prescriptions as part of the drug regimen review** - elements of the antibiotic review should include dosing and administration data, to ensure health care professionals are making appropriate adjustments for renal function and potential drug interactions (note: pharmacists should review indication and justification of use to verify that antibiotics are used in accordance with facility-specific treatment guidelines).

- **Establish standards on laboratory testing** - health care facilities should establish standards on laboratory testing to monitor for adverse drug events related to the use of antibiotics.
- **Review microbiology culture results** - reviewing microbiology culture results can add an additional level of feedback to prescribing health care professionals on initial antibiotic selection and subsequent modifications of therapy once data is available; health care professionals can be given a predefined set of criteria and/or guidance developed to help optimize antibiotic use.
- **Reduce antibiotic prophylaxis for the prevention of urinary tract infections (UTI)** - efforts to educate health care professionals on the potential harm of antibiotics for UTI prophylaxis could reduce unnecessary antibiotic exposure and improve resident outcomes.
- **Optimize the use of superficial cultures for the management of chronic wounds** - obtaining specimens for wound culture can help guide antimicrobial treatment, however, reliance on superficial swab cultures alone may drive inappropriate or unnecessary antibiotic use. Superficial wound swabs cannot differentiate bacterial colonization from infection and there may be a lack of correlation between organisms identified by superficial swab cultures compared with deep tissue cultures. Reviewing the indications for obtaining cultures in residents with chronic wounds (e.g., presence of purulent drainage) and assessing the type of specimen submitted for culture may identify opportunities for improving antibiotic use in residents with chronic wounds.
- Nursing homes and other health care facilities should monitor both antibiotic use practices and outcomes related to antibiotics in order to

guide practice changes and track the impact of new interventions; data on adherence to antibiotic prescribing policies and antibiotic use should be shared with health care professionals to maintain awareness about the progress being made in an antibiotic stewardship. Examples of antibiotic use and outcome measures may be found below.

- Process measures (tracking how and why antibiotics are prescribed) - perform reviews on residents' medical records for new antibiotic starts to determine whether the clinical assessment, prescription documentation, and antibiotic selection were in accordance with health care facility antibiotic use policies and practices (note: when conducted over time, monitoring process measures can assess whether antibiotic prescribing policies are being followed by health care professionals).
- Antibiotic use measures (tracking how often and how many antibiotics are prescribed) - track the amount of antibiotics used in a health care facility to review patterns of use and determine the impact of new stewardship interventions. Some antibiotic use measures (e.g., prevalence surveys) provide a snap-shot of information; while others, like nursing home initiated antibiotic starts and days of therapy (DOT) are calculated and tracked on an ongoing basis. Selecting which antibiotic use measure to track should be based on the type of practice intervention being implemented. Interventions designed to shorten the duration of antibiotic courses, or discontinue antibiotics based on post-prescription review (i.e., “antibiotic time-out”), may not necessarily change the rate of antibiotic starts, but would decrease the antibiotic DOT (note: antibiotic use data from health care facilities to improve antibiotic stewardship efforts is important both for individual facility

improvements and for public health action; expansion of electronic health records in health care facilities will allow for organizations to obtain systems which integrate pharmacy and laboratory data and make antibiotic use and resistance data to inform stewardship efforts more accessible to health care professionals and leadership).

- Antibiotic outcome measures (tracking the adverse outcomes and costs from antibiotics) - monitor clinical outcomes such as rates of *C. difficile* infections, antibiotic-resistant organisms, and/or adverse drug events to demonstrate that antibiotic stewardship activities are successful in improving resident outcomes (note: nursing homes and other health care organizations already tracking these clinical outcomes for their infection prevention program can submit data on *C. difficile* and selected antibiotic-resistant bacteria, such as methicillin-resistant *Staphylococcus aureus* (MRSA) and carbapenem-resistant Enterobacterales (CRE) into the CDC's NHSN Laboratory-identified event reporting module for long-term care facilities).
- Health care organizations should provide antibiotic stewardship education to health care professionals, residents, and families (note: there are a variety of mechanisms for disseminating antibiotic education to nursing home staff including: flyers, pocket-guides, newsletters, or electronic communications; however, interactive academic detailing [e.g., face-to-face interactive workshops] has the strongest evidence for improving medication prescribing practices).
- Health care organizations should engage residents and their family members in antibiotic use and stewardship educational efforts to ensure health care professionals have their support to make appropriate antibiotic use decisions; working with residents and families may reduce the

perception that their expectations may be a barrier to improving antibiotic use in health care facilities.

Influenza Treatment and Chemoprophylaxis

Health care organizations can also optimize infection treatment by effectively treating influenza. Specific information and recommendations regarding influenza treatment and chemoprophylaxis may be found below. The information found below was derived from materials provided by the CDC and *Clinical Infectious Diseases* (CDC, 2022; Uyeki, 2018).

- Neuraminidase inhibitors are chemically related antiviral medications that block the viral neuraminidase enzyme and have activity against both influenza A and B viruses; neuraminidase inhibitors include: oseltamivir, zanamivir, and peramivir.
- Oseltamivir (available as a generic or under the trade name Tamiflu) for oral administration is FDA-approved for the early treatment of uncomplicated influenza in people two weeks and older, and for chemoprophylaxis to prevent influenza in people one year and older.
- Zanamivir (trade name Relenza) for oral inhalation is FDA-approved for early treatment of uncomplicated influenza in people seven years and older, and to prevent influenza in people five years and older; it is not recommended for use in people with underlying respiratory disease, including people with asthma.
- Peramivir (trade name Rapivab) for intravenous administration is FDA-approved for early treatment of uncomplicated influenza in people six months and older.

- An endonuclease inhibitor has a different mechanism of action than a neuraminidase inhibitor; endonuclease inhibitors interfere with viral RNA transcription and block virus replication in both influenza A and B viruses; baloxavir marboxil is an endonuclease inhibitor.
- Baloxavir marboxil (trade name Xofluza) for oral administration is FDA-approved for early treatment of uncomplicated influenza in otherwise healthy non-high risk people five years to less than 12 years and for all persons 12 years and older, and for post-exposure prophylaxis of influenza in people five years and older; baloxavir is not recommended for immunocompromised persons.
- When considering the use of influenza antiviral medications, health care professionals should consider the patient's age, weight, and renal function; presence of other medical conditions; indications for use (i.e., chemoprophylaxis or therapy); and the potential for interaction with other medications (note: evidence suggests that gastrointestinal symptoms such as nausea and vomiting are increased with oral oseltamivir compared with placebo; these adverse events may be less likely when oseltamivir is taken with food).
- Co-administration of baloxavir with polyvalent cation-containing products may decrease plasma concentrations of baloxavir which may reduce efficacy; health care professionals should avoid co-administration of baloxavir with polyvalent cation-containing laxatives, antacids, or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc).
- Concurrent administration of antiviral drugs with intranasal live attenuated influenza vaccine (LAIV) may inhibit viral replication of LAIV and thereby decrease the effectiveness of LAIV vaccination; LAIV should not be given if oseltamivir or zanamivir was administered within 48 hours of planned

vaccination, or if peramivir was administered within five days of planned vaccination, or if baloxavir was administered within 17 days of planned vaccination; if LAIV is given, and antiviral medications are subsequently administered up to two weeks after vaccination, the effectiveness of LAIV might be reduced, and individuals who receive these antiviral medications within two weeks after receiving LAIV should be revaccinated with another appropriate influenza vaccine (e.g., IIV or RIV4).

- Dose adjustment of oseltamivir is recommended for patients with creatinine clearance between 10 and 60 mL/min and patients with end-stage renal disease (ESRD) undergoing hemodialysis or continuous peritoneal dialysis receiving oseltamivir for the treatment or chemoprophylaxis of influenza. Oseltamivir is not recommended for patients with ESRD who are not undergoing dialysis; the duration of treatment and chemoprophylaxis is the same as recommended for patients with normal renal function. The dose of intravenous peramivir should be reduced for patients with baseline creatinine clearance below 50 mL/min.
- Health care professionals should test for influenza in high-risk patients, including immunocompromised persons who present with influenza-like illness, pneumonia, or nonspecific respiratory illness (e.g., cough without fever) if the testing result will influence clinical management.
- Test for influenza in patients who present with acute onset of respiratory symptoms with or without fever, and either exacerbation of chronic medical conditions (e.g., asthma, chronic obstructive pulmonary disease [COPD], heart failure) or known complications of influenza (e.g., pneumonia) if the testing result will influence clinical management.
- Health care professionals should consider influenza testing for patients who are not at high risk for influenza complications who present with influenza-

like illness, pneumonia, or nonspecific respiratory illness (e.g., cough without fever) if the results might influence antiviral treatment decisions or reduce the use of unnecessary antibiotics, further diagnostic testing, and time in the emergency department, or if the results might influence antiviral treatment or chemoprophylaxis decisions for high-risk contacts.

- Collect upper respiratory tract specimens for influenza testing as soon after illness onset as possible, preferably within four days of symptom onset.
- Nasopharyngeal specimens should be collected over other upper respiratory tract specimens to increase detection of influenza viruses.
- If nasopharyngeal specimens are not available, nasal and throat swab specimens should be collected and combined together for influenza testing over single specimens from either site (particularly over throat swabs) to increase detection of influenza viruses.
- Mid-turbinate nasal swab specimens should be collected over throat swab specimens to increase detection of influenza viruses.
- Health care professionals should not collect or routinely test specimens for influenza from nonrespiratory sites such as blood, plasma, serum, cerebrospinal fluid, urine, and stool.
- Health care professionals should start antiviral treatment as soon as possible with a single neuraminidase inhibitor (NAI) (either oral oseltamivir, inhaled zanamivir, or intravenous peramivir) and not use a combination of NAIs; health care professionals should not routinely use higher doses of FDA-approved NAI drugs for the treatment of seasonal influenza.
- Treat uncomplicated influenza in otherwise healthy ambulatory patients for five days with oral oseltamivir or inhaled zanamivir, or a single dose of

intravenous peramivir; consider longer duration of antiviral treatment for patients with a documented or suspected immunocompromising condition or patients requiring hospitalization for severe lower respiratory tract disease (especially pneumonia or acute respiratory distress syndrome [ARDS]), as influenza viral replication is often protracted.

- Investigate and empirically treat bacterial coinfection in patients with suspected or laboratory-confirmed influenza who present initially with severe disease (e.g., extensive pneumonia, respiratory failure, hypotension, and fever), in addition to antiviral treatment for influenza.
- Investigate and empirically treat bacterial coinfection in patients who deteriorate after initial improvement, particularly in those treated with antivirals.
- Consider investigating bacterial coinfection in patients who fail to improve after three to five days of antiviral treatment.
- Investigate other causes besides influenza virus infection in influenza patients who fail to improve or deteriorate despite antiviral treatment.
- Influenza NAI resistance testing can be considered for: patients who develop laboratory-confirmed influenza while on or immediately after NAI chemoprophylaxis; patients with an immunocompromising condition and evidence of persistent influenza viral replication and remain ill during or after NAI treatment; patients with laboratory-confirmed influenza who inadvertently received subtherapeutic NAI dosing; patients with severe influenza who do not improve with NAI treatment and have evidence of persistent influenza viral replication (e.g., after seven to ten days).

- Consider antiviral chemoprophylaxis for the duration of the influenza season for individuals who are at very high risk of developing complications from influenza and for whom influenza vaccination is contraindicated, unavailable, or expected to have low effectiveness.
- Consider antiviral chemoprophylaxis for the duration of the influenza season for individuals who have the highest risk of influenza-associated complications, such as recipients of hematopoietic stem cell transplant in the first 6 - 12 months post transplant and lung transplant recipient.
- Consider short-term antiviral chemoprophylaxis in conjunction with prompt administration of inactivated influenza vaccine for unvaccinated individuals who are at high risk of developing complications from influenza in whom influenza vaccination is expected to be effective (but not yet administered) when influenza activity has been detected.
- Consider short-term antiviral chemoprophylaxis for unvaccinated individuals, including health care professionals who are in close contact with persons at high risk of developing influenza complications during periods of influenza activity when influenza vaccination is contraindicated or unavailable and these high-risk persons are unable to take antiviral chemoprophylaxis.
- Use an NAI (oral oseltamivir or inhaled zanamivir) if pre exposure chemoprophylaxis for influenza is administered rather than an adamantane antiviral.
- Administer pre exposure antiviral chemoprophylaxis for individuals who are at very high risk of developing complications from influenza (e.g., severely immunocompromised persons such as hematopoietic stem cell transplant recipients) for whom influenza vaccination is contraindicated, unavailable,

or expected to have low effectiveness, as soon as influenza activity is detected in the community and continued for the duration of community influenza activity.

- Test for influenza and switch to antiviral treatment dosing in persons receiving pre-exposure antiviral chemoprophylaxis who become symptomatic, preferably with an antiviral drug with a different resistance profile, if not contraindicated.
- If chemoprophylaxis is given, health care professionals should administer post exposure antiviral chemoprophylaxis as soon as possible after exposure, ideally no later than 48 hours after exposure.
- Health care professionals should not administer once-daily post exposure antiviral chemoprophylaxis if >48 hours elapsed since exposure; full-dose empiric antiviral treatment should be initiated as soon as symptoms occur, if treatment is indicated.
- Administer post exposure antiviral chemoprophylaxis in a non outbreak setting for seven days after the most recent exposure to a close contact with influenza.
- Test for influenza and switch to antiviral treatment dosing in persons receiving post exposure antiviral chemoprophylaxis who become symptomatic, preferably with an antiviral drug with a different resistance profile if not contraindicated.
- Administer an NAI (inhaled zanamivir or oral oseltamivir) if post exposure chemoprophylaxis for influenza is given, rather than an adamantane antiviral.

- Active surveillance for additional cases should be implemented as soon as possible when one case of laboratory-confirmed influenza is identified in a long-term care facility.
- Outbreak control measures should be implemented as soon as possible, including antiviral chemoprophylaxis of residents, and active surveillance for new cases, when two cases of health care-associated laboratory-confirmed influenza are identified within 72 hours of each other in residents of the same ward or unit.
- Implementation of outbreak control measures can be considered as soon as possible if one or more residents has suspected health care-associated influenza and results of influenza molecular testing are not available on the day of specimen collection.
- When an influenza outbreak is identified in a long-term care facility, influenza testing should be done for any resident with one or more acute respiratory symptoms, with or without fever, or any of the following without respiratory symptoms: temperature elevation, temperature reduction, or behavioral change.
- Empiric antiviral treatment should be administered as soon as possible to any resident with suspected influenza during an influenza outbreak without waiting for the results of influenza diagnostic testing.
- Antiviral chemoprophylaxis should be administered as soon as possible to all exposed residents who do not have suspected or laboratory-confirmed influenza regardless of influenza vaccination history, in addition to implementation of all other recommended influenza outbreak control measures, when an influenza outbreak is identified in a long-term care facility.

- Antiviral chemoprophylaxis should be administered to residents on outbreak-affected units, in addition to implementing active daily surveillance for new influenza cases throughout the health care facility.
- Consider antiviral chemoprophylaxis for unvaccinated health care professionals and other staff, including those for whom chemoprophylaxis may be indicated based upon underlying conditions for the duration of the outbreak.
- Consider antiviral chemoprophylaxis for health care professionals and other staff who receive inactivated influenza vaccine during an institutional influenza outbreak for 14 days postvaccination.
- Consider antiviral chemoprophylaxis for health care professionals and other staff regardless of influenza vaccination status to reduce the risk of short staffing in health care facilities and wards where clinical staff are limited and to reduce staff reluctance to care for patients with suspected influenza.
- Administer antiviral chemoprophylaxis for 14 days and continue for at least seven days after the onset of symptoms in the last case identified during an institutional influenza outbreak.
- During periods of community co-circulation of influenza viruses and SARS-CoV-2, empiric antiviral treatment of influenza is recommended as soon as possible for individuals in health care facilities.
- Influenza and COVID-19 have overlapping signs and symptoms; testing can help distinguish between influenza virus infection and SARS-CoV-2 infection; health care professionals should not wait for the results of influenza testing, SARS-CoV-2 testing, or multiplex molecular assays that detect influenza A

and B viruses and SARS-CoV-2 to initiate empiric antiviral treatment for influenza.

- Co-infection with influenza A or B viruses and SARS-CoV-2 can occur and should be considered, particularly in individuals with severe respiratory disease.
- A positive SARS-CoV-2 test result does not preclude influenza virus infection; for individuals with suspected influenza who are started on empiric antiviral treatment with oseltamivir, the use of influenza molecular assays or multiplex assays that detect both influenza viruses and SARS-CoV-2 can inform clinical management.
- A positive influenza test result does not preclude SARS-CoV-2 infection.

Managing COVID-19

Specific information and recommendations regarding the management of COVID-19 may be found below. The information found below was derived from materials provided by the National Institutes of Health unless, otherwise, specified (National Institutes of Health, 2022; National Institutes of Health, 2023).

- Everyone who has symptoms that are consistent with COVID-19 and people with known high-risk exposures to SARS-CoV-2 should be tested for SARS-CoV-2 infection; such testing should employ either a nucleic acid amplification test (NAAT) or an antigen test to detect SARS-CoV-2; testing may also be used for screening and determining the length of a patient's isolation period, when applicable.
- Individuals of all ages are at risk for SARS-CoV-2 infection and severe disease. However, the probability of severe COVID-19 is higher in people

aged ≥ 65 years, those living in a nursing home or long-term care facility, those who are not vaccinated against COVID-19 or who have poor responses to COVID-19 vaccines, and those with chronic medical conditions. Evidence indicates that patients with cardiovascular disease, chronic kidney disease, chronic obstructive pulmonary disease, diabetes with complications, neurocognitive disorders, and obesity are at increased risk of severe COVID-19. The risk appears to be higher in patients with multiple comorbid conditions. Other conditions that may lead to a high risk of severe COVID-19 include cancer, cystic fibrosis, immunocompromising conditions, liver disease (especially in patients with cirrhosis), pregnancy, and sickle cell disease. Transplant recipients and people who are taking immunosuppressive medications may also have a higher risk of severe COVID-19.

- Patients with SARS-CoV-2 infection can experience a range of clinical manifestations, from asymptomatic to critical illness. In general, adults with SARS-CoV-2 infection can be grouped into the following severity of illness categories:
 - **Asymptomatic or presymptomatic infection** - individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test [NAAT] or an antigen test) but do not have symptoms consistent with COVID-19
 - **Mild illness** - individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste, and loss of smell) but do not have shortness of breath, dyspnea, or abnormal chest imaging

- **Moderate illness** - individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have an oxygen saturation measured by pulse oximetry (SpO₂) ≥94% on room air at sea level
- **Severe illness** - individuals who have SpO₂ <94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO₂/FiO₂) <300 mm Hg, a respiratory rate >30 breaths/min, or lung infiltrates >50%
- **Critical illness** - individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction
- Symptom management should be initiated for all nonhospitalized adults with mild to moderate COVID-19; for individuals who are at high risk of progression to severe disease, several antiviral therapeutic options are available to reduce the risk of hospitalization or death.
- The main goal of therapeutic management for nonhospitalized patients is to prevent progression to severe disease, hospitalization, or death; other goals may include accelerating symptom recovery and viral clearance. Several factors may affect the selection of the best treatment option for a specific patient. These factors include the clinical efficacy and availability of the treatment option, the feasibility of administering parenteral medications, the potential for significant drug-drug interactions, the time from symptom onset, and the in vitro activities of the available products against the currently circulating SARS-CoV-2 variants and subvariants.
- Treatment of symptoms includes using over-the-counter antipyretics, analgesics, or antitussives for fever, headache, myalgias, and cough; patients should be advised to drink fluids regularly, and to avoid

dehydration. Rest is recommended as needed during the acute phase of COVID-19, and ambulation and other forms of activity should be increased according to the patient's tolerance. Patients should be educated about the variability in time to symptom resolution and complete recovery.

- Health care professionals should consider ritonavir-boosted nirmatrelvir in most high-risk, nonhospitalized patients with mild to moderate COVID-19 (e.g., patients over the age of 65). When ritonavir-boosted nirmatrelvir is not clinically appropriate (e.g., because of significant drug-drug interactions), health care professionals should consider using remdesivir (note: ritonavir-boosted nirmatrelvir has high efficacy; has been shown to reduce hospitalization and death when administered to high-risk, unvaccinated, nonhospitalized patients within five days of symptom onset; and is an oral medication). Specific information regarding ritonavir-boosted nirmatrelvir (Paxlovid) may be found below. The information found below was derived from materials provided by the National Library of Medicine (National Library of Medicine, 2023).

Ritonavir-boosted nirmatrelvir (Paxlovid)

Medication notes - the FDA issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved Paxlovid, which includes nirmatrelvir, a SARS-CoV-2 main protease inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset. Paxlovid should be

administered orally with or without food. Paxlovid includes 300 mg of nirmatrelvir (two 150 mg tablets) with 100 mg of ritonavir (one 100 mg tablet); all three tablets taken together twice daily for five days. The most common adverse reactions associated with Paxlovid include the following: diarrhea, hypertension, muscle pain, and a distorted sense of taste.

Safety notes - contraindications associated with Paxlovid include: a history of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components; co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and resistance. Warnings and precautions associated with Paxlovid include: anaphylaxis and other hypersensitivity reactions were reported with Paxlovid; if signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue Paxlovid and initiate supportive care; drug interactions are possible; may lead to drug resistance.

Considerations for special patient populations - reduce the Paxlovid dosage in patients with moderate renal impairment (eGFR ≥ 30 to < 60 mL/min); Paxlovid is not recommended for use in patients with severe renal impairment (eGFR < 30 mL/min) or patients with end stage renal disease (eGFR < 15 mL/min) receiving dialysis.

- Before prescribing ritonavir-boosted nirmatrelvir, health care professionals should review patients' concomitant medications, including over-the-counter medications and herbal supplements, to evaluate potential drug-drug interactions.

- Nirmatrelvir is an orally bioavailable protease inhibitor that is active against M^{PRO}, a viral protease that plays an essential role in viral replication; the FDA issued an Emergency Use Authorization (EUA) for ritonavir-boosted nirmatrelvir for the treatment of mild to moderate COVID-19 in nonhospitalized adults and pediatric patients aged ≥ 12 years and weighing ≥ 40 kg who are at high risk of disease progression.
- Patients should complete the 5-day treatment course of ritonavir-boosted nirmatrelvir (note: if a patient requires hospitalization after starting treatment, the full 5-day treatment course of ritonavir-boosted nirmatrelvir should be completed unless there are drug-drug interactions that preclude its use; ritonavir-boosted nirmatrelvir is expected to be active against all Omicron subvariants).
- Health care professionals should consider molnupiravir as a therapeutic option when the other recommended antiviral treatment options are not available, feasible to use, or clinically appropriate (note: evidence suggests that molnupiravir has lower clinical efficacy than the other treatment options).
- Molnupiravir is the oral prodrug of beta-D-N4-hydroxycytidine, a ribonucleoside that has exhibited antiviral activity against SARS-CoV-2 in vitro and in clinical trials; the FDA issued an EUA for molnupiravir for the treatment of mild to moderate COVID-19 in nonhospitalized patients aged ≥ 18 years who are at high risk of disease progression and for whom alternative treatment options are not accessible or clinically appropriate (note: evidence suggests that molnupiravir is active against the Omicron variant and its subvariants).
- Ritonavir is a strong cytochrome P450 3A4 inhibitor and a P-glycoprotein inhibitor; it may increase blood concentrations of certain concomitant

medications and increase the potential for serious drug toxicities; patients should be appropriately monitored.

- Ritonavir-boosted nirmatrelvir is not recommended in patients with an estimated glomerular filtration rate (eGFR) of <30 mL/min.
- If health care professionals use remdesivir in patients with renal impairment, they should consider the use of the lyophilized powder formulation of remdesivir, which contains less sulfobutylether beta-cyclodextrin sodium than the solution formulation (note: the FDA product label for remdesivir does not recommend its use in patients with an eGFR of <30 mL/min; however, evidence suggests that remdesivir can be used in patients with an eGFR of <30 mL/min if the potential benefits outweigh the risks).
- Interactions between ritonavir-boosted nirmatrelvir and chemotherapeutic agents should be managed in consultation with the patient's specialist providers.
- Advanced planning (e.g., reserving infusion slots, identifying alternative infusion sites) may be needed to increase access to IV remdesivir; IV remdesivir can be administered in skilled nursing facilities, home health care settings, and outpatient facilities such as infusion centers (note: if treating facilities cannot provide a 3-day course of remdesivir IV infusions to all eligible patients, prioritizing patients who will benefit the most from the therapy becomes necessary).
- Health care professionals should avoid the use of colchicine for the treatment of nonhospitalized patients with COVID-19.

- Health care professionals should avoid the use of ivermectin for the treatment of COVID-19.
- Health care professionals should avoid the use of metformin for the treatment of COVID-19 in nonhospitalized patients (note: patients with COVID-19 who are receiving metformin for an underlying condition should continue this therapy as directed by their health care professional).
- A patient's usual medication and/or supplement regimen should be continued after the diagnosis of COVID-19; angiotensin-converting enzyme (ACE) inhibitors; angiotensin receptor blockers (ARBs); statin therapy; nonsteroidal anti-inflammatory drugs; and oral, inhaled, and intranasal corticosteroids that are prescribed for comorbid conditions should be continued as directed; patients should be advised to avoid the use of nebulized medications in the presence of others to avoid potential aerosolization of SARS-CoV-2; antiretroviral therapy should not be switched or adjusted for the theoretical purpose of preventing or treating SARS-CoV-2 infection.
- Patients with COVID-19 who are receiving anticoagulant or antiplatelet therapies for underlying conditions should continue these medications unless significant bleeding develops or other contraindications are present.
- Before prescribing ritonavir-boosted nirmatrelvir (Paxlovid) to patients who are receiving anticoagulant or antiplatelet therapy, health care professionals should carefully review the patient's concomitant medications to evaluate potential drug-drug interactions; it may be necessary to modify the dosage of the antithrombotic agent, switch to another antithrombotic agent, or prescribe an alternative COVID-19 therapy.

- Health care professionals may want to consider routine screening for venous thromboembolism (VTE) in patients with COVID-19 who do not have signs or symptoms of VTE, regardless of the status of their coagulation markers.
- For patients with COVID-19 who experience rapid deterioration of pulmonary, cardiac, or neurological function or sudden, localized loss of peripheral perfusion, health care professionals should consider evaluating the patients for thromboembolic disease.
- When diagnostic imaging is not possible, patients with COVID-19 who are highly suspected to have thromboembolic disease should be managed with therapeutic anticoagulation.
- Patients with COVID-19 who require extracorporeal membrane oxygenation or continuous renal replacement therapy or who have thrombosis related to catheters or extracorporeal filters should be treated with antithrombotic therapy as per the standard institutional protocols for those without COVID-19.
- When a patient is receiving an immunomodulating medication, health care professionals should be consulted about the risks and benefits associated with a temporary dose reduction or discontinuation; the risks and benefits will depend on the medication's indication and the severity of the underlying condition.
- Decisions regarding stopping or reducing the doses of immunosuppressive drugs in patients with COVID-19 should be made in consultation with the appropriate specialists; health care professionals should consider factors such as the underlying disease, the specific immunosuppressants being used, the potential for drug-drug interactions, and the severity of COVID-19.

- Immunosuppressive medications can reduce the host immune responses that suppress viral replication, increasing the risk of prolonged viral shedding and infection; health care professionals should consider adjusting the doses of immunosuppressive medications or substituting certain immunosuppressive medications, if possible, to improve the patient's immune response to infection; when making decisions about stopping or reducing the dose of immunosuppressive drugs, health care professionals should balance the potential benefit of enhancing the patient's immune response to COVID-19 with the risk of exacerbating the underlying condition; health care professionals should also consider the role of immunomodulation in the treatment of COVID-19.
- Health care professionals should be aware that many immunosuppressive drugs, particularly biologic agents, have long half-lives or prolonged periods of biologic activity; patients may remain immunosuppressed long after the drugs are stopped; care should be taken to not stop glucocorticoids abruptly, since this may result in adrenal insufficiency; for medications other than glucocorticoids, decisions about dose adjustments should be made on a case-by-case basis (e.g., for some autoimmune diseases, temporary cessation of immunosuppression is often possible, and restarting medications seven to 14 days after symptom resolution may be appropriate).
- Health care professionals should consider prompt treatment with antiviral drugs for patients with mild to moderate COVID-19 who are immunocompromised.
- For most patients with COVID-19 who are immunocompromised, health care professionals should use antiviral drugs and immunomodulatory

therapies at the doses and durations that are recommended for the general population.

- In some cases, immunomodulatory drug regimens may need to be adjusted to reduce the risk of drug-drug interactions, overlapping toxicities, and secondary infections.
- Ritonavir can inhibit the metabolism of many cancer-directed therapies and should only be given after consulting with specialty pharmacists and other appropriate specialists; case reports described reoccurring COVID-19 symptoms and positive SARS-CoV-2 test results in some patients who have completed treatment with ritonavir-boosted nirmatrelvir; there is currently no evidence to support routinely administering longer courses or a second course of ritonavir-boosted nirmatrelvir; patients with COVID-19 who are immunocompromised should not delay or avoid taking ritonavir-boosted nirmatrelvir due to concerns about the rebound of symptoms after treatment completion.
- The optimal duration of treatment with remdesivir in patients who are immunocompromised is unknown; case reports suggest that the drug can suppress, but does not always eliminate, viral replication in this population; some health care professionals may choose to extend the course of antiviral therapy past five to 10 days in patients who are immunocompromised, given the risk of prolonged viral replication; although remdesivir was not shown to confer a benefit in patients with more severe respiratory impairment due to COVID-19 (i.e., those who require high-flow nasal cannula [HFNC] oxygen, noninvasive ventilation [NIV], or mechanical ventilation), health care professionals may consider using remdesivir along with immunomodulatory therapy in patients who are immunocompromised.

- Patients who are immunocompromised may experience delayed development of favorable adaptive responses and a prolonged period of viral replication; for patients who are immunocompromised, who are receiving minimal levels of conventional oxygen, and who are earlier in the course of COVID-19 (e.g., those with <10 days of symptoms), the preferred approach may be emphasizing supportive care, using antiviral therapy, and avoiding corticosteroids; this strategy may reduce the duration of viral replication and the risk of secondary infections; dexamethasone should be added if the patient has escalating oxygen requirements.
- For patients who are immunocompromised and who were on chronic corticosteroids, the optimal dose of dexamethasone for the treatment of COVID-19 is unknown; the recommended dose of dexamethasone is 6 mg, which is equivalent to 40 mg of prednisone; this is the minimum dose of steroid that should be used; maintenance doses of corticosteroids should be discontinued while a patient is receiving dexamethasone, and they should be resumed as soon as possible after recovery from COVID-19 or after completion of the course of dexamethasone.
- Individuals with HIV should receive COVID-19 vaccines, regardless of their CD4 T lymphocyte (CD4) cell count or HIV viral load, because the potential benefits outweigh the potential risks.
- Individuals with advanced or untreated HIV who received an initial 2-dose series of an mRNA COVID-19 vaccine should receive a third dose of that vaccine at least 28 days after the second dose (note: advanced HIV is defined as people with CD4 counts <200 cells/mm³, a history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV).

- Individuals with HIV should receive booster doses of COVID-19 vaccines, as recommended.
- Health care professionals should consider deferring influenza vaccination for symptomatic patients with COVID-19 until these patients are no longer moderately or severely ill and have completed their COVID-19 isolation period.
- Health care professionals should use the same approach for diagnosing SARS-CoV-2 infection in people with HIV as in people without HIV.
- Patients with HIV who are receiving ritonavir-based or cobicistat-based antiretroviral therapy (ART) can receive the 5-day course of ritonavir-boosted nirmatrelvir (Paxlovid) to treat COVID-19 without altering or interrupting their ART (i.e., they can continue using the ritonavir or cobicistat dose associated with their ART in addition to the dose of ritonavir used with nirmatrelvir).
- In patients with advanced HIV who have suspected or laboratory-confirmed SARS-CoV-2 infection, health care professionals should consider HIV-associated opportunistic infections in the differential diagnosis of clinical symptoms and consider consulting an HIV specialist.
- When starting treatment for COVID-19 in patients with HIV, health care professionals should pay careful attention to potential drug-drug interactions and overlapping toxicities among COVID-19 treatments, antiretroviral (ARV) medications, antimicrobial therapies, and other medications.
- Patients with HIV should be offered the opportunity to participate in clinical trials of vaccines and potential treatments for COVID-19, when applicable.

- Patients with HIV who develop COVID-19, including those who require hospitalization, should continue their ART and opportunistic infection treatment and prophylaxis whenever possible.
- Health care professionals treating COVID-19 in people with HIV should consult an HIV specialist before adjusting or switching a patient's ARV medications.
- An ARV regimen should not be switched or adjusted (i.e., by adding ARV drugs to the regimen) for the purpose of preventing or treating SARS-CoV-2 infection.
- Health care professionals should consult an HIV specialist to determine the optimal time to initiate ART in people who present with COVID-19 and a new diagnosis of HIV.
- Health care professionals should advise individuals with asymptomatic SARS-CoV-2 infection or mild COVID-19 symptoms to seek influenza vaccination when they no longer require isolation.
- An influenza vaccine and a COVID-19 vaccine may be administered concurrently at a different injection site.
- Patients who are suspected of having either influenza or COVID-19 should be started on empiric treatment for influenza with oseltamivir as soon as possible and without waiting for the influenza test result.
- Antiviral treatment for influenza can be stopped when influenza has been ruled out by the results of a nucleic acid detection assay; the assay should be performed on upper respiratory tract specimens for nonintubated patients and on both upper and lower respiratory tract specimens for intubated patients.

- Evidence suggests that patients who are being treated for cancer may be at increased risk of severe COVID-19, and clinical outcomes of COVID-19 are generally worse in people with cancer than in people without cancer.
- Health care professionals should perform diagnostic molecular or antigen testing for SARS-CoV-2 in patients with cancer who develop signs and symptoms that suggest acute COVID-19; health care professionals should also perform diagnostic molecular testing in asymptomatic patients prior to procedures that require anesthesia and before initiating cytotoxic chemotherapy and long-acting biologic therapy.
- Decisions about administering cancer-directed therapy to patients with acute COVID-19 and those who are recovering from COVID-19 should be made on a case-by-case basis; health care professionals should consider the indication for chemotherapy, the goals of care, and the patient's history of tolerance to the treatment.
- Health care professionals who are treating COVID-19 in patients with cancer should consult a hematologist or oncologist before adjusting cancer-directed medications.
- Health care professionals should pay careful attention to potential overlapping toxicities and drug-drug interactions between drugs used to treat COVID-19 (e.g., ritonavir-boosted nirmatrelvir [Paxlovid], dexamethasone) and cancer-directed therapies, prophylactic antimicrobials, and other medications.
- Some patients with COVID-19 may have additional infections that develop during the course of treatment; these co-infections may complicate treatment and recovery; older adults or those with certain comorbidities or immunocompromising conditions may be at higher risk for these infections.

The use of immunomodulators such as dexamethasone, interleukin-6 inhibitors (e.g., tocilizumab, sarilumab), or Janus kinase inhibitors (e.g., baricitinib, tofacitinib) to treat COVID-19 may also be a risk factor for infectious complications; however, when these therapies are used appropriately, the benefits outweigh the risks. Infectious complications in patients with COVID-19 may be categorized as follows:

- **Coinfections at presentation** - although most individuals present with only SARS-CoV-2 infection, concomitant viral infections, including influenza and other respiratory viruses, were reported; community-acquired bacterial pneumonia was also reported, but it is uncommon, with a prevalence that ranges from 0% to 6% of people with SARS-CoV-2 infection. Antibacterial therapy is generally not recommended unless additional evidence for bacterial pneumonia is present (e.g., leukocytosis, the presence of a focal infiltrate on imaging).
- **Reactivation of latent infections** - there are case reports of underlying chronic hepatitis B virus and latent tuberculosis infections reactivating in patients with COVID-19 who receive immunomodulators as treatment, although the data are currently limited; reactivation of herpes simplex virus and varicella zoster virus infections was also reported; cases of severe and disseminated strongyloidiasis were reported in patients with COVID-19 during treatment with tocilizumab and corticosteroids. Health care professionals may consider initiating empiric treatment (e.g., with the antiparasitic drug ivermectin), with or without serologic testing, in patients who require immunomodulators for the treatment of COVID-19 and have come from areas where *Strongyloides* is endemic (i.e., tropical, subtropical, or warm temperate areas).

- **Nosocomial infections** - patients with COVID-19 may acquire common nosocomial infections, such as health care-acquired pneumonia (including ventilator-associated pneumonia), line-related bacteremia or fungemia, catheter-associated urinary tract infection, and *Clostridioides difficile*-associated diarrhea. Early diagnosis and treatment of these infections are important for improving outcomes in patients.
- **Opportunistic fungal infections** - invasive fungal infections, including aspergillosis and mucormycosis, were reported in patients with COVID-19; although these infections are relatively rare, they can be fatal, and they may be seen more commonly in patients who are immunocompromised or receiving mechanical ventilation. The majority of mucormycosis cases are associated with diabetes mellitus or the use of corticosteroids. The approach for managing these fungal infections should be the same as the approach for managing invasive fungal infections in health care settings.
- As observed with other respiratory viral infections, reinfection after recovery from prior infection was reported for SARS-CoV-2. Reinfection may occur as initial immune responses to the primary infection wane over time. Breakthrough SARS-CoV-2 infections (i.e., infection in individuals who completed the primary vaccine series with or without booster doses) also occurs. When compared with infection in people who are unvaccinated, breakthrough infection appears less likely to lead to severe illness or symptoms that persist ≥ 28 days; the time to breakthrough infection was reported to be shorter for patients with immunocompromising conditions (i.e., solid organ or bone marrow transplant recipients or people with HIV) than for those without immunocompromising conditions.

Managing Post-COVID Conditions

The term Post-COVID Conditions may refer to the long-term effects associated with COVID-19. Specific information and recommendations regarding the management of Post-COVID Conditions may be found below. The information found below was derived from materials provided by the CDC unless, otherwise, specified (CDC, 2022).

- Post-COVID Conditions are associated with a spectrum of physical, social, and psychological consequences, as well as functional limitations that can present substantial challenges to patient health, overall well-being, and quality of life.
- Post-COVID Conditions can be considered a lack of return to a usual state of health following acute COVID-19 illness; Post-COVID Conditions might also include development of new or recurrent symptoms or unmasking of a pre-existing condition that occurs after the symptoms of acute COVID-19 illness resolved.
- Most patients appear to recover from acute COVID-19 illness within four weeks; however, some patients may continue to have on-going symptoms or new or recurrent symptoms and conditions after the acute phase (note: the CDC considers Post-COVID Conditions to be present if recovery does not occur after the 4-week acute COVID-19 phase; the CDC uses the 4-week timeframe in describing Post-COVID Conditions to emphasize the importance of initial clinical evaluation and supportive care during the initial 4 to 12 weeks after acute COVID-19).
- Patients suffering from Post-COVID Conditions may present with persistent symptoms and conditions that begin at the time of acute COVID-19 illness; experience new-onset signs, symptoms, or conditions following

asymptomatic disease or a period of acute symptom relief or remission; have an evolution of symptoms and conditions that include some persistent symptoms (e.g., shortness of breath) with the addition of new symptoms or conditions over time (e.g., cognitive difficulties); display a worsening of pre-existing symptoms or conditions.

- Factors that may further complicate the presentation of Post-COVID Conditions include the following: pre-COVID comorbidities; physical deconditioning at baseline or after a prolonged acute disease course that can be nonspecific to COVID-19; physical and mental health consequences of illness with a long or complicated disease course, including depression and anxiety; social, environmental, and economic stressors caused by the COVID-19 pandemic.
- A wide range of other new or ongoing symptoms and clinical findings can occur in individuals with varying degrees of illness from acute SARS-CoV-2 infection, including patients who had mild or asymptomatic SARS-CoV-2 infection; these effects can overlap with multiorgan complications, or with effects of treatment or hospitalization; this category is heterogeneous, as it can include patients who have clinically important but poorly understood symptoms (e.g., difficulty thinking or concentrating, post-exertional malaise) that can be persistent or intermittent after initial acute infection with SARS-CoV-2; commonly reported symptoms include: dyspnea or increased respiratory effort, fatigue, cognitive impairment or "brain fog," cough, chest pain, headaches, heart palpitations, tachycardia, myalgia, paresthesia, abdominal pain, diarrhea, sleep difficulties, fever, lightheadedness, decreased mobility, pain, rash, mood changes, menstrual cycle irregularities, erectile dysfunction, and post-exertional malaise (note: post-exertional malaise may refer to the worsening of symptoms following

even minor physical or mental exertion, with symptoms typically worsening 12 to 48 hours after activity and lasting for days or weeks).

- Multiorgan system effects of SARS-CoV-2 infection were documented in most, if not all, body systems, including cardiovascular, pulmonary, renal, dermatologic, neurologic, gastrointestinal, endocrine, and psychiatric. Autoimmune conditions can also occur after COVID-19; a wide variety of health effects can persist after the acute COVID-19 illness resolved (e.g., pulmonary fibrosis, myocarditis); patients who experienced multisystem inflammatory syndrome (MIS) during or after COVID-19 illness may be at higher risk for on-going multiorgan system effects and Post-COVID Conditions; it is unknown how long multiorgan system effects might last and whether the effects could lead to chronic health conditions (note: multisystem inflammatory syndrome [MIS] may refer to a condition associated with COVID-19 in which different body parts become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs).
- Many Post-COVID Conditions can be diagnosed clinically based on history and findings on physical examination; others might require directed diagnostic testing.
- For most patients with possible Post-COVID Conditions, health care professionals may choose a conservative diagnostic approach in the first four to 12 weeks following SARS-CoV-2 infection; laboratory and imaging studies can often be normal or nondiagnostic in patients experiencing Post-COVID Conditions and symptoms may improve or resolve during the first few months after acute infection in some patients, further supporting an initial conservative approach to diagnostic testing; however, workup and testing should not be delayed when there are signs and symptoms of urgent

and potentially life-threatening clinical conditions (e.g., pulmonary embolism, myocardial infarction, pericarditis with effusion, stroke, renal failure); symptoms that persist beyond three months should prompt further evaluation.

- For patients who report previous infection with SARS-CoV-2, in addition to standard vital signs (i.e., blood pressure, heart rate, respiratory rate, pulse-oximetry, and body temperature) and body mass index, health care professionals should evaluate ambulatory pulse-oximetry for individuals presenting with respiratory symptoms, fatigue, or malaise; orthostatic vital signs should be evaluated for individuals reporting postural symptoms, dizziness, fatigue, cognitive impairment, or malaise.
- • For most patients, the goal of medical management of Post-COVID Conditions is to optimize function and quality of life; health care professionals, in consultation with the relevant specialists, should develop a comprehensive management plan based on their patients' presenting symptoms, underlying medical and psychiatric conditions, personal and social situations, and their treatment goals.
- Effective Post-COVID management may include the following:
 - Providing holistic patient-centered management approaches to improve patient quality of life and function and partnering with patients to identify achievable health goals;
 - Facilitating standardized, trauma-informed approaches to assessing symptoms and conditions;
 - Setting expectations with patients and their families that outcomes from Post-COVID Conditions differ among patients (e.g., some

patients may experience symptom improvement within the first three months, whereas others may continue to experience prolonged or worsening of symptoms);

- Continuing follow-up over the course of illness, with considerations of broadening the testing and management approach over time if symptoms do not improve or resolve, while remaining transparent that there is much more to learn about Post-COVID Conditions;
- Establishing partnerships with specialists for physical and mental health care, when needed, which may include comprehensive rehabilitation services;
- Connecting patients to social services when available, including assistance for other hardships (e.g., financial, family illness, bereavement, and caregiving) and resources on disability and reasonable accommodations for work or school, and connections to patient support groups.
- Many Post-COVID Conditions can be improved through already established symptom management approaches (e.g., breathing exercises to improve symptoms of dyspnea); creating a comprehensive rehabilitation plan may be helpful for some patients, and might include physical therapy, occupational therapy, speech therapy, language therapy, or vocational therapy, as well as neurologic rehabilitation for cognitive symptoms; a conservative physical rehabilitation plan might be indicated for some patients (e.g., persons with post-exertional malaise) and consultation with a physiatrist for cautious initiation of exercise and recommendations about pacing may be useful; gradual return to activity as tolerated could be helpful for most patients.

- Optimizing management of underlying medical conditions might include counseling on lifestyle components such as nutrition, sleep, and stress reduction (e.g., meditation and yoga).
- FDA-approved or over-the-counter medications, as well as vitamin or electrolyte supplements, may be helpful for indicated illnesses (e.g., headache and anxiety) or documented deficiencies (e.g., vitamin deficiency) after carefully weighing the benefits and risks of pharmaceutical interventions; health care professionals should inquire about any unprescribed medications, herbal remedies, supplements, or other treatments that patients may be taking for their Post-COVID Conditions and evaluate for drug interactions. Health care professionals should also conduct medication reconciliations (note: the term medication reconciliation may refer to a process of comparing the medications an individual is taking (or should be taking) with newly ordered medications) (Joint Commission, 2023). Medication reconciliations are intended to identify and resolve medication discrepancies; medication reconciliations should address medication duplications, omissions, and interactions, and the need to continue current medications; the type of information health care professionals should use to reconcile medications include (among others) medication name, dose, frequency, route, and purpose; health care professionals should identify the information that needs to be collected in order to reconcile current and newly ordered medications and to safely prescribe medications in the future (Joint Commission, 2023).
- Recognizing and validating the impact of illness on quality of life should be part of the ongoing health care professional and patient interaction. Health care professionals should encourage patients to take part in support groups.

- Patients with disabilities may require close follow-up related to functional limitations. Many adults with disabilities already experience challenges in accessing health services, and they may need different clinical management of their symptoms after SARS-CoV-2 infection, especially if their long-term symptoms are difficult to distinguish from their underlying chronic conditions.

Section 6 Summary

It is absolutely essential that health care organizations optimize infection treatment. Health care facilities should follow recommendations provided by organizations such as the CDC to help treat and manage infections. Health care organizations should develop and/or update organizational policies and procedures to reflect such recommendations.

Section 6 Key Concepts

- The sixth key aspect of organizational improvement is optimizing infection treatment.
- The CDC recommends that all nursing homes and other health care facilities take steps to improve antibiotic prescribing practices and reduce inappropriate use.
- Antibiotic stewardships require leadership commitment.
- Nursing homes and other health care facilities should identify individuals accountable for antibiotic stewardship activities.
- When an influenza outbreak is identified in a long-term care facility, influenza testing should be done for any resident with one or more acute

respiratory symptoms, with or without fever, or any of the following without respiratory symptoms: temperature elevation, temperature reduction, or behavioral change.

- Empiric antiviral treatment should be administered as soon as possible to any resident or patient with suspected influenza during an influenza outbreak without waiting for the results of influenza diagnostic testing.
- Everyone with symptoms that are consistent with COVID-19 and people with known high-risk exposures to SARS-CoV-2 should be tested for SARS-CoV-2 infection.
- Symptom management should be initiated for all nonhospitalized adults with mild to moderate COVID-19; for individuals who are at high risk of progression to severe disease; several antiviral therapeutic options are available to reduce the risk of hospitalization or death.
- The main goal of therapeutic management for nonhospitalized patients with COVID-19 is to prevent progression to severe disease, hospitalization, or death.
- Health care professionals should consider ritonavir-boosted nirmatrelvir in most high-risk, nonhospitalized patients with mild to moderate COVID-19.
- Post-COVID Conditions can be considered a lack of return to a usual state of health following acute COVID-19 illness.
- For most patients, the goal of medical management of Post-COVID Conditions is to optimize function and quality of life.
- Many Post-COVID Conditions can be improved through already established symptom management approaches.

Section 6 Key Terms

Antibiotic stewardship - a set of commitments and actions designed to maximize the treatment of infections while reducing the adverse events associated with antibiotic use

Hives - pink/red raised areas of skin that are intensely itchy

Angioedema - localized edema without hives affecting the abdomen, face, extremities, genitalia, oropharynx, or larynx

Anaphylaxis - a life-threatening allergic reaction

Antibiograms - tables developed by a microbiology laboratory showing the percent susceptibility for a panel of common bacteria tested against a panel of common antibiotics

Antibiotic time out - a formal process designed to prompt a reassessment of the ongoing need for and choice of an antibiotic with data, such as: the clinical response, additional diagnostic information, and alternate explanations for the status change which prompted the antibiotic start

Process measures - tracking how and why antibiotics are prescribed

Antibiotic use measures - tracking how often and how many antibiotics are prescribed

Antibiotic outcome measures - tracking the adverse outcomes and costs from antibiotics

Breakthrough SARS-CoV-2 infection - infection in individuals who completed the primary vaccine series with or without booster doses

Post-COVID Conditions - the long-term effects associated with COVID-19

Post-exertional malaise - the worsening of symptoms following even minor physical or mental exertion, with symptoms typically worsening 12 to 48 hours after activity and lasting for days or weeks

Multisystem inflammatory syndrome (MIS) - a condition associated with COVID-19 in which different body parts become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs

Medication reconciliation - a process of comparing the medications an individual is taking (or should be taking) with newly ordered medications (Joint Commission, 2023)

Section 6 Personal Reflection Question

How can health care professionals ensure infection treatment recommendations are followed within their health care organization?

Section 7: Preventing Patient Safety Events

Patient safety events can jeopardize an individual's health, overall well-being, and quality of life. Patient safety events can also lead to death, which is why the seventh key aspect of organizational improvement is preventing patient safety events. Specific information and recommendations regarding patient safety events may be found below. The information found below was derived from materials provided by the Joint Commission (Joint Commission, 2021; Joint Commission, 2023).

- The term patient safety event may refer to an event, incident, or condition that could have resulted or did result in harm to a patient.

- To help prevent patient safety events, health care organizations should work towards becoming a learning organization; a learning organization is one in which people learn continuously, thereby enhancing their capabilities to create and innovate.
- Learning organizations uphold the following five principles: team learning, shared visions and goals, a shared mental model, individual commitment to lifelong learning, and systems thinking.
- In a learning organization, patient safety events are viewed as opportunities for learning and improvement.
- Leaders in learning organizations typically adopt a transparent, nonpunitive approach to reporting so that the organization can report to learn and can collectively learn from patient safety events.
- In order to become a learning organization, a health care organization must have a fair and just safety culture, a strong reporting system, and a commitment to put data to work by driving improvement (note: when patient safety events are continuously reported, experts within the organization can define the problems, identify solutions, achieve sustainable results, and disseminate the changes or lessons learned to the rest of the health care organization).
- In a learning organization, the organization provides health care professionals and other staff with information regarding improvements based on reported concerns.
- Organization leaders and staff provide the foundation for an effective patient safety system by promoting learning; motivating health care professionals to uphold a fair and just safety culture; providing a

transparent environment in which quality measures and patient harm events are freely shared with health care professionals; modeling health care professional behavior; addressing intimidating behavior that might undermine the safety culture; providing the resources and training necessary to take on improvement initiatives.

- A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for health care organizations striving to become learning organizations.
- In a strong safety culture, the health care organization has an unrelenting commitment to safety and to do no harm.
- The safety culture of a health care organization is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety.
- Qualities of a safety culture include the following: health care professionals that value transparency, accountability, and mutual respect; safety is the first priority; behaviors that undermine a culture of safety are not acceptable, and thus should be reported to organizational leadership by health care professionals, patients, and families for the purpose of fostering risk reduction; collective mindfulness is present so health care professionals realize that systems have the potential to fail and health care professionals are focused on finding hazardous conditions or close calls at early stages before a patient may be harmed; health care professionals do not view close calls as evidence that the system prevented an error but rather as evidence that the system needs to be further improved to prevent any defects; health care professionals do not deny or cover up errors but rather want to report errors to learn from mistakes and improve the system flaws

that contribute to or enable patient safety events; health care professionals know that their leaders will focus not on blaming health care professionals involved in errors but on the system issues that contributed to or enabled the patient safety event; by reporting and learning from patient safety events, health care professionals create a learning organization.

- A safety culture operates effectively when the organization fosters a cycle of trust, reporting, and improvement.
- In health care organizations that have a strong safety culture, health care professionals trust their coworkers and leaders to support them when they identify and report a patient safety event (note: when trust is established, staff are more likely to report patient safety events, and organizations can use these reports to inform their improvement efforts).
- In the trust-report-improve cycle, leaders foster trust, which enables health care professionals and other staff to report, which enables the health care organization to improve; in turn, health care professionals and other staff see that their reporting contributes to actual improvement, which bolsters their trust; thus, the trust-report-improve cycle reinforces itself and helps improve patient outcomes.
- Leaders, health care professionals, and other staff should ensure that unprofessional behaviors within their health care organization are addressed, so as not to inhibit others from reporting safety concerns.
- A fair and just safety culture is required for health care professionals to trust that they can report patient safety events without being treated punitively; in order to accomplish this, health care organizations should provide and encourage the use of a standardized reporting process for health care professionals to report patient safety events (note: a fair and just culture

holds individuals accountable for their actions but does not punish individuals for issues attributed to flawed systems or processes).

- Leaders within a health care organization should assess errors and patterns of behavior in a manner that is applied consistently, with the goal of eliminating behaviors that undermine a culture of safety.
- When there is continuous reporting for adverse events, close calls, and hazardous conditions, the health care organization can analyze the patient safety events, change the process or system to improve safety, and disseminate the changes or lessons learned to the rest of the organization.
- When health care organizations collect data or measure health care professional compliance with evidence-based care processes or patient outcomes, they can manage and improve those processes or outcomes and, ultimately, improve patient safety; the effective use of data enables organizations to identify problems, prioritize issues, develop solutions, and track to determine success; objective data can be used to support decisions, influence health care professionals to change their behaviors, and to comply with evidence-based care guidelines (note: objective data may refer to information free of subjective judgment, bias, or opinion; information that can be measured or verified by another individual).
- Health care organizations should collect data to monitor conditions in the environment; identify risks for acquiring and transmitting infections; guide decisions and to understand variation in the performance of processes supporting safety and quality; have an organization wide, integrated patient safety program; evaluate the effectiveness of a medication management system; monitor performance; improve performance on an ongoing basis.

- When the data is collected and appropriate analytic techniques are applied, it enables the health care organization to monitor the performance of a system, detect variation, and identify opportunities to improve; this can help the health care organization not only understand the current performance of organization systems but can also help it predict its performance going forward.
- Analyzing data with tools such as run charts, statistical process control (SPC) charts, and capability charts can help a health care organization determine what occurred in a system and provide clues as to why the system responded as it did.
- Health care organizations should ensure that data and subsequent information is presented in a clear manner to health care professionals; information is shared with the appropriate groups throughout the health care organization; opportunities for improvement and actions to be taken are communicated; improvements are recognized.
- Proactive risk reduction prevents harm before it reaches the patient; by engaging in proactive risk reduction, a health care organization can correct process problems in order to reduce the likelihood of experiencing adverse events.
- In a proactive risk assessment the health care organization evaluates a process to see how it could potentially fail, to understand the consequences of such a failure, and to identify parts of the process that need improvement.
- When conducting a proactive risk assessment, health care organizations should prioritize high-risk, high-frequency areas; areas of risk are identified from internal sources such as ongoing monitoring of the environment,

results of previous proactive risk assessments, from results of data collection activities.

- Hazardous (or unsafe) conditions provide an opportunity for a health care organization to take a proactive approach to reduce harm; organizations also benefit from identifying hazardous conditions, while designing new processes that could impact patient safety (note: a hazardous condition may refer to any circumstance that increases the probability of a patient safety event).
- A number of tools are available to help health care organizations conduct a proactive risk assessment. One of the best known of these tools is the Failure Modes and Effects Analysis (FMEA); A FMEA can be used to prospectively examine how failures could occur during high-risk processes and, ultimately, how to prevent them.
- To achieve the best outcomes, patients and families should be actively engaged in decisions about their health care and should have broader access to information and support.
- A patient-centered approach to health care can help health care organizations assess and enhance patient engagement.
- To achieve patient engagement safety must be a priority; patients and families should be partners at every level of care; staffing levels should be sufficient; and the health care organization should have a focus on measurement, learning, and improvement.
- Health care organizations can adopt a number of strategies to support and improve patient engagement, including the following: promoting a culture

change, adopting transitional care models, and leveraging health information technology capabilities.

- A sentinel event is a type of patient safety event.
- As previously mentioned, a sentinel event is an unanticipated event in a health care setting that results in death or serious physical or psychological injury to a patient(s), not related to the natural course of the patient's illness.
- Sentinel events are not only events that occur during the care and treatment of individuals; physical and verbal violence, abductions, and power failures are all potential sentinel events that can affect the health care organization and its residents.
- Examples of sentinel events include the following:
 - Suicide of any resident receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge.
 - Homicide of any resident receiving care, treatment, and services while on site of a health care organization or while under the care or supervision of the organization.
 - Homicide of a health care professional, staff member, visitor, or vendor while on site at a health care organization or while providing care or supervision to residents.
 - Severe morbidity leading to permanent harm or severe harm (note: permanent harm may refer to an event or condition that reaches the individual, resulting in any level of harm that permanently alters and/or affects an individual's baseline health or wellbeing)

- Sexual abuse/assault of any resident receiving care, treatment, and services while on site at a health care organization or while under the care or supervision of the organization
- Sexual abuse/assault of a health care professional, staff member, visitor, or vendor while on site at a health care organization or while providing care or supervision to residents
- Physical assault (leading to death, permanent harm, or severe harm) of any resident receiving care, treatment, and services while on site at the organization or while under the care or supervision of a health care organization
- Physical assault (leading to death, permanent harm, or severe harm) of a health care professional, staff member, visitor, or vendor while on site at the organization or while providing care or supervision to residents
- Abduction of any resident receiving care, treatment, and services
- Any elopement (that is, unauthorized departure) of a resident from a staffed around-the-clock care setting, leading to death, permanent harm, or severe harm to the resident
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct resident care caused by equipment operated and used by the organization (note: to be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present)
- Fall in a staffed-around-the-clock care setting or fall in a care setting not staffed around the clock during a time when staff are present

resulting in any of the following: any fracture, surgery, casting, traction, death, or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)

- All sentinel events should be reviewed by health care organizations.
- An appropriate response to a sentinel event includes all of the following:
 - A formalized team response that stabilizes the resident, discloses the event to the resident and family, and provides support for the family as well as the staff involved in the event
 - Notification of organization leadership
 - Immediate investigation
 - Completion of a comprehensive systematic analysis for identifying the causal and contributory factors
 - Strong corrective actions derived from the identified causal and contributing factors that eliminate or control system hazards or vulnerabilities and result in sustainable improvement over time
 - Timeline for implementation of corrective actions
 - Systemic improvement with measurable outcomes
- A health care organization should complete a comprehensive systematic analysis to identify the causal and contributory factors to any known sentinel event. A comprehensive systematic analysis is defined as a process for identifying basic or causal factors underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis, for example, is one common type of comprehensive

systematic analysis. The organization can determine its internal process, tools, and methodologies to conduct such an analysis. Any comprehensive systematic analysis should include a bibliography of recent evidence-based literature to guide the organization in developing a strong corrective action plan with the use of evidence-based practices or tools.

- A health care organization's comprehensive systematic analysis should identify system vulnerabilities so that they can be eliminated or mitigated. It should not focus on individual health care professional's performance, but should seek out underlying system-level causations that manifested in personnel-related performance issues.
- Health care organizations should consider the following guidelines when developing causative factor statements:
 - Clearly show the cause-and-effect relationship
 - Use specific and accurate descriptors for what occurred, rather than negative and vague words
 - Classify a failure to act as a causal factor only when there is a preexisting duty to act
- An end-product of the comprehensive systematic analysis is a corrective action plan. The corrective action plan identifies the strategies that the health care organization intends to implement to reduce the risk of similar events occurring in the future.
- The health care organization should identify at least one intermediate or stronger action to eliminate or mitigate system hazards or vulnerabilities identified in the comprehensive systematic analysis. The corrective action plan should address the following:

- Identifying corrective actions to eliminate or reduce system hazards or vulnerabilities directly related to causal and contributory factors
- Identifying who is responsible for implementing corrective actions
- Determining timelines to complete corrective actions
- Developing strategies to evaluate the effectiveness of the corrective actions
- Developing strategies to sustain the change

Section 7 Summary

Health care organizations should work to prevent patient safety events. Health care facilities should follow recommendations provided by organizations such as the Joint Commission to help prevent patient safety events. Health care organizations should develop and/or update organizational policies and procedures to reflect such recommendations.

Section 7 Key Concepts

- The seventh key aspect of organizational improvement is preventing patient safety events.
- Health care organizations should work towards becoming a learning organization; a learning organization is one in which people learn continuously, thereby enhancing their capabilities to create and innovate.
- In a learning organization, patient safety events are viewed as opportunities for learning and improvement.

- A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for health care organizations striving to become learning organizations.
- A safety culture operates effectively when the organization fosters a cycle of trust, reporting, and improvement.
- A patient-centered approach to health care can help health care organizations assess and enhance patient engagement.
- A sentinel event is a type of patient safety event.
- All sentinel events should be reviewed by health care organizations.

Section 7 Key Terms

Patient safety event - an event, incident, or condition that could have resulted or did result in harm to a patient (Joint Commission, 2021)

Learning organization - an organization in which people learn continuously, thereby enhancing their capabilities to create and innovate (Joint Commission, 2021)

Objective data - information free of subjective judgment, bias, or opinion; information that can be measured or verified by another individual (Joint Commission, 2021)

Hazardous condition - any circumstance that increases the probability of a patient safety event (Joint Commission, 2021)

Failure Modes and Effects Analysis (FMEA) - a type of analysis that can be used to prospectively examine how failures could occur during high-risk processes and, ultimately, how to prevent them (Joint Commission, 2021)

Permanent harm - an event or condition that reaches the individual, resulting in any level of harm that permanently alters and/or affects an individual's baseline health or wellbeing (Joint Commission, 2023)

Comprehensive systematic analysis - a process for identifying basic or causal factors underlying variation in performance, including the occurrence or possible occurrence of a sentinel event (Joint Commission, 2023)

Corrective action plan - an end-product of the comprehensive systematic analysis; a plan that identifies the strategies that a health care organization intends to implement to reduce the risk of similar events occurring in the future (Joint Commission, 2023)

Section 7 Personal Reflection Question

How can health care professionals establish a cycle of trust, reporting, and improvement within their health care organization?

Section 8: Emergency Preparedness and Response

Safety measures can prevent emergencies. However, emergencies may still occur in health care facilities. That being the case, health care professionals should be prepared to meet health care emergencies, and embrace the eighth and final key aspect of organizational improvement, which is emergency preparedness and response. This section of the course will highlight emergency procedures. Health care organizations may use the information found within this section to develop training and educational offerings to health care professionals.

Emergency Procedures

First Aid for a Conscious Choking Adult

When presented by a conscious choking adult (or older adult), health care professionals should consider the procedure highlighted below. The information found below was derived from materials provided by the American Red Cross (American Red Cross, 2018).

- Check the scene and the resident; ask the resident if he or she is choking; the health care professional should identify himself or herself and ask the resident if he or she requires help; if the resident is coughing forcefully, encourage continued coughing.
- Give five back blows - the health care professional should position himself or herself behind the resident, lean the resident forward and strike the resident firmly between the shoulder blades using the heel of the hand.
- Give five abdominal thrusts - while still standing behind the resident, wrap the arms around the resident's waist; place the thumb side of the fist just above the resident's belly button; clasp the fist with the other hand and give quick, upward thrusts into the abdomen (note: if the resident is too big to reach around, the health care professional should give chest thrusts instead of abdominal thrusts; to give chest thrusts, place the thumb side of the fist over the center of the resident's breastbone instead of above the resident's belly button, grab the fist with the other hand and give quick, upward thrusts).
- Continue giving back blows and abdominal thrusts until: the object is forced out; the resident becomes unconscious; the resident can breathe or cough forcefully.

- Engage in the following completion steps, when appropriate: complete all required documentation; adjust equipment for safety (e.g., lower the resident's bed to the level specified in the resident's care plan; make sure the wheels on the bed are locked; place the resident's method of calling for help within reach; lower or raise the side rails according to the resident's care plan); ensure the resident's comfort and good body alignment, when applicable; clean up the work area; engage in hand hygiene, when appropriate (note: the resident should receive a medical evaluation after the emergency is complete).

Adult Basic Life Support for Health Care Professionals

Basic life support may refer to a type of care that can be applied to an individual who is experiencing a health care emergency, such as: cardiac arrest, respiratory distress, or an obstructed airway. Basic life support may include cardiopulmonary resuscitation (CPR). Cardiopulmonary resuscitation (CPR) may refer to an emergency life saving procedure that may be performed when an individual's heart stops beating. Specific information regarding basic life support may be found below. The information found below was derived from materials provided by the American Heart Association (American Heart Association, 2020).

- First, verify scene safety.
- The health care professional should then check for responsiveness; call for help, if appropriate; activate emergency response system via mobile device, if appropriate; obtain an automated external defibrillator (AED) and emergency equipment (or send someone to do so) (note: an automated external defibrillator [AED] may refer to a medical device designed to analyze the heart rhythm and deliver an electric shock to individuals with ventricular fibrillation to restore the heart rhythm to normal).

- Determine if the resident is breathing or only gasping and check pulse (simultaneously); determine if the pulse can definitely be felt within 10 seconds.
- If the resident is breathing normally and a pulse is felt, monitor until emergency responders arrive.
- If the resident is not breathing normally and a pulse is felt, provide rescue breathing, one breath every six seconds or 10 breaths/min; check pulse every two minutes; if there is not a pulse, start CPR; if there is potential for an opioid overdose, administer naloxone if available per protocol (note: an opioid overdose may refer to a life-threatening emergency that is related to opioid use).
- If the resident is not breathing normally or only gasping, and a pulse is not felt, start CPR; perform cycles of 30 compressions and two breaths; use an AED as soon as it is available (note: by this time in all scenarios, an emergency response system or backup should be activated, and an AED and emergency equipment are retrieved or someone should be retrieving them).
- When the AED arrives, check rhythm and determine if there is a shockable rhythm (note: a shockable rhythm may refer to a heart rhythm that may be treated with defibrillation).
- If there is a shockable rhythm, give one shock; resume CPR immediately for two minutes (until prompted by the AED to allow rhythm check); continue until Advanced Life Support (ALS) providers take over or the victim starts to move.

- If there is not a shockable rhythm, resume CPR immediately for two minutes (until prompted by the AED to allow rhythm check); continue until ALS providers take over or the victim starts to move.

Adult Bradycardia Event

Bradycardia may refer to a slow heart rate (e.g., a resident's heart beats fewer than 60 times per minute). When presented by an adult bradycardia event, health care professionals should consider the procedure highlighted below. The information found below was derived from materials provided by the American Heart Association (American Heart Association, 2020).

- First, assess the appropriateness for clinical condition (e.g., heart rate).
- Then identify and treat underlying cause (e.g., maintain resident airway; assist breathing as necessary; oxygen [if hypoxemic]; cardiac monitor to identify rhythm; monitor blood pressure and oximetry; IV access; 12-Lead ECG if available; consider possible hypoxic and toxicologic causes).
- Assess if a persistent bradyarrhythmia is causing: hypotension, altered mental status, signs of shock, ischemic chest discomfort, and/or acute heart failure.
- If the assessment is negative, monitor and observe.
- If the assessment is positive, administer atropine (note: atropine dose - first dose: 1 mg bolus; repeat every 3 - 5 minutes; maximum dose: 3 mg).
- If atropine is ineffective, consider the following: transcutaneous pacing, dopamine infusion, or epinephrine infusion (note: transcutaneous pacing may refer to a temporary method of cardiac pacing that may be used on individuals with severe symptomatic bradyarrhythmias caused by high-

grade atrioventricular block, sinus node dysfunction, or bradycardic arrest; dopamine IV infusion - usual infusion rate is 5 - 20 mcg/kg per minute; epinephrine IV infusion - 2 - 10 mcg per minute infusion, which may be titrated to response).

Adult Tachycardia Event

Tachycardia in adults refers to a heart rate of more than 100 beats per minute. When presented by an adult tachycardia event, health care professionals should consider the procedure highlighted below. The information found below was derived from materials provided by the American Heart Association (American Heart Association, 2020).

- First, assess appropriateness for clinical condition.
- Then identify and treat the underlying cause (maintain patent airway; assist breathing as necessary; oxygen [if hypoxemic]; cardiac monitor to identify rhythm; monitor blood pressure and oximetry; IV access; 12-lead ECG, if available).
- Assess if a persistent tachyarrhythmia is causing: hypotension, altered mental status, signs of shock, ischemic chest discomfort, and/or acute heart failure.
- If the assessment is negative, consider vagal maneuvers (if regular); adenosine (if regular); β -blocker or calcium channel blocker; expert consultation; or adenosine only if regular and monomorphic; antiarrhythmic infusion (note: if refractory, consider underlying cause; need to increase energy level for next cardioversion; addition of anti-arrhythmic drug; expert consultation).

- If the assessment is positive, consider synchronized cardioversion, sedation, or if regular narrow complex, consider adenosine (note: if refractory, consider underlying cause; need to increase energy level for next cardioversion; addition of anti-arrhythmic drug; expert consultation; synchronized cardioversion is a procedure that applies a transthoracic electrical current to the anterior chest to terminate a life-threatening or unstable tachycardic arrhythmia).

Opioid-Associated Emergency for Health Care Professionals

An opioid-associated emergency may refer to an emergency that is related to opioid use and characterized by potential or actual opioid poisoning and respiratory depression. Specific information regarding an opioid-associated emergency may be found below. The information found below was derived from materials provided by the American Heart Association (American Heart Association, 2020).

- If a health care professional suspects opioid poisoning, he or she should check for responsiveness; call for assistance, when appropriate; activate the emergency response system, when appropriate; obtain naloxone and an AED, if available (note: naloxone is a medication approved by the U.S. Food and Drug Administration [FDA] designed to rapidly reverse an opioid overdose).
- The health care professional should determine if the resident is breathing normally.
- If the resident is breathing normally, the health care professional should prevent deterioration; tap and shout; open the airway and reposition;

consider naloxone; consider transport; the health care professional should also maintain an ongoing assessment for responsiveness and breathing.

- If the resident is not breathing normally, the health care professional should determine if the resident has a pulse.
- If the resident has a pulse, the health care professional should support ventilation; open the airway and reposition; provide rescue breathing or a bag-mask device; administer naloxone.
- If the resident does not have a pulse, the health care professional should start CPR; use an AED; consider naloxone; consider basic life support/ cardiac arrest procedures.

Section 8 Summary

Health care professionals should be prepared to meet health care emergencies. When responding to an emergency, health care professionals should follow recommendations provided by organizations such as the American Heart Association. Health care organizations should develop and/or update organizational policies and procedures to reflect such recommendations.

Section 8 Key Concepts

- The eighth key aspect of organizational improvement is emergency preparedness and response.
- Health care professionals should adequately perform emergency procedures, when necessary.

Section 8 Key Terms

Basic life support - a type of care that can be applied to an individual who is experiencing a health care emergency, such as cardiac arrest, respiratory distress, or an obstructed airway

Cardiopulmonary resuscitation (CPR) - an emergency life saving procedure that may be performed when an individual's heart stops beating

Automated external defibrillator (AED) - a medical device designed to analyze the heart rhythm and deliver an electric shock to individuals with ventricular fibrillation to restore the heart rhythm to normal

Opioid overdose - a life-threatening emergency that is related to opioid use

Shockable rhythm - a heart rhythm that may be treated with defibrillation

Bradycardia - a slow heart rate

Transcutaneous pacing - a temporary method of cardiac pacing that may be used on individuals with severe symptomatic bradyarrhythmias caused by high-grade atrioventricular block, sinus node dysfunction, or bradycardic arrest

Tachycardia - a heart rate of more than 100 beats per minute

Synchronized cardioversion - a procedure that applies a transthoracic electrical current to the anterior chest to terminate a life-threatening or unstable tachycardic arrhythmia

Opioid-associated emergency - an emergency that is related to opioid use and characterized by potential or actual opioid poisoning and respiratory depression

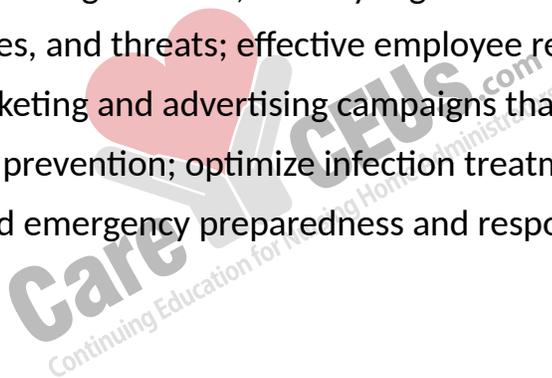
Naloxone - a medication approved by the U.S. Food and Drug Administration (FDA) designed to rapidly reverse an opioid overdose

Section 8 Personal Reflection Question

How can health care organizations ensure that health care professionals are prepared to respond to health care emergencies?

Conclusion

Health care organizations should work to continually improve in order to meet the growing demands of government agencies and residents. Health care organizations should also improve to ensure safe and effective care is delivered to those in need. Health care organizations can improve through the eight key aspects of organizational improvement, which include: establish a mission, vision, and values for a health care organization; identify organizational strengths, weaknesses, opportunities, and threats; effective employee recruitment and motivation; develop marketing and advertising campaigns that adhere to relevant laws; maximize infection prevention; optimize infection treatment; prevent patient safety events; and emergency preparedness and response.



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