TOP DEFICIENCIES SEEN IN HOME HEALTH AND HOW TO DECREASE YOUR AGENCY’S VULNERABILITY

Presented by:
Sharon M. Litwin, RN, BSHS, MHA, HCS-D
Senior Manager - Coding & Clinical Consulting
Healthcare Provider Solutions
INTRODUCTION

- Explain the types of deficiencies
- Discuss examples of commonly seen deficiencies
- Identify steps your Agency can take to avoid deficiencies
- Discuss processes your Agency can implement to comply with difficult CoPs
TYPES OF DEFICIENCIES
DEFICIENCIES

• Types:
  • Standard Level
  • Condition Level
  • Immediate Jeopardy (IJ)

• Increase in Condition Level Deficiencies and IJ seen
• Can lead to Non-Monetary and/or Monetary Sanctions
• SOM- Appendix Q- guidance for identifying immediate jeopardy revised 3/2019
  • IJ increased to $21,800 per day per citation!
LEVEL 1 STANDARDS - HIGHEST PRIORITY STANDARDS

- Process standards that are associated with high-quality patient care
- Administrative standards that closely relate to the agency’s ability to deliver high-quality patient care
- Surveyors must review all of these standards during a standard survey
- **Examples:**
  - Investigation of complaints
  - Initial assessment visit
  - Plan of care
CONDITION LEVEL VS STANDARD LEVEL DEFICIENCIES

- Each condition has standards that are associated with it
  - G tags

- Standard level deficiency
  - Not compliant with one of the standards (G tags) under a condition

- Condition level deficiency
  - Non-compliant with:
    - The entire condition or,
    - Several of the standards associated under the condition or,
    - Scope and severity warranted
CONDITION LEVEL VS STANDARD LEVEL DEFICIENCIES

- Standard Level:
  - Must write a plan of correction
  - May or may not have a follow up survey to check compliance and completion of corrective action plan
  - Follow-up visit depends on the scope and severity of the deficiency
CONDITION LEVEL VS STANDARD LEVEL DEFICIENCIES

- **Condition Level**
  - Must write a detailed plan of correction
  - The state or accrediting body notifies Medicare that agency has a Condition Level Deficiency
    - Agency is at risk of losing Medicare certification if the condition is not 'abated’ (i.e., fixed quickly – typically within 10 days)
  - Typically, will have a return visit in 45 days from last day of survey
IMMEDIATE JEOPARDY (IJ)

- SOM- Appendix Q- guidance for identifying immediate jeopardy revised.
- Immediate Jeopardy (IJ)- Defined- HHA’s non-compliance with a CoP has placed the health & safety of patients at risk for serious harm, serious injury, serious impairment or death.
- Immediate Jeopardy (IJ)- Most severe & egregious threat to health & safety of patient
- Immediate Jeopardy carries the most serious sanctions for the providers
- HHA Must FIX IJs immediately - Don’t wait for written report
- Follow up survey within 7 - 27 days
SANCTIONS

- Will be given for immediate jeopardy
- May be given for:
  - Condition level deficiency
  - Repeat standard level deficiency (often escalates to a Condition)
- Types:
  - Directed education
  - Directed plan of care
  - Interim management provided by CMS designee
  - Monetary (CMP)
  - Suspension of payments for all new admissions
MONETARY PENALTIES

- The per-day penalty begins accruing on the final day of the survey that identifies non-compliance.
- The penalty continues until the agency achieves compliance or when the provider agreement is terminated.
- Agencies have up to six months to comply, beginning from the last day of the original survey that determined non-compliance or CMS will terminate the agency.
- CMP are Massive – can be given per citation per day:
  - $500-$21,800 per day.
TOP HOME HEALTH DEFICIENCIES

Quality, Certification & Oversight Reports
# 2020 TOP HOME HEALTH CITATIONS

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<tr>
<th>Rank</th>
<th>Tag Number</th>
<th>Tag Description</th>
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<tbody>
<tr>
<td>#1</td>
<td>G574</td>
<td>POC must include the following</td>
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<tr>
<td>#2</td>
<td>G536</td>
<td>Review of all current Medications</td>
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<td>#3</td>
<td>G682</td>
<td>Infection Prevention</td>
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<td>#4</td>
<td>G572</td>
<td>Plan of Care</td>
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<td>#5</td>
<td>G710</td>
<td>Provide services in Plan of Care</td>
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<td>G578</td>
<td>Conformance with physician orders</td>
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<td>#7</td>
<td>G580</td>
<td>Only as ordered by a physician</td>
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<td>#8</td>
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§484.60(a)(2) – Standard: Content Individualized Plan of Care
G574 -(A)(2) THE INDIVIDUALIZED PLAN OF CARE

Must include the following:

- (i) All pertinent diagnoses;
- (ii) The patient’s mental, psychosocial, and cognitive status;
- (iii) The types of services, supplies, and equipment required;
- (iv) The frequency and duration of visits to be made;
- (v) Prognosis;
- (vi) Rehabilitation potential;
- (vii) Functional limitations;
Must include the following:

- (viii) Activities permitted;
- (ix) Nutritional requirements;
- (x) All medications and treatments;
- (xi) Safety measures to protect against injury;
- (xii) A description of the patient’s risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors.
G574 -(A)(2) THE INDIVIDUALIZED PLAN OF CARE

- Must include the following:
  - (xiii) Patient and caregiver education and training to facilitate timely discharge;
  - (xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;
  - (xv) Information related to any advanced directives; and
  - (xvi) Any additional items the HHA or physician may choose to include.
G574 – KEY AREAS OF NONCOMPLIANCE

- Goals are nonspecific – all patients had the same goals addressing standard areas such as infection control, medication knowledge and falls.
  - Goals not specific to the patient’s diagnoses, orders and interventions.

- Medication issues - examples:
  - Patient taking Warfarin daily, no safety measures noted.
  - Patient taking Insulin, no diagnosis for diabetes listed on POC.

- POC documents Low Sodium Diet and visit notes document patient on Regular diet.
G574 – KEY AREAS OF NONCOMPLIANCE

- Intervention issues

- **Examples:**
  - Daily weights ordered - no weights documented in visit notes.
  - Therapy orders did not include specific procedures and modalities to be provided.

- No documentation of the patient’s risk for emergency department visits and hospital readmission or interventions to address the risk factors noted on the POC.

- Orders for disciplines did not include the frequency, and duration of the services to be provided.
G574 – INDIVIDUALIZED PLAN OF CARE

Action Plan:

- Ensure -
  - Documentation of all pertinent diagnoses and related interventions on the POC
  - Goals are specific to the patient’s diagnoses, orders and interventions
  - Orders for all disciplines include the frequency, and duration of the service provided
  - Documentation of the patient’s risk for ER visits and hospital readmission and interventions to address the risk factors noted on the POC.
  - Therapy orders include the specific procedures and modalities to be provided
  - Complete medication orders including an indicator for the administration of PRN medications
  - Orders state WHO is going to do a procedure and WHEN

- If problem is noted, consider adding indicator to QAPI program.
§484.60 CARE PLANNING, COORDINATION OF SERVICES, & QUALITY OF CARE
§484.60(a)(1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state license, certification, or registration.

If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan.
The CARES Act allowed NPs, CNSs, and PAs (as those terms are defined in the Act), to practice at the top of their state licensure to certify eligibility for home health services, establish and periodically review the home health plan of care, and supervise the provision of items and services for beneficiaries under the Medicare home health benefit.

NPs, CNSs, and PAs are required to practice in accordance with state law in the state in which the individual performs services.

CMS amended the regulations so that the allowed practitioner can also perform the face-to-face encounter for the patient they are certifying eligibility.

These regulation changes were not time limited to the period of the COVID–19 PHE.

In the 2021 final rule CMS finalized regulation text changes at §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 regarding allowed practitioner certification as a condition for payment for home health services.
“Patient-specific measurable outcome” is a change in health status, functional status, or knowledge, which occurs over time in response to a health care intervention that provides end-result functional and physical health improvement/stabilization.

Patient-specific goals must be individualized to the patient based on the patient’s medical diagnosis, physician’s orders, comprehensive assessment and patient input.

Progress/non-progress toward achieving the goals is evaluated through measurable outcomes.

The HHA must include goals for the patient, as well as patient preferences and service schedules, as a part of the plan of care (See §484.60(a)(2) below).

“Periodically reviewed” means every 60 days or more frequently when indicated by changes in the patient’s condition (see §484.60(c)(1)).
G572 – INTERPRETIVE GUIDELINES

- The patient's physician orders for treatments and services are the foundation of the plan of care.
- If the HHA misses a visit or a treatment or service as required by the plan of care, which results in any potential for clinical impact upon the patient, then the HHA must notify the responsible physician of such missed treatment or service.
- The physician decides whether the treatment or service may be skipped or whether additional intervention is required by the HHA due to the clinical impact on the patient.
G572 – INTERPRETIVE GUIDELINES

- If the patient or the patient’s representative refuses care that could impact the patient’s clinical wellbeing (such as dressing changes or essential medication) on more than one occasion, then the HHA must attempt to identify the reason for the refusal.

- If the HHA is unable to identify and address the reason for the refusal, then the HHA must communicate with the patient’s responsible physician to discuss how to proceed with patient care.
G572 – INTERPRETIVE GUIDELINES

- The physician should not be approached to reduce the frequency of services based solely on the availability of HHA staff.

- In instances where the HHA receives a general referral from a physician that requests HHA services but does not provide the actual plan of care components (i.e., treatments and observations) for the patient, the HHA will not be able to create a comprehensive plan of care to include goals and services until a home visit is done and sufficient information is obtained to communicate with and receive approval from the physician.
G572 – KEY AREAS OF NONCOMPLIANCE

- Goals not individualized to patient/use of EMR “canned text”
- Lack of documentation related to patient involvement in goal development
- Outcomes not measurable
- Physician not notified of change in patient condition/refusal of ordered treatment/missed visit
- Lack of documentation of verbal orders for POC being confirmed/received from physician.
G572 – PLAN OF CARE

Action Plan:

- Ensure all patients have an individualized written plan of care that addresses the issues identified in the comprehensive assessment
  - Example: Diagnoses with specific patient interventions & measurable goals and outcomes rather than generic pulled over from EMR.
- Ensure all physician orders are obtained prior to initiation of services/confirmation of POC
- Ensure physician notification of ALL changes in patient condition/refusal of ordered treatment/missed visit
G572 – PLAN OF CARE

Action Plan:

- Ensure documentation related to patient involvement in goal development, specify location/area within EMR to document.
- Provide education to all staff regarding Plan of care requirements.
- Hold staff accountable.
- If problem noted, may need to change process and/or incorporate into QAPI program.
§484.75(b) STANDARD: RESPONSIBILITIES OF SKILLED PROFESSIONALS
G710 – PROVIDE SERVICES ON POC

- §484.75(b)(3) Providing services that are ordered by the physician as indicated in the plan of care.

- All services provided **must** be ordered by the physician.
- Services provided must be as stated in orders.
G710 – KEY AREAS OF NONCOMPLIANCE

- All services provided must be ordered by the physician –

  Examples:
  - Therapy provided ultrasound treatment, however there were no physician orders for ultrasound.
  - Nursing documented care provided for new skin tear, but no orders for care, no documentation of physician notification of skin tear.
  - Nursing documents wound care performed- lack of specific wound care which complies to physician orders.
  - Documentation of patient taking Tylenol for hip pain, however Tylenol not noted in medication profile.
G710 – KEY AREAS OF NONCOMPLIANCE

- Services provided must be as stated in orders/on POC
  
  **Examples:**
  
  - Daily weights ordered on POC - no weights documented in visit notes
  - Wound care to left forearm wound includes wound to be covered with Tegaderm, wound documentation states wound covered with bordered gauze
  - Blood Pressure parameters on POC for physician notification systolic >180, diastolic >90. Patient visit note with BP documented as 194/96, no documentation of physician notification
G710 – PROVIDE SERVICES ON POC

Action Plan:

- Ensure -
  - Physician orders are obtained for all services provided
  - All therapy orders include the specific procedures and modalities to be provided
  - Complete orders for all medications patient is taking
  - Orders state WHO is going to do a procedure and WHEN
  - Clinicians are following prescribed orders
  - All verbal orders are recorded in the plan of care and timed

- Educate all staff in providing services as ordered on POC
- Hold staff accountable
- If problem is noted, consider adding indicator to QAPI program
§484.60(b) STANDARD: CONFORMANCE WITH PHYSICIANS ORDERS
G578 – CONFORMANCE WITH PHYSICIAN ORDERS –STANDARD INCLUDES G580

- §484.60(b) Standard: Conformance with physician orders.

- G580 - §484.60(b)(1) Drugs, services, and treatments are administered only as ordered by a physician

- Interpretive guidelines:
  - Drugs, services and treatments are ordered by the physician that established and periodically reviews the plan of care. See §484.60(a)(1).
G578/G580 – KEY AREAS OF NONCOMPLIANCE

- All Drugs, services and treatments are administered only as ordered by the physician.

Examples:
- Tylenol 325mg 2 tabs every 4 hours as needed.
  - Order does not include reason for PRN administration
- Percocet ordered for post-op pain control. Patient tells nurse he is not taking as it makes him dizzy. Pain currently at 8/10. No documentation of nurse contacting physician re: not taking Percocet due to side effect/ pain 8/10.
- Daily weights ordered on POC - no weights documented in visit notes.
G578/G580 – KEY AREAS OF NONCOMPLIANCE

- All Drugs, services and treatments are administered only as ordered by the physician.

Examples:
- Blood Sugars ordered 4 x/day - no documentation of BS in visit notes.
- Documentation states therapy progressed a Left Total Knee patient to full weight bearing, however physician orders are for partial weight bearing.
- No documentation of instruction/competence/compliance in administering IV antibiotic for patient.
- Documentation of flushing PICC line with 20ml NS when 10ml is ordered.
G578/G580 – CONFORMANCE WITH PHYSICIAN ORDERS

Action Plan:

- Ensure -
  - Thorough review of medication list on POC and in interim orders
  - Clinicians are following prescribed orders
  - Clinicians are providing ALL services/treatments as ordered
  - Orders are specific and clear
  - Specific documentation of interventions must be done - do not simply reference as ordered.

- QAPI Quality Indicators or PIP and Concurrent Ongoing Audits are tools to achieve compliance to orders
§484.60(c) STANDARD: REVIEW AND REVISION OF PLAN OF CARE
§484.60(c)(1) The HHA must promptly alert the relevant physician(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

G590 – PROMPTLY ALERT RELEVANT PHYSICIAN OF CHANGES
Interpretive guidelines:

- For “responsible physician” see §484.60(a)(1).
- The signature and date of the review by the responsible physician verifies the interval between plan of care reviews.
- The plan of care may include orders for treatment or services received from physicians other than the responsible physician; such orders must be approved by the responsible physician and incorporated into an updated plan of care.
Interpretive guidelines:

- In the event of a change in patient condition or needs that suggest outcomes are not being achieved and/or that the patient’s plan of care should be altered, the HHA should notify both the responsible physician and the physician(s) associated with the relevant aspect of care.

- Changes in physician orders during the plan of care certification period do not automatically restart the timeframe for physician review of the plan of care.
G590 – KEY AREAS OF NONCOMPLIANCE

- Certifying physician was not notified of new order for change in dose of Blood Pressure medication by Cardiologist
- Recertification Plan of Care not signed by physician until day 72, no documentation of verbal order for recertification/approval of recert POC.
- Change in dose of Lasix and Potassium by Nephrologist, PCP/Certifying Physician not notified.
- Patient reports fall 2 days prior, no documentation of physician notification.
- Patient reports right buttocks hurts, nurse assesses and documents 2cm in diameter red, non-blanchable area. No documentation of physician notification.
G590 - PROMPTLY ALERT RELEVANT PHYSICIAN OF CHANGES

Key Points:
- Many Condition level deficiencies and Immediate Jeopardy from lack of physician notification.
- Lack of physician notification leads to Emergent care without hospitalization in many cases.

Action Plan:
- Ensure process to notify both the responsible physician and the physician(s) associated with the relevant aspects of care of any changes.
- Ensure process for clinician to obtain verbal order for recertification/approval of recert POC and document order.
- Ensure process for tracking of POC/physician signature.
- Recommend Quality Indicator or PIP if problematic due to the serious nature.
§484.55(c)(5) STANDARD: CONTENT OF THE COMPREHENSIVE ASSESSMENT - MEDICATION REVIEW
§484.55(c)(5) A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.
G536 – INTERPRETIVE GUIDELINES

- The patient’s clinical record should identify all medications that the patient is taking (both prescription and non-prescription) as well as times of medication administration and route.

- As part of the comprehensive assessment the HHA nurse should consider, and the clinical record should document, that the HHA nurse considered each medication the patient is currently taking for possible side effects and the list of medications in its entirety for possible drug interactions.

- The HHA should have policies that guide HHA clinical staff in the event there is a concern identified with a patient’s medication that should be reported to the physician.
G536 – INTERPRETIVE GUIDELINES

- In rehabilitation therapy only cases, the patient’s therapist must submit a list of patient medications, which the therapist must collect during the comprehensive assessment, to an HHA nurse for review.
- The HHA should contact the physician if indicated.
A review of all medications the patient is currently using in order to identify any:

- Potential adverse effects and drug reactions
- Including ineffective drug therapy
- Significant side effects
- Significant drug interactions,
- Duplicate drug therapy, and
- Noncompliance with drug therapy
The HHA should have policies that guide HHA clinical staff in the event there is a concern identified with a patient’s medication that should be reported to the physician. 

Including Significant Drug-Drug interactions - What Severity Level? When and how do you notify physician and get return communication?

- Therapist must submit a list of patient meds to an HHA nurse for review.
- The HHA should contact the physician if indicated.
- The RN needs to document the Med review in Therapy only cases in a standardized location of the clinical record.
G536- KEY AREAS OF NONCOMPLIANCE

- Clinical records not having evidence of a review of all medications that the patient was currently using.

- Medication Profile discrepancies:
  - Medication profile dose discrepancy with dose noted on discharge instructions, no documentation of physician notification/clarification.
  - PRN medication without a qualifier for PRN administration.
  - Medications on med profile without including a dose, frequency or route.
  - Insulin sliding scale SQ before meals without defining the dosage parameters.
  - Visit notes include patient taking pain med that was not on medication profile/order.
  - Oxygen not included on medication profile.
G536 - REVIEW OF ALL CURRENT MEDS

Action Plan:

- Audit to ensure an ongoing medication review is completed for all patients; have specific locations for documentation.
- Ensure all PRN medications identify a reason and timeframe.
- Ensure the physician is notified of any medication discrepancies, side effects, problems, or reactions.
- Every Staff, every visit should ask the patient & caregiver if any new prescribed or OTC meds, any side effects, if they are taking their prn drugs and what the response is.
- Provide education to all staff regarding medication review process.
- If problem is noted, consider adding indicator to QAPI program.
§484.70 INFECTION PREVENTION & CONTROL

3 STANDARDS IN THE CONDITION:
PREVENTION, CONTROL, EDUCATION
6 standard precautions, identified by the CDC & Healthcare Infection Control Practices Committee (HICPAC), apply during any episode of patient care:

1. Hand Hygiene;
2. Environmental Cleaning and Disinfection;
3. Injection and Medication Safety;
4. Appropriate Use of Personal Protective Equipment;
5. Minimizing Potential Exposures; and
6. Reprocessing of reusable medical equipment between each patient and when soiled.
Hand Hygiene

- Hand Hygiene should be performed at a minimum:
  - Before contact with a patient;
  - Before performing an aseptic task (e.g., insertion of IV, preparing an injection, performing wound care);
  - After contact with the patient or objects in the immediate vicinity of the patient;
  - After contact with blood, body fluids or contaminated surfaces;
  - Moving from a contaminated body site to a clean body site during patient care; and
  - After removal of personal protective equipment (PPE).
Environmental cleaning and disinfection presents a unique challenge for HHA personnel. The HHA staff have little control over the home environment but must maintain clean equipment and supplies during the home visit, during transport of reusable patient care items in a carrying case in the staff vehicle, and for use in multiple patients’ homes.
Appropriate Use of Personal Protective Equipment

- Appropriate Use of Personal Protective Equipment (PPE) is the use of specialized clothing or equipment worn for protection and as a barrier against infectious materials or any potential infectious disease exposure.
- PPE protects the caregiver’s skin, hands, face, respiratory tract, and/or clothing from exposure.
- Examples of PPE include: gloves, gowns, face masks, eye protections if there is the potential for exposure to blood or body fluids of any patient.
- The selection of PPE is determined by the expected amount of exposure to the infectious materials, durability of the PPE, and suitability of the PPE for the task.
INFECTION CONTROL WITH COVID-19 - PPE

- Action Plan
- Staff training/competency in appropriate PPE use
- Home visits to assess compliance
- Ensure staff knowledgeable in:
  - Guidelines/Appropriate use:
    - Gown
    - N95 or facemask if N95 not available
    - Face shield or goggles
    - Gloves
    - Donning/Doffing – Competency
    - Proper disposal
    - Where/How to obtain
Key areas of noncompliance seen on home visits:

- Handwashing – not done between glove changes; dirty to clean, supply bag on floor (your agency policy is key), Laptop placed onto dirty area. Going into Supply bag without washing hands (contaminates entire bag).
- Cleansing of equipment after patient use prior to putting in bag, car, another patient house – Agency Policy.
DEFCENCY - G682 - INFECTION PREVENTION

Action Plan:

- Ensure all staff receive annual training/education regarding standard precautions. Document training/education.
- Reinforcement - Include review of one standard precaution during each staff meeting.
- Routine home visits with staff to ensure staff compliance with standard precautions.
- All staff held accountable.
- If problem noted, may need to change process and/or incorporate into QAPI program.
- Frequent Infection control and prevention in-services and competencies should be done during the pandemic!
- Keep updated on all CDC guidance as it is changing frequently during the PHE.
§484.70 INFECTION PREVENTION & CONTROL

3 STANDARDS IN THE CONDITION:
PREVENTION, CONTROL, EDUCATION
G684 – INFECTION CONTROL

- **Control** - The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA’s quality assessment and performance improvement (QAPI) program.

- The infection control program must include:
Interpretive guidelines:

- The HHA should have a program for the surveillance, identification, prevention, control and investigation of infectious and communicable diseases specific to care and services provided in the home setting.
- The CDC defines surveillance as “the ongoing, systematic collection, analysis, interpretation and evaluation of health data closely integrated with the timely dissemination of this data to those who need it.”
- As part of its infection control program the HHA should:
  - (1) observe and evaluate services from all disciplines to identify sources or causative factors of infection, track patterns and trends of infections; and
  - (2) establish a corrective plan for infection control (if appropriate) and monitor the effectiveness of the corrective plan. Cross Reference to §484.65(a), QAPI Program Scope.
G684 – KEY AREAS OF NONCOMPLIANCE

- Lack of:
  - Process for tracking infections
  - Notifying physician of new infections
  - Infection surveillance as part of agency QAPI
  - Tracking/trending/analyzing infection data
  - Identification of Agency infection rate(s)
Action Plan:

- Electronic or paper infection surveillance form initiated by field clinician identifying signs and symptoms of infections, notifying physician, identifying new antibiotics.
  - Clinicians must be educated to the process.
  - Lack of sufficient infection surveillance documents do not mean you do not have infections

- Infection surveillance form goes to QAPI coordinator to track, trend, analyze

- Identify Agency infection rate(s)

- Implement Quality Indicators when trends of a particular infection are noted
  - Ex. Development of UTIs

- Hold clinicians accountable
EMERGENCY PREPAREDNESS
E0039 – EP TESTING REQUIREMENTS
Testing: The Agency must conduct exercises to test the emergency plan *at least annually*. The Agency must do the following:

- (i) Participate in a full-scale exercise that is community-based; or
  - (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise every 2 years; or
  - (B) If the Agency experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.
E0039 – EP TESTING REQUIREMENTS

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise is conducted, that may include, but is not limited to the following:

• (A) A second full-scale exercise that is community-based or individual, facility based functional exercise; or
• (B) A mock disaster drill; or
• (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
E0039 – EP TESTING REQUIREMENTS

- NOTE: Testing / Drills must be done ANNUALLY!

- (iii) Analyze the HHA’s response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA’s emergency plan, as needed.
  - Identify any gaps during EP drill and make an action plan to ensure is resolved.

- QSO-21-15-ALL

EP TESTING EXEMPTION & GUIDANCE

- An HHAs testing exercises require they be based on the individual facility’s risk assessment, policies and procedures, and communication plan and support the patient population it serves.

- Testing exercises should vary, based on the HHAs requirements, by cycles and frequency of testing.

- The intent is that testing exercise provide a comprehensive testing and training for staff, volunteers, and individuals providing services under arrangement as well community partners.

- Testing exercises must be based on the HHAs identified hazards, to include natural or man-made disasters.

- This should include EID outbreaks.

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-15-ALL
Emerging Infectious Diseases (EIDs)

As HHAs develop or make revisions to their emergency preparedness plans, EID’s are a potential threat which can impact the operations and continuity of care within a healthcare setting and should be considered.

Adding EID’s within an HHAs risk assessment ensures that HHAs consider having infection prevention personnel involved in the planning, development and revisions to the emergency preparedness program, as these individuals would likely be coordinating activities within the facility during a potential surge of patients.

EID’s may be localized to a certain community or be widespread (as seen with the COVID-19 PHE) and therefore plans for coordination with local, state, and federal officials are essential.

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-15-ALL
EP TESTING EXEMPTION & GUIDANCE

- HHAs are expected to test their response to emergency events as outlined within their comprehensive emergency preparedness program.
- Testing exercises should not test the same scenario year after year or the same response processes.
- The intent is to identify gaps in the facility’s emergency program as it relates to responding to various emergencies and ensure staff are knowledgeable on the facility’s program.
- In the event gaps are identified, facilities should update their emergency programs as outlined within the requirements for After-Action Report (AAR).

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-15-ALL
EP TESTING EXEMPTION & GUIDANCE

Participation

- The regulations do not specify a minimum number of staff, or the roles of staff in the exercises.
- It is strongly encouraged that facility leadership and department heads participate in exercises.
- If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, staff who work in this clinical area should participate in the exercise for a clear understanding of their roles and responsibilities.
- HHAs can review which members of staff participated in the previous exercise and include those who did not participate in the subsequent exercises to ensure all staff members have an opportunity to participate and gain insight and knowledge.

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-15-ALL
Exemption Based on Actual Emergency

- March 26, 2021 CMS Released Updated Guidance for Emergency Preparedness – Appendix Z of the State Operations Manual (SOM)

- An actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the full-scale exercise requirement and exempts the facility for engaging in their next required community-based full-scale exercise or individual, facility-based exercise for following the actual event.

- HHAs must be able to demonstrate this through written documentation.

- With the changed requirements as a result of the 2019 Burden Reduction final rule (81 FR 63859) for outpatient providers required to conduct full-scale exercises only every other year, opposite of their exercises of choice, these facilities are exempt from their next required full-scale or individual facility-based exercise.

- The intent is to ensure that facilities conduct at least one exercise per year.

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-15-ALL
TESTING SCENARIO # 1

- HHA conducted a required full-scale community-based exercise in January 2019 and completed the optional exercise of its choice in January 2020 (opposite year), and experiences an actual emergency in March 2020, the HHA is exempt from next required full-scale community based or individual facility-based exercise in January 2021.

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-15-ALL
TESTING SCENARIO # 2

- If the HHA conducted a required full-scale community-based exercise in January 2020, and has the optional exercise of its choice scheduled for January 2021, and experiences an actual emergency in March 2020, the HHA is exempt from next required full-scale community based or individual facility-based exercise in January 2022, but must still conduct the required exercise of choice in January 2021.

- The exemption is based on the HHAs required full-scale exercise, not the exercise of choice, therefore the exemption may not be applicable until two years following the activation of the emergency plan, dependent on the cycle the HHA has determined and the actual emergency event.

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-51-ALL
EXEMPTION BASED ON ACTUAL EMERGENCY GUIDANCE

• HHAs must document that they had activated their emergency program based on an actual emergency.

• Documentation may include, but is not limited to:
  • A section 1135 waiver issued to the facility (time limited and event-specific);
  • documentation alerting staff of the emergency;
  • documentation of facility closures;
  • meeting minutes which addressed the time and event specific information.

• The HHA must also have completed an after action review and integrated corrective actions into their emergency preparedness program

• It is recommended that HHAs retain, at a minimum, the past 2 cycles (4 years) of emergency testing exercise documentation.

• This would allow surveyors to assess compliance on the cycle of testing required for HHAs

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-51-ALL
E0039 – EP TESTING REQUIREMENTS

Action Plan:

- Ensure Compliance with Exemption:
  - Through/complete documentation of activating your agency’s emergency plan
  - Understanding your agency’s annual cycle
  - Understanding that the exemption is based on an actual emergency
  - Agency conducts the required exercises
Survey Preparation:

- HHA leadership should be able to explain the participation of management and staff during scheduled exercises.
- Have documentation of the exercises, the ARR, and any additional documentation to support the exercise.
- If the HHA did not participate in a full-scale community based exercise, have documentation of the HHAs efforts to identify one, including the dates, personnel and agencies contacted and the reasons for the inability to participate.
- Have documentation of the HHAs analysis and response to the exercise and how the HHA updated its EP based on the analysis.

Reference: CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group/ March 26, 2021/ Ref: QSO-21-51-ALL
IN CONCLUSION:

- KNOW THE RULES! All Clinical Managers have easy access to continually review the SOM (CoPs with IGs)!
- Staff Education – If there is lack of understanding of the rules, the rules will not be followed.
- When unsure how to implement a reg, ASK!
- Frequent Mock Surveys- by an objective qualified person in your agency or an outside qualified entity performed the way a surveyor will. But be sure this person understands the COP’s and knows what to look for.
- Determines your vulnerabilities and have Task forces for those complex areas you identify.
- Let your QAPI program help you- Based on high volume, high risk, problem prone areas you find on mock survey, past near misses, past survey deficiencies, IQIES Outcome Reports. Involve all staff having them rotate through.
QUESTIONS?
THANK YOU!

Sharon M. Litwin, RN, BSHS, MHA, HCS-D
Senior Manager – Coding & Clinical Consulting
Healthcare Provider Solutions
615-399-7499
healthcareprovidersolutions.com