7. Q: **Late Adopter FAQs** (06/14/19)

Since the memorandum QSO19-07-NH release, CMS has answered questions which we would like to share:

- **How will facilities be notified of Group One or Group Two late adopter status?**
  
  **CMS Response:** Available through CASPER, the March 2019 Five Star Provider Preview Report was recently released on Friday, March 22, 2019 and includes notice of Group identification as well as notice to late adopters who are not subject to enforcement remedies but are being closely monitored as outlined in memorandum QSO19-07-NH.

- **Will the subset late adopter list (235) be shared with the Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs)?**
  
  **CMS Response:** Yes, the list was shared with the National Coordinating Council who will disseminate to the QIN-QIOs, with the understanding that it is not to be shared beyond their organization.

- **Is the list of the universal late adopters (approx. 1500) available to the public?**
  
  **CMS Response:** Yes, upon request. Please contact [DNH_BehavioralHealth@cms.hhs.gov](mailto:DNH_BehavioralHealth@cms.hhs.gov) to make an inquiry.

- **Is the list of the 235 late adopter facilities subject to enforcement outlined in memorandum QSO19-07-NH public information?**
  
  **CMS Response:** No, a listing of the 235 late adopters is not public information. However, it can be obtained by submitting a FOIA request.

- **If a late adopter facility is receiving Technical Assistance (TA) (from CMS or another source), are they exempt from policy memorandum QSO19-07-NH?**
  
  **CMS Response:** No, the policy is equally applicable to late adopters receiving TA.

- **Where can State Agencies (SAs) obtain a list of late adopters subject to enforcement remedies?**
  
  **CMS Response:** The CMS Regional Offices (ROs) have disseminated late adopter lists to the SAs. SAs can contact their respective RO for that information.

Any other questions regarding memorandum QSO19-07-NH may be directed to the Enforcement Mailbox – [DNH_Enforcement@cms.hhs.gov](mailto:DNH_Enforcement@cms.hhs.gov).

6. Q: From the Office of Civil Rights regarding usage of cell phone for official business and the security protections surrounding those usages. (03-21-19)

From a HIPAA Security Rule compliance perspective

1. **Transmission of ePHI:** The covered entity (or business associate) must implement technical security measures for any electronic protected health information (ePHI) it transmits over an electronic communications network, to guard against unauthorized access to the ePHI. See 45 CFR 164.312(e). I believe OCR views text messages containing ePHI sent electronically from mobile phone as coming under this provision. The “technical security measures” for the PHI in
transit is usually encryption, and I understand that there are commercial text encryption products available.

2. **Storage of ePHI**: For ePHI that is stored (for example, saved or stored on the mobile phone), the covered entity (or business associate) must assess whether it is a reasonable and appropriate safeguard in its environment to implement a mechanism to encrypt and decrypt ePHI. If it determines it is not reasonable and appropriate to implement encryption/decryption, the CE/BA must document why it is not reasonable and appropriate and implement an equivalent alternative measure if reasonable and appropriate. See 45 CFR 164.312(a)(iv) and 45 CFR. 164.306(d)(3). So for stored ePHI, encryption is not required by the Security Rule, but in this day and age it is hard to argue that encryption is not reasonable and appropriate.

Here is some guidance from OCR and NIST:


https://www.healthit.gov/faq/can-you-use-texting-communicate-health-information-even-if-it-another-provider-or-professional

Here is some guidance from OCR’s web site:

https://www.hhs.gov/hipaa/for-professionals/faq/2006/does-the-security-rule-allow-for-sending-electronic-phi-in-an-email/index.html (discusses emails, but would be applicable to text messages with ePHI as well)

https://www.hhs.gov/hipaa/for-professionals/faq/2021/what-is-encryption/index.html

And if the text service stores ePHI in a cloud, here is some guidance:

https://www.hhs.gov/hipaa/for-professionals/faq/2075/may-a-hipaa-covered-entity-or-business-associate-use-cloud-service-to-store-or-process-ephi/index.html

5. Q. The dentist would like to have a trained dental assistant to provide oral care to every patient at least once per day. This would be at the facility’s expense. The provider was told by the SA that the dental assistant would also need to be a CNA “because the federal guidance clearly states that ADLs must be provided by CNAs.” This dentist is interested in providing trained “oral care specialists” to come and provide regular oral care to the residents for a fee that will be paid by the nursing center. Is there any regulation that would prohibit anyone other than a CNA to provide this type of care for residents of a nursing center?

A. After careful review of the Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities Final Rule (October 4, 2016) and the Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities Proposed Rule (July 15, 2016), no language was found in either rule which identifies a specific health care provider working within their State laws and scope of practice as the designated dental and oral care provider.

A facility is not prohibited from offering added services which are provided by a dental assistant (who is not also certified as a CNA), however in addition to the dental assistant the certified nursing assistants are still required to provide activities of daily living which include oral care at other times during each day.

(CMS CO 12/11/19)

The dental assistant is expected to have a background check and be trained in the facility’s abuse and neglect polices. (CMS Region X, 01/02/19)

4. Q: We are a non-smoking facility. Residents are informed prior to admission if we are aware they are a smoker, and all residents are informed at the time of admission that smoking is not allowed anywhere on the facility campus.

Of course, there are those people who choose to admit under the non-smoking policy and subsequently choose to leave the facility campus to smoke. We then perform a smoking evaluation to determine their ability to smoke independently. The resident’s must exit facility property to smoke, they may or may not be able to move to the office campus location safely or independently. Our smoking policy states that residents must be able to leave the premises without the support of facility staff and if the resident requires supervision or assistance while choosing to smoke off campus facility staff will not provide that service. Family or friends or a party arranged for by the resident will be required for those who need assistance. Does the facility have any culpability/responsibility for residents who need nursing home level of care but who want to smoke? (CMS CO 12/12/18)

A. If a facility chooses to be non-smoking, it must inform the residents of this special characteristic prior to admission. Keep in mind that if the no smoking policy is new, the facility must accommodate current residents who wish to continue smoking, as described in the Survey & Certification policy memo 12-04-NH on Smoking Safety in
For residents being admitted under the non-smoking policy, the facility must fully explain the non-smoking policy, including what options are available to a resident who wishes to continue smoking. As with any resident who wishes to leave the facility for any reason, there should be a policy which addresses how the facility determines whether the resident may leave independently, or requires accompaniment by a friend, family member, caregiver, or facility staff. The facility must also ensure that the resident understands the risks of his or her decisions and is able to verbalize understanding of the risks and any necessary safety precautions. Additionally, for residents who wish to regularly leave the nursing home campus, the care plan should address this type of activity and be evaluated and revised as needed, per federal requirements at §483.21(b).

Lastly, you ask, “Does the facility have any culpability/responsibility for residents who need nursing home level of care but who want to smoke?” Yes, as required by the Requirements for Participation in Medicare/Medicaid, and as stated above, the facility is responsible for identifying and taking steps to reduce any risk to the health and safety of its residents. This includes risks posed by smoking (for the resident who smokes, and those who may be affected by their smoking). This responsibility is not removed by allowing the resident to go off campus.

3. Q. You ask if facilities are allowed to require the resident/family to pay for 1:1 sitters or companions? What are the facility’s responsibilities for screening prior to admission? And what Ftag would be cited. You provided three scenarios which demonstrate this practice. We will answer your questions directly and add our comments to the scenarios as appropriate.

First, you ask if facilities are allowed to require the resident/family to pay for 1:1 sitters or companions.

CMS Response: After careful research, we believe that regulations at 483.10(f)(11) (Ftag F571) and 489.32 prohibit facilities from requiring residents or their representatives to hire a sitter to provide care and services that are already included in the Medicare or Medicaid payment. Please see the regulation language at F571 that addresses this:

§483.10(f)(11) The facility must not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts).

The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with §489.32 of this chapter.
We would like to clarify that the highlighted reg language at F571 (above) goes on to state that requested services may be charged to the resident in accordance with 42 CFR 489.32, which states:

§489.32  Allowable charges: Noncovered and partially covered services.

(a) Services requested by beneficiary. If services furnished at the request of a beneficiary (or his or her representative) are more expensive than, or in excess of, services covered under Medicare—

(1) A provider may charge the beneficiary an amount that does not exceed the difference between—

(i) The provider's customary charges for the services furnished; and

(ii) The provider's customary charges for the kinds and amounts of services that are covered under Medicare.

(2) A provider may not charge for the services unless they have been requested by the beneficiary (or his or her representative) nor require a beneficiary to request services as a condition of admission.

(3) To avoid misunderstanding and disputes, a provider must inform any beneficiary who requests a service for which a charge will be made that there will be a specified charge for that service.

As you see in number 2 above, the services must be requested by the beneficiary, and cannot be a condition of admission.

Lastly, the reg language at F571 goes on to specifically address privately hired nurses or aides. However, as the highlighted language below suggests, this is only when requested by the resident (or representative), the services are not required to achieve goals in the resident’s care plan, when the resident/representative is informed there will be a charge, and if payment is not made by Medicare/Medicaid. This means that a private duty sitter must be requested by the resident and/or family, and cannot be hired to perform the duties that facility staff are required to perform to achieve care plan goals, for example, such as to provide supervision to keep a resident free from falls.

(ii) Items and services that may be charged to residents’ funds. Paragraphs (f)(11)(ii)(A) through (L) of this section are general categories and examples of items and services that the facility may charge to residents’ funds if they are requested by a resident, if they are not required to achieve the goals stated in the resident’s care plan, if the facility informs the resident that there
will be a charge, and if payment is not made by Medicare or Medicaid:

(J) Non-covered special care services such as privately hired nurses or aides.

Next, you ask what the facility’s responsibilities are for screening prior to admission, and what Ftags should be reviewed? We presume you are referring to screening of potential residents prior to admission. Facilities have a responsibility to be able to meet the needs of the residents they admit. For example, a facility without a ventilator unit cannot meet the needs of a resident on a ventilator, and therefore, should not admit anyone requiring such care. Facilities are required to determine their capacity and capability to care for the residents they admit based on their facility assessment (Ftag 838). Included in the facility assessment is the requirement to identify the resources needed to care for the facility’s residents. Resources includes the number of, and competencies of the staff needed to care for the population admitted to the facility.

Additionally, facilities must have sufficient staff to provide services to not only assure resident safety, but to also provide care and services that will assist any residents they admit in attaining or maintaining their highest practicable physical, mental and psychosocial well-being. To provide sufficient staffing, facilities must consider the number, acuity and diagnoses of the facility’s resident population in accordance with the facility assessment required at 483.70(e). See additional guidance at F725 (Sufficient Nursing Staff), F741 (Sufficient/Competent Staff-Behavioral Health Needs), and F838 (Facility Assessment).

Lastly, as addressed in the first question, if a facility requires the resident or their family to hire a private duty aide or companion, surveyors should review F571.

Scenario 1: Resident is in the hospital, the hospital has a sitter to avoid falls due to dementia, impulsivity, restlessness, etc. The hospital case manager tells the family prior to discharge that nursing facilities will not accept the resident unless the family hires a sitter prior to transfer. In addition, the facility does not complete a criminal history check on the person as they are not a contractor for the facility.

We believe the most relevant F-tags for this concern would be F571 (if it is determined the facility requires the family to hire a private duty aide/companion). Additionally, this scenario identifies the following potential concerns:

- F607, which requires policies and procedures be developed and implemented to prohibit and prevent abuse, neglect, exploitation and misappropriation of resident property. Specifically, if a facility permits privately paid sitters/companions in the facility, policies and procedures should address how the facility assures the privately paid sitters are screened for a history of abuse, neglect, exploitation, and misappropriation of property;
• F725 or F741, which are requirements that the facility have sufficient numbers of staff with adequate competencies to meet nursing and behavioral health needs; and
• F620, the admissions agreement should be reviewed to ensure there are no conditions related to a requirement to pay privately for a sitter/companion.

Scenario 2: Resident admitted from the hospital with Dementia and Parkinson’s got up on his own multiples times and wandered into other resident rooms.

CMS Response: With regard to scenario 2, the facility again cannot require the resident or family to pay privately for a sitter/companion because the facility has a responsibility to provide supervision to keep the resident free from accidents at F689. Additionally, at F741, the facility is responsible to provide sufficient staff to provide direct services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

Scenario 3: Resident was admitted with pneumonia and weakness with severe cognitive impairment. Resident is confused, calling out frequently, requiring staff to spend a lot of time with her to provide emotional support and to prevent self-transfer attempts. Twenty-two days after admission staff contacted family and requested a sitter due to increased behaviors.

CMS Response: Again, F571 prohibits facilities from requiring a privately paid sitter/companion to meet the resident’s needs. F-tags related to physician notification (F580) and nursing staff competencies in identifying a change in condition (F726) may also apply.

Scenario 4: Resident admitted with dementia, and seizures on hospice. The resident experienced two falls within the first two days of admission. The IDT talked with the family and said the resident needed a sitter for safety. The resident was invoiced and paid for “sitter” services to protect his safety.

CMS Response: F571 prohibits facilities from requiring a privately paid sitter/companion to meet the resident’s needs. F689 which relates to Accidents and Supervision applies in this situation as well. (10/4/18)

3. Questions and answers related to IDR (11/06/18)

a. If a facility does not agree with the IDR decision, what recourse does the facility have?
   • The facility may request a hearing with the Administrative Law Judge

b. Is a facility allowed to dispute the scope and severity of a citation?
   • SOM 7212.3: Facilities may not dispute: Scope and severity assessments of deficiencies with the exception of scope and
severity assessments that constitute substandard quality of care or immediate jeopardy.

c. What are the timelines relating to requesting an IDR?
   • Chapter 7 of the SOM, section 7212.3 states the request must be made within the same 10 calendar day period the facility has for submitting an acceptable plan of correction to the surveying entity. The facility’s full argument is due with the request. The information the facility wants the panel to consider is due no later than 15 days prior to the scheduled IDR session. Historically IDR is held the Third Thursday of the month.

d. Is the facility allowed to have an attorney or other individual represent them during an IDR that may not be an employee?
   • If in the initial request, the facility indicates it will have an attorney with then, then yes. The Department will schedule our attorney to be present. We have not been asked if a non-facility person may represent/present the facility case. We do not see an issue; however, the facility would need to ensure that HIPAA requirements are met.

d. How many members are on the IDR panel?
   • There are five panel members. Two from the provider community (ICHA Executive Director and a DON), two from the Department (Division Administrator & State Training Coordinator), and the State Ombudsman.

2) What is the correct address for residents to request a hearing for an involuntary discharge notice? (09/18/18)

Department of Health and Welfare
Administrative Procedures Section (APS)
P. O. Box 83720
Boise, Idaho 83720-0036
Fax 208/639-5741
Email APS@dhw.idaho.gov

1) Has non-alcohol based (benzalkonium chloride) hand sanitizer been approved for use in health Care settings? (09/18/18)

No

From CMS 09/04/18

CMS addresses hand hygiene in regulation and interpretive guidance located at §483.80 Infection Control, F880, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-
CMS expects adherence to nationally accepted standards of practice from expert organizations in infection prevention and control such as, but not limited to, the Centers for Disease Prevention and Control (CDC), the Society for Healthcare Epidemiology of America (SHEA) and Infectious Disease Society of America (IDSA). The CDC Guidelines for Hand Hygiene in 2002 recommended that Alcohol-based hand rubs (ABHRs) be used routinely when hands are not visibly soiled. Further, “No recommendation could be made regarding the routine use of nonalcohol-based hand rubs for hand hygiene in healthcare settings,” and categorized this as an unresolved issue. More recently, the SHEA/IDSA Compendium on Strategies to Prevent Healthcare-Associated Infection through Hand Hygiene, 2014 reviewed the current literature stating, “For routine hand hygiene, choose an ABHR with at least 62% alcohol”. The CDC website for Handwashing: Clean Hands Save Lives recommends to use an ABHR that contains at least 60% alcohol. There are many formulations available for ABHRs used in the healthcare setting, but they must minimally contain between 60-95% alcohol.

In 2017 final rulemaking, the FDA deferred its decision to include benzalkonium chloride as safe and effective for use as an Over-the-Counter (OTC) health care antiseptic. Health care antiseptic products include health care personnel hand washes, health care personnel hand rubs, surgical hand scrubs, surgical hand rubs, and patient antiseptic skin preparations (i.e., patient preoperative and preinjection skin preparations). The decision is deferred to allow more time for completion and analysis of studies to address the safety and effectiveness data gaps. Further information on deferral can be found here: https://www.regulations.gov/document?D=FDA-2016-N-0124-0262.

From the CDC

CDC continues to recommend the use of alcohol-based hand sanitizers in healthcare settings. CDC does not have specific recommendations for use of any non-alcohol-based hand sanitizer.

Non-alcohol-based hand sanitizers may:
1) not work equally well for all classes of germs (for example, Gram-positive versus Gram-negative bacteria, Cryptosporidium [https://www.cdc.gov/parasites/crypto/index.html], norovirus [https://www.cdc.gov/norovirus/index.html]);
2) cause germs to develop resistance to the sanitizing agent;
3) merely reduce the growth of germs rather than kill them outright; or
4) be more likely to irritate skin than alcohol-based hand sanitizers.

A thorough review of the topic, including an evidence-based review of the efficacy of hand sanitizers based upon active ingredient, can be found in the CDC’s “Guidelines for Hand Hygiene in Health-Care Settings” (https://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf).
Please refer to the following CDC websites for additional information: “Hand Hygiene in Healthcare Settings” (https://www.cdc.gov/handhygiene/index.html) and Hand Hygiene in Healthcare Settings | Hand Hygiene | CDC www.cdc.gov

In the United States, hospital patients get an estimated 722,000 infections each year. That’s about 1 infection for every 25 patients. Infections that patients get in the hospital can be life-threatening and hard to treat. Hand hygiene is one of the most important ways to prevent the spread of infections.