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Nursing Facility Regulatory Summary
February 2013 – February 2014

Prepared by:
Jennifer L. Hilliard, J.D. | Public Policy Attorney | LeadingAge | 2519 Connecticut Ave, NW, Washington, DC 20008 | P 202-508-9444 | LeadingAge.org | jhilliard@leadingage.org

Final Rules

CMS: Medicare and Medicaid Programs; Requirements for Long-Term Care (LTC) Facilities; Hospice Services, 78 Fed. Reg. 38594 (June 27, 2013)

http://www.gpo.gov/fdsys/pkg/FR-2013-06-27/pdf/2013-15313.pdf

This Final Rule, which became effective on Aug. 26, 2013, revises SNF/NF requirements for arranging provision of hospice care. It is intended to "improve quality and consistency of care between hospices and LTC facilities in the provision of hospice care to LTC residents," and to "help eliminate duplication of and/or missing services."

Overview:

- The Rule clarifies facilities' responsibilities for developing a written agreement with a hospice if a resident elects hospice services, i.e., to ensure that "SNFs and NFs choosing to arrange for the provision of hospice care through an agreement with one or more Medicare-certified hospice providers will have in place a written agreement with the hospice that specifies the roles and responsibilities of each entity."

- The responsibilities of facilities choosing not to contract for hospice services are also clarified, i.e., to "assist the resident in transferring to a facility that will arrange for hospice services when the resident requests a transfer."

- The requirements at [new] 483.75(t) are consistent with requirements in the Hospice Conditions of Participation. However, recognizing distinctions in the roles of the SNF/NF and hospice, CMS advises the requirements are intended to "complement" rather than totally "mirror" those of hospice.

- LTC facilities will be required to have only one written agreement with each hospice that provides services in the facility. The Final Rule does not require facilities to have an individual agreement with a hospice for each resident receiving hospice services.

Provisions of the Final Rule:

- LTC facilities may either arrange for the provision of hospice services through an agreement with one or more Medicare-certified hospices, or decline to arrange for the provision of hospice services and assist the resident in transferring to a facility that will arrange for hospice services when a resident requests a transfer.

- If hospice care is furnished in a LTC facility, the facility must:

    - Ensure hospice services meet professional standards and principles and timeliness.

        - "Timeliness of services'' means the facility ensures that the hospice provides services to the resident in a way that meets their needs in a timely manner, e.g., by increasing pain medication to ensure an optimal comfort level.

    - Have a written agreement signed by authorized representatives of the hospice and the LTC facility before hospice care is furnished.

        - The written agreement must include:

            - The services the hospice will provide.

            - Hospice responsibilities for determining the appropriate hospice plan of care.

            - The services the LTC facility will continue to provide.

            - A communication process, including documentation between the facility and the hospice.

            - A provision that the LTC facility immediately notifies hospice about:

                - A significant change in status;

                - Clinical complications suggesting a need to alter the plan of care;

                - A need to transfer the resident for any condition; and

                - The resident's death.

- The hospice assumes responsibility for determining the appropriate course of hospice care.
- The facility remains responsible for furnishing 24-hr room and board; meets the resident's personal care and nursing needs in coordination with hospice; and ensures care based on resident needs.
- A delineation of hospice responsibilities, including medical direction and management; nursing; counseling (spiritual, dietary, and bereavement); social work; medical supplies, DME, and drugs necessary for palliation of pain/symptoms associated with the terminal illness and related conditions; all other hospice services necessary for care of the resident's terminal illness and related conditions.
- When LTC facility staff members are responsible for administration of prescribed therapies, they may administer the therapies where permitted by State law and as specified by the facility.
- The facility must report all alleged mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of property by hospice staff, to the hospice administrator immediately upon becoming aware of the alleged violation.
- A delineation of hospice and facility responsibilities to provide bereavement services to facility staff.

- LTC facilities arranging for hospice care must designate a member of the interdisciplinary team responsible for working with hospice to coordinate care.
    - The interdisciplinary team member must have a clinical background, function within their State scope of practice act, and have the ability to assess the resident or have access to someone that has the skills and capabilities to assess the resident.
- The designated interdisciplinary team member is responsible for:
    - Collaborating with hospice and coordinating facility staff participation in the hospice care planning process.
    - Communicating with hospice and other providers participating in care for the terminal illness, related conditions, and other conditions.

- Ensuring the LTC facility communicates with the hospice medical director, attending physician, and other practitioners participating in care as needed to coordinate hospice care with that provided by others.
- Obtaining the following information from the hospice:
  - The most recent hospice plan of care specific to the resident;
  - Hospice election form;
  - Physician certification and recertification of terminal illness;
  - Names and contact information for hospice staff involved in the resident's care;
  - How to access the hospice's 24-hour on-call system;
  - Hospice medication information specific to the resident; and
  - Hospice physician and attending physician (if any) orders specific to the resident.
- Ensuring that the LTC facility staff provides orientation to hospice staff.

- LTC facilities providing hospice care must ensure that each resident's plan of care includes both the most recent hospice plan of care and a description of the services furnished by the LTC facility to "attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being." [483.25-Quality of Care].

CMS: Medicare and Medicaid Programs; Requirements for Long-Term Care (LTC) Facilities; Notice of Facility Closure, 78 Fed. Reg. 16795 (Mar. 19, 2013)

http://www.gpo.gov/fdsys/pkg/FR-2013-03-19/pdf/2013-06276.pdf

This Rule, which became effective on April 18, 2013, finalizes, "with technical changes," the Interim Final Rule with Comment (IFR), published by CMS on Feb. 18, 2011 and became effective on Mar. 23, 2011. The IFR implemented Section 6113 of the ACA to "ensure that, in the case of a facility closure, individuals serving as administrators provide written notification of the impending closure and a plan for the relocation of residents at least 60 days prior to the impending closure or, if the Secretary terminates the facility's participation in Medicare or Medicaid, not later than the date the Secretary determines appropriate." Any accompanying Survey & Certification Letter is detailed at Page 35, *infra*.

Provisions of the Final Rule

- **Admission Transfer and Discharge - 483.12(a)(8) -** In the case of a facility closure, any individual who is the administrator of the facility must provide written notification prior to

the impending closure to the State Survey Agency (SA), the State LTC ombudsman, the residents, and the legal representatives or other responsible parties, as well as provide a plan for the transfer and adequate relocation of the residents.

- **Administration**

    - 483.75(r) requires the administrator to submit to the SA, the State LTC ombudsman, residents and legal representatives or other responsible parties, written notification of an impending closure at least 60 days prior to the date of closure; or, in the case of a facility where the Secretary terminates the facility's participation in the Medicare and/or Medicaid programs, not later than the date that the Secretary determines appropriate for such notification.

    - Administrators are required to ensure the facility does not admit any new residents on or after the date written notification is submitted.

    - Administrators must include in the written notice a plan approved by the State for the transfer and adequate relocation of residents by a date specified prior to closure, including assurances that residents will be transferred to the most appropriate facility or other setting in terms of quality, services, and location, and taking into consideration the needs, choice, and best interests of each resident.

    - In the IFR, CMS advised it "expects that closure plans will clearly identify the steps to be taken by the facility; and the individual responsible for ensuring successful implementation." Examples provided included:

        - Assessment of residents' care needs and the provision of appropriate services.

        - A plan for communicating with staff and/or unions.

        - Continuation of appropriate staffing levels and paychecks at the facility.

        - Provision of necessary supplies.

        - Identification of available facilities where residents could be transferred, along with an assessment of the quality of care provided by these facilities (for example, Minimum Data Set (MDS) OSCAR data).

        - A process for relocation of residents.

        - Operation and management of the facility and oversight of those managing the facility.

        - The roles and responsibilities of the facility's Administrator or replacement.

- Sources of supplemental funding to assist in keeping a facility open until residents are transferred.

- A plan for communicating with the Secretary, the State LTC ombudsman, residents and legal representatives of the residents or other responsible parties.

- CMS states in the Preamble to the Final Rule that further guidance will be issued regarding the elements of a closure plan.

- 483.75(s) requires facilities to have in place policies and procedures that will ensure the administrator's duties and responsibilities involve providing the appropriate notices. *[*This requirement is not explicitly mandated under the ACA. However, as stated in the Preamble to the IFR, CMS believes it is "implicitly authorized by the terms of section 6113 of the [ACA] and explicitly permitted by the general rulemaking authority of sections 1819(d)(4)(B) and 1919(d)(4)(B) of the [Social Security]Act, which permit the Secretary to issue rules relating to the health, safety and well-being of residents, and rules concerning physical facilities."]*

- Facilities will be cited for a deficiency under survey for failure to comply.

- **Administrator Sanctions: Long-Term Care Facility Closures (488.446)**

  - In accordance with the ACA, civil monetary penalties (CMPs) will be imposed on the individual administrator that fails to comply with the requirements at Sec. 483.75(r). CMS notes in the Preamble they agree with comments received citing potential situations where an administrator may have no control over closure procedures and "may encounter a situation where adequate time to submit a notification of closure to the specified entities as required by §483.75(r)(1), was not given, " e.g., if an administrator is hired to oversee a facility's impending closure, although he/she was not present when the decision was made to close; or an administrator is employed fewer than 60 days prior to closure. CMS states however, that "the lack of previous involvement does not relieve the administrator (at the time of closing) of the responsibility for implementing the plan and the procedures as required to the extent possible." Under these circumstances, the administrator would be expected to provide the closure notice as soon as possible and begin implementing the plan for closure, working with the SA for transferring the residents. In other words, from the time the administrator was made aware of the closure, he or she would be responsible for compliance with the regulation.

  - Under the provisions of the ACA, any individual who is the administrator of the facility that fails to comply with the requirements will be subject to a CMP of up to $100,000; may be subject to exclusion from participation in any

Federal health care program (as defined in Section 1128B(f) of the Act); and will be subject to any other penalties that may be prescribed by law."

- CMS states that the statutory language, i.e., "up to $100,000" established a maximum limit, but "…afforded CMS the discretion to determine the actual amount of the sanctions…Due to the many possible combinations of violations that could be cited, the amount of the penalty will be determined based on the survey findings." E.G., if it is determined that an administrator completely fails to take the necessary and timely actions to adhere to the closure requirements, potentially causing harm to residents, the administrator could be subject to additional CMPs.
- Any sanctions levied against an administrator could also be reviewed by the State's licensing agency for possible disciplinary action, including suspension or termination of the administrator's license, in those States where applicable.
- Interpretive guidelines are being developed that will establish criteria for determination of its CMP amounts.

o 498.5(m) allows for appeal by an administrator of a SNF/NF, entitling the administrator to a hearing before an Administrative Law Judge (ALJ); to request the Departmental Appeals Board (DAB) review of the hearing decision; and to seek judicial review of the Board's decision.

- **Facility Closure / Continued Payments -** Provides that the Secretary may, as deemed appropriate, continue to make payments to the SNF (or, for a NF, to the State) with respect to residents of a LTC facility that has submitted a notification of closure beginning on the date the notification is submitted and until/ending on the date the residents are successfully relocated.

Proposed Rules

CMS: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918 (Jan. 10, 2014) – Comments Due March 7, 2014

http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf

This proposed rule would implement new criteria for identifying protected classes of drugs, institute revisions to promote competition in Part D plans, enact changes to the regulatory definition of negotiated prices, and make changes to ensure that plan choices are meaningful for beneficiaries. While the proposed rule would have an indirect impact on nursing facility providers, its overall impact on long-term care is significant.

Key Changes Proposed:

- **New Criteria for Drug Categories or Classes of Clinical Concern:** In the first year of the Medicare prescription drug benefit, CMS implemented a policy that required all Part D plans to include on their formularies "all or substantially all" Part D drugs within six drug classes—antineoplastics, anticonvulsants, antiretrovirals, antipsychotics, antidepressants, and immunosuppressants. The Affordable Care Act (ACA) later codified this policy, and allowed CMS to specify criteria for identifying protected classes through notice and comment rulemaking. CMS proposes to change the categories or classes of Part D drugs of clinical concern using criteria established through this notice and comment rulemaking. Under the proposed criteria, CMS would require formulary inclusion of all drugs within the antineoplastic, anticonvulsant, and antiretroviral drug classes (subject to proposed exceptions), but would no longer require all drugs from the antidepressant and immunosuppressant drug classes to be on all Part D formularies. Although antipsychotics do not meet the criteria, they will remain protected at least through 2015 while CMS evaluates additional considerations and the need for any other formulary exceptions.

- **Price Concessions in Negotiated Prices:** In response to anti-competitive tactics that have contributed to inconsistencies in bidding, payments, and market price signals for Medicare Part D plans, the rule proposes to revise the regulatory definition of negotiated prices to require all price concessions from pharmacies to be reflected in negotiated prices. The proposed rule would require greater cost savings for beneficiaries in return for offering preferred cost sharing so that sponsors cannot incentivize use of selected pharmacies, including the sponsors' own related-party pharmacies that charge higher rates than their competitors.

- **Plan Choices:** CMS proposes that Prescription Drug Plans Sponsors offer no more than two Part D plans in the same service area. CMS seeks comments on ways to ensure that a plan sponsor's basic Part D bid represents its lowest-premium plan offering. This provision would not be effective until 2016. The proposed rule would also prohibit Medicare Advantage (MA) plans from offering new plans that simply replace plans that CMS has required to be terminated or consolidated due to low enrollment.

- **Overpayments:** The proposed regulation also would implement the ACA requirement that MA plans and Part D sponsors report and return identified Medicare overpayments.

- **Improved MA Risk-adjustment Data Validation (RADV) Audit Process:** The proposed rule would strengthen RADV by streamlining the RADV audit process by combining error rate calculation appeals and medical record review-determination appeals into one combined process.

- **Expanded Part D Data Sharing:** CMS proposes to expand the release of unencrypted prescriber, plan and pharmacy identifiers contained in prescription drug event (PDE) records to give researchers broader access to health care data. This would support

CMS's growing role as a value-based purchaser of health care. The release of this data would still be subject to CMS's "minimum necessary," "legitimate researcher" and "non-release for commercial purposes" policies as required by law.

- **Expanded Prevention and Health Improvement Incentives:** The rule proposes to expand rewards and incentive programs that do not discriminate against any MA beneficiaries that focus on encouraging participation in activities that promote improved health, efficient use of health care resources and prevent injuries and illness.

- **Physician and Practitioner Enrollment in Medicare:** Section 6405 of the ACA requires that physicians and non-physician practitioners who order durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) or certify home health care must be enrolled in Medicare. The statute also permits the Secretary of HHS to extend these Medicare enrollment requirements to physicians and non-physician practitioners who order or certify all other categories of items or services in Medicare, including covered Part D drugs. CMS is proposing to require that physicians or non-physician practitioners who write prescriptions for covered Part D drugs must be enrolled in Medicare for their prescriptions to be covered under Part D.

CMS: Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 78 Fed. Reg. 79082 (Dec. 27, 2013) – Comments Due Feb. 25, 2014

http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30724.pdf

This proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It is also intended "to ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations."

While many of the included healthcare providers are already required to have emergency/disaster plans in place, CMS cites a lack of uniformity and insufficiency in both existing requirements and provider preparedness in proposing these regulations.

Key Definitions: "Emergency" or "disaster" can be defined as an event affecting the overall target population or the community at large that precipitates the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a governor, the Secretary of the Department of Health and Human Services (HHS), or the President of the United States."

System Elements: CMS has identified four (4) core elements that are central to a comprehensive and effective emergency preparedness system:

- **Emergency plan:** Based on a risk assessment, develop an emergency plan using an all-hazards approach focusing on capacities and capabilities.
    - Risk assessment and planning: This proposed rule would require that prior to establishing an emergency plan, a risk assessment would be performed based on utilizing an "all-hazards" approach. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the provider and supplier considering the particular types of hazards which may most likely occur in their area.
- **Policies and procedures:** Develop and implement policies and procedures based on the plan and risk assessment.
- **Communication:** Develop and maintain a communication plan that complies with both Federal and State law. Resident/Patient care must be well-coordinated within the facility, across health care providers, and with State and local public health departments and emergency systems.
    - Patient care must be well-coordinated within the facility, across health care providers, and with state and local public health departments and emergency systems to protect patient health and safety in the event of a disaster.
- **Training and testing:** Develop and maintain training and testing programs, including initial and annual trainings, conducting drills and exercises or participate in an actual incident that tests the plan.
    - A well-organized, effective training program must include providing initial training in emergency preparedness policies and procedures. The facility must ensure that staff can demonstrate knowledge of emergency procedures and provide this training at least annually. Facilities would be required to conduct drills and exercises to test the emergency plan.

Applicability: CMS' proposed emergency preparedness requirements would apply to 17 provider and supplier types.

1. Religious Nonmedical Health Care Institutions
2. Ambulatory Surgical Centers (ASCs)
3. Hospices
4. Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs (PRTFs)
5. Programs of All-Inclusive Care for the Elderly (PACE)
6. Hospitals
7. Transplant Centers

8. Long Term Care (LTC) Facilities-Skilled Nursing Facilities (SNFs)/Nursing Facilities (NFs)
9. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
10. Home Health Agencies (HHAs)
11. Comprehensive Outpatient Rehabilitation Facilities (CORFs)
12. Critical Access Hospitals (CAHs)
13. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
14. Community Mental Health Centers (CMHCs)
15. Organ Procurement Organizations (OPOs)
16. Rural Health Clinics (RHCs); Federally Qualified Health Centers (FQHCs)
17. End-Stage Renal Disease (ESRD) Facilities

- The proposed hospital requirements and expectations serve as the base, from which other provider-type requirements follow.
    - CMS' proposal includes variations across provider and supplier categories and/or in accordance with the unique nature of the populations being served. "The variations are based on existing statutory and regulatory policies and differing needs of each provider or supplier type and the individuals to whom they provide health care services."
    - All providers and suppliers would be required to establish an emergency preparedness plan that addresses the four core elements.

CMS Requested Feedback:

- All in-patient/resident providers would be required to have policies and procedures to maintain various subsistence needs for residents/patients and staff (including, but not limited to food, water, supplies, etc.). Comment is requested on whether this should be a requirement; in what quantities; and for what time period these subsistence needs would be maintained.
- Testing of emergency generators - The CMS proposal calls for hospitals, critical access (CAHs), and long term care facilities to test their emergency generator systems annually for 4 hours at 100% of the power load. Since this would exceed current NFPA testing and inspection expectations, CMS is requesting feedback and information on this proposal, and, in particular, on the associated costs.
- Development and implementation of emergency preparedness policies and procedures - CMS is proposing that these policies and procedures be reviewed and updated at least annually. Comment is requested on the timing of the proposed updates.

CMS Requested Feedback on Alternative Approaches to Implementation:

- Targeted approaches to emergency preparedness - Covering one or a subset of provider classes rather than imposing it on all at once.

- A phase in approach - Implementing the requirements over a longer time horizon, or differential time horizons for the respective provider classes. The current proposal calls for implementation for all within 1 year from publication of the final rule.
- Variation of the primary requirements - For example, the current proposal calls for requiring two annual training exercises. Feedback is requested on whether both should be required annually, semi-annually, or if training should be an annual or semi-annual requirement.
- Integration with current requirements - Comments are solicited on how the proposed requirements will be integrated with/satisfied by existing policies and procedures which regulated entities may have already adopted.

AOA/ACL: State Long-Term Care Ombudsman Program, 78 Fed. Reg. 36449 (June 18, 2013), Comments Due Aug. 19, 2013

http://www.gpo.gov/fdsys/pkg/FR-2013-06-18/pdf/2013-14325.pdf

The Ombudsman Program and related functions have been delineated in Title VII of the Older Americans Act (OAA) since 1992; however, to date, no regulations have been promulgated for any Title VII program. The absence of regulatory guidance has resulted in variation across states in interpretation of the State LTC Ombudsman program provisions. This Rule would provide regulatory guidance and greater clarity / consistency in implementation.

Topics addressed in the NPRM:

- Definitions of:
  - Immediate family
  - Office of the State Long-Term Care Ombudsman
  - Representative of the Office of the State Long-Term Care Ombudsman
  - Establishment of the Office of the State Long-Term Care Ombudsman,
  - Functions and Responsibilities of the State Long-Term Care Ombudsman
  - State Agency (SA) Responsibilities Related to the Long-Term Care Ombudsman Program
  - Functions and Duties of the Office of the State Long-Term Care Ombudsman
  - Conflicts of Interest
- States would have 1 year from publication of the final rule to comply; the AoA does not anticipate any substantial financial impact on states or long-term care providers.

CMS: Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment, 78 Fed. Reg. 25013 (Apr. 29, 2013), Comments Due: June 28, 2013

http://www.gpo.gov/fdsys/pkg/FR-2013-04-29/pdf/2013-09991.pdf

Incentive Reward Program (IRP) - This rule would increase rewards paid to Medicare beneficiaries and others whose tips about suspected fraud lead to the recovery of funds.

- The IRP potential reward amount for information on individuals and entities who are or have engaged in acts or omissions resulting in the imposition of a sanction would change from 10% of the overpayments recovered in the case or $1,000, whichever is less, to 15% of the final amount collected applied to the first $66,000,000 for the sanctionable conduct.
    - Rewards are not given for the same or substantially similar information that was the basis for a payment of a share of the amounts collected under the False Claims Act or any state False Claims Act, or if the same or substantially similar information is the subject of a pending False Claim Act case.
    - An individual is not eligible for a reward under the IRP if he or she is eligible for a reward for furnishing the same or substantially similar information to the Federal government under any other Federal reward program or payment under Federal law.

Provider Enrollment Provisions

- Providers /suppliers seeking to enroll in or revalidate their enrollment in Medicare must disclose any current or previous direct or indirect affiliation with a provider / supplier with uncollected debt.
- **Medicare Debt:** Denial of enrollment would be allowed:
    - If the provider, supplier, or current owner thereof had an ownership relationship with a previously enrolled provider or supplier that had a Medicare debt, i.e., was the owner of another provider or supplier that had a Medicare debt when the latter's enrollment was voluntarily or involuntarily terminated or revoked and the owner left the provider or supplier that had the Medicare debt within 1 year of that provider / supplier's voluntary termination, involuntary termination, or revocation;
    - The Medicare debt has not been fully repaid;
    - If CMS determines the uncollected debt poses an undue risk of fraud, waste, or abuse.
        - An 'undue risk determination' would be made via consideration of factors including, but not limited to:
            - Amount of the Medicare debt;

        - Length and timeframe the enrolling provider, supplier, or owner thereof was an owner of the prior entity;
        - Percentage of the enrolling provider's, supplier's, or owner's ownership of the prior entity;
        - Scope and breadth of ownership interests (e.g., amount of ownership; direct versus indirect ownership).

- **Extended repayment schedule:** The enrolling provider or supplier would be able to avoid a denial if the enrolling provider, supplier or owner thereof agrees to an extended repayment schedule for the entire outstanding Medicare debt of the revoked provider or supplier.
- **Felony Convictions:** Denial of enrollment or revocation of Medicare billing privileges would be allowed:
    - If the provider, supplier, owner or managing employee thereof (*There is no current denial or revocation of enrollment based on managing employees' felony conviction) was convicted of a Federal or state felony offense (crimes against persons/financial crimes; any felony that placed the Medicare program or its beneficiaries at immediate risk; any felony that would result in mandatory exclusion) that CMS has determined to be detrimental to the best interests of the Medicare program and its beneficiaries within the past 10 years preceding enrollment or revalidation of enrollment.
        - The current enumerated list of felonies would be eliminated; enrollment may be denied or revoked based upon any such felony conviction.
    - If the provider or supplier has a pattern or practice of billing for services that do not meet Medicare requirements.
- **All Medicare providers/suppliers:** CMS would expand the scope of requirements for submission of claims for services rendered prior to revocation to include all Medicare providers / suppliers.
    - All providers and suppliers, e.g., DMEPOS suppliers, rural health clinics, SNFs, except for home health agencies (HHAs), would have 60 days after the effective date of their revocation to submit remaining claims for services furnished prior to the date of the revocation letter;
        - For HHAs, the date would be 60 days after the later of: (1) The effective date of revocation; or (2) the date the HHA's last payable episode ends (*HHAs can currently bill for episodes that began before termination and be paid for up to 30 days following the termination date).

- **Effective Date of Re-enrollment:** A revoked provider/supplier is barred from participating in Medicare from the effective date of revocation until the end of the re-enrollment bar, a minimum of 1 yr., but not greater than 3 yrs.
    - To address situations where revocation is based on a Federal exclusion or debarment, felony conviction, license revocation or suspension, or non-operational status, all re-enrollment bars would begin 30 days after CMS/CMS contractor mails notice of the revocation determination to the provider or supplier. The rationale for this is that "[d]ue to possible delays in the updating of databases with criminal conviction and licensure information, the revocation effective dates for these actions can be months prior to the date the contractor mails the revocation letter."
- **Corrective Action Plans (CAP):** A provider / supplier would not be able to submit a CAP unless the revocation was based on the determination of noncompliance with enrollment requirements, i.e., "revoking billing privileges, e.g., for minor noncompliance, when the problem can be quickly and easily corrected via a CAP could lead to unfair results."
    - For all other revocations, CMS believes a CAP "should not be available or would be impractical," e.g., "if a provider is revoked based on OIG exclusion or felony conviction, no amount of corrective action would be able to change this."
    - Providers / suppliers would have one opportunity to correct all deficiencies that served as the basis of the revocation through a CAP.

Survey & Certification Letters

Installation of Automatic Sprinkler Systems in Nursing Homes – August 13, 2013 Deadline, S&C-13-55-LSC (Aug. 16, 2013, rev. Nov. 15, 2013, rev. Dec. 20, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-55.pdf

Original S&C Letter: This letter addresses the status of the Notice of Proposed Rulemaking (NPRM) allowing requests for a time-limited extension with respect to the Aug. 13, 2013 nursing home sprinkler mandate.

- **Generally:**
    - Since the Final Rule to the Feb. 7, 2013 Notice of Proposed Rule-Making (NPRM) that would permit time-limited extensions for nursing homes in the process of a re-build or major renovation has not yet been promulgated, CMS advises it "does not have authority to allow extensions of the Aug. 13, 2013 deadline."

- CMS "will take note of any facility that is in this circumstance as we review plans of correction." However, "in the absence of the final rule, a deficiency will be issued if the facility is not in compliance with the regulation in force at the time of the survey."
- As of June, 2013, CMS estimates approximately 1281 facilities nationwide are not fully sprinklered; 1142 are partially sprinklered (or unknown); 139 are unsprinklered.

- **Survey and Enforcement**
  - LSC surveys will continue as part of scheduled annual surveys, or in response to complaints involving with LSC deficiencies.
  - On or after August 13, 2013, "LSC surveys finding a facility without a complete automatic sprinkler system installed in accordance with NFPA 101, LSC, 2000 Edition and NFPA 13, Installation of Sprinkler Systems, 1999 edition will be cited on the CMS 2567 at deficiency tag K056 as not in compliance with CMS requirements at 42 CFR 483.70(a)(8)."
  - Facilities in an open enforcement cycle, i.e., beginning prior to Aug. 13, 2013, should have that prior enforcement cycle completed before compliance with the new sprinkler requirement is evaluated.
  - Facilities without complete systems that are in an enforcement cycle beginning before Aug. 13, 2013 will be cited in that open cycle if LSC is a part of the deficiencies being considered.
  - Facilities cited for not meeting the sprinkler requirement will be required to submit a plan of correction (POC) to correct the deficiency.
  - CMS will generally not impose a civil monetary penalty (CMP) for facilities newly subject to the sprinkler requirement "if the POC ensures, by means of appropriate and timely investment, contracts in place, and completed plans for installation, that full sprinkler status will be achieved within 3 months of the survey."
  - This does not preclude immediate imposition of CMPs where noncompliance is serious, particularly if the necessary plans have not been completed. CMPs may also be imposed for other deficiencies.
  - When an LSC deficiency is cited, the normal enforcement track will follow. Facilities not in substantial compliance within 3 months from the date of noncompliance will be subject to the denial of payment of new admissions (DPNA); and to termination at the end of 6 months.

- **Scope and Severity**
  - Failure to meet the requirement for a complete automatic sprinkler system will be cited at tag K056, usually at the "potential for harm" scope and severity (S/S)

level of D, E, or F, at a minimum. Absence of a sprinkler system would always be cited at F or higher.

- Citation at "harm", i.e., G, H or I will be "rare, as actual harm is usually not manifest unless there has been a recent fire or other sprinkler issue causing harm."
- Citation at "immediate jeopardy", J, K or L, which allows for potential jeopardy and places the facility at risk of termination within 23 days, will also be "rare, but possible if there are grave circumstances in place."
- States are instructed to choose scope D, E, or F, based on how many residents face potential harm.
- Examples and enforcement are included for (1) Fully Sprinklered Facilities with Minor Problems with LSC Compliance; (2) Fully Sprinklered Facilities with Major Problems; (3) Partially Sprinklered Facilities; and (4) No Sprinkler System.

- **Canopies and Overhangs**
  - Sect. 5-13.8.1, NFPA 13 requires sprinklers installed under exterior roofs or canopies exceeding 4' in width, with an exception for noncombustible or limited combustible construction.
  - Canopies and overhangs were addressed in a July 13, 2007 Survey & Certification Letter (http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter07-29.pdf) stating that "Existing waivers may be continued until CMS regulations require that the facility become fully sprinklered." The Aug. 13, 2013 sprinkler mandate "means that waivers previously granted for unsprinklered overhangs or canopies must be ended."
  - The memo also described how Fire Safety Evaluation System (FSES) applied to sprinklers, i.e., "Facilities may only use the FSES to comply with these requirements until CMS regulations require that the facility become fully sprinklered. CMS states it "will engage with any facility that was granted a waiver, but has not yet installed sprinklers in overhangs or canopies (and which therefore fall into the "partially sprinklered category") to schedule the waiver phase-out as part of their POC.
  - "Sprinklers can be omitted if the canopy construction assembly is comprised totally of non-combustible or limited combustible materials."
  - Cloth awnings that are not part of the roof or building structure do not need to be sprinklered.
- **Facilities in Re-build or Major Renovation**
  - CMS "appreciates that some facilities have delayed the installation of sprinklers in an older nursing home that is likely soon to be replaced by a new facility, or is undergoing a major modification. While [CMS] currently lacks authority to

acknowledge the unique circumstances involved with such facilities, [CMS] requests that [these facilities] maintain close communication with the State Agency and CMS. Certain information will be of value as [CMS] continues to work on this matter." Examples of useful information may be found in Attachment 2.

Nov. 15, 2013 Revision:

- **Generally**
  - The Revised Letter includes an additional "Attachment Four" specifying actions a nursing home may take to lower exposure to fire risks and reduce the scope and severity rating of a sprinkler-related deficiency to a "level C", no more than potential for minimal harm, while the system is being installed. Reduction to Level C would allow the nursing home to be found to be in substantial compliance so long as the duration of exposure does not exceed 6 months. Substantial compliance means that a denial for new admissions or termination would not apply for the deficiency in question.
  - CMS recognizes in the Letter that "unique factors apply in the case of facilities that are in the process of installing full sprinkler systems," e.g., capital outlay, moving of residents during construction, dependence on other entities such as local authorities granting required construction permits, construction companies, etc.
  - Due to these factors, CMS has identified a series of "extraordinary protective actions" that a facility can take while still in process of installing sprinkler systems or building a replacement facility. CMS notes that in rare cases it may find that these protections, together with only a short exposure period before full installation is achieved, "has so reduced the fire injury risk that no more than a potential for minimal harm remains (i.e., C level scope and severity)."
- **Attachment Four: Extraordinary Protections that May Substantially Reduce Fire Injury Risk on a Temporary Basis During Sprinkler System Installation or Building Replacement**
  - While a deficiency citation will remain until the need for extraordinary measures is eliminated through complete installation of a sprinkler system, CMS may lower the rated scope and severity to "C" level if all elements of either Option I or Option II below are met and are confirmed by a revisit survey.
  - CMS does not consider the items severable. Partial implementation, e.g., acting on only a few of the items, will not result in lowering the scope and severity for a deficiency cited for failure to meet the sprinkler mandate. Further, CMS notes that implementation of this package of protections does not necessarily mean that a CMP or other sanction is precluded for the time period before the added protective measures were applied, and the original (higher) deficiency scope and severity will be maintained for public reporting until full sprinkler status is achieved.

- **Option I - Immediate, Extraordinary, and Sustained Risk Mitigation during Sprinkler Installation**
    - Fire Watch 24/7: A 24-hour fire watch is in place. The fire watch consists of one or more dedicated personnel who are without other duties or assignments, making hourly rounds of any non-sprinklered areas of the building on a 24 hour basis, 7 days per week. The number of personnel should be appropriate to the size and geography of the unsprinklered areas.
    - Posting of Fire Watch Staffing Information: Consistent with facility's fulfillment of requirements at 42 CFR 483.10(G), the facility posts the information regarding the addition of a fire watch on each shift.
    - Construction: The building is constructed completely of material (e.g., concrete) with a fire resistance rating of not less than 2 hours that does not rely on the use of the FSES to comply with any construction type deficiencies.
    - Smoke Alarms and Extinguishers: The facility is in full compliance with CMS requirements for smoke alarms (42 CFR § 483.70(a)(7). The facility maintains free-standing fire extinguishers in common areas and on each residential floor unless the Medical Director determines that such placement on each floor is contraindicated due to the limited placement options.
    - Fire Drills: The facility conducts fire drills in the unsprinklered areas at least monthly on each shift. Note, it does not matter if the facility is installing the sprinkler system in the existing building or in a replacement building. So, if the owner is building a replacement facility, the 'extraordinary protections' would need to be in place in the existing facility where residents currently reside.
    - Staff Training: The facility conducts monthly training of all staff who are employed in all unsprinklered areas with regard to fire safety awareness, fire prevention, mitigation, protection of residents from hazards during a fire outbreak, supervision of activities that present fire risk (e.g., smoking).
    - Staffing: The facility has increased resident direct care staff levels on each floor in all unsprinklered residential areas. The number of staff should be based on resident acuity, and sufficient to ensure increased evacuation readiness and resident care. The facility provides, to the State survey agency and CMS, monthly staffing reports for the unsprinklered areas that track weekly staffing levels documenting the increased staff level maintained until full sprinkler status is achieved.

- Fire Inspections: The facility contracts or arranges with the local Fire Marshall's office, or other independent and qualified inspection service approved by the State survey agency, for monthly fire inspection of all unsprinklered areas. The facility arranges for the inspection reports to be submitted monthly to the State survey agency and the CMS Regional Office.
- State Monitoring: The State survey agency maintains onsite monitoring, unless the CMS Regional Office [RO] determines that onsite monitoring is not needed.
- Minimization of Risk Duration: Insofar as risk exposure is a function of both degree and duration, CMS will not consider risk to be reduced to 'Level C' unless the facility limits the duration of time in which the unsprinklered areas will remain without an installed system of automatic sprinklers, including evidence that:
    - Installation construction has begun, or the facility has filed all necessary permits with the local authorities to begin installation and has received permit approval for the installation; and
    - Installation will be completed within 6 months, or the remaining protected portion of the facility (floor, wing, etc.) that does not have an automatic installed sprinkler system is vacated from any use by any resident.

o **Option II - Removal of Residents from Unsprinklered Areas**

- The unsprinklered area of the facility is entirely vacated from any use by residents.
    - The deficiency remains but CMS may lower the scope and severity rating of the deficiency if the vacated, unsprinklered portion of the facility does not pose any significant fire hazard to any area in which residents reside. At a minimum, the facility must ensure that there is a smoke barrier between the unsprinklered, vacated area and any area in which residents reside or congregate.
    - Requests for reevaluation of the scope and severity, based on meeting the above mitigation measures must be sent to the appropriate CMS Regional Office (RO) and the State Survey Agency (SA), together with the documentation, contracts, attestations and any other material necessary to consider the request.
    - Upon confirmation via a revisit survey that the terms are met, the RO may authorize a finding that the risk has been so lowered via the extraordinary protections that the scope and severity rating of

the deficiency may be reduced to the level of no more than potential for minimal harm ("C" level).

- This qualifies the nursing home to be found in substantial compliance so long as the duration of exposure does not exceed 6 months. Substantial compliance means that a denial for new admissions or termination would not apply for the deficiency in question.
- No deficiency citation for Tag K56 may be rated at scope and severity level of "A" or "B" under any circumstances; and no citation may be rated at the "C" level except on the basis of the above criteria, confirmed by a revisit survey, and approved by the CMS RO.

- **Additional revisions**
  - **Attachment Three - Automatic Sprinkler Requirement Q&A for Nursing Homes**
    - ***Q1) Out Buildings:*** *Are out buildings without access by nursing home residents required to be sprinklered, such as a laundry facility, in order for the facility to be considered fully sprinklered?*
    - A1) No, out buildings (fully detached w/o a combustible covered walkway) without access by nursing home residents are not required to be sprinklered for a facility to be considered fully sprinklered.
    - ***Q3) Walk-in Coolers and Freezers:*** *Are walk-in type coolers and freezers required to be sprinklered for a facility to be considered fully sprinklered?*
    - A3) Yes, walk in coolers and freezers are required to be sprinklered by section 5.1 and formal interpretation 78-6. NFPA 13, 1999 Edition, Section 5-1.1(1) specifies that a complete sprinkler system must have 'Sprinklers installed throughout the premises'. This includes walk-in coolers and freezers attached to the exterior of the facility unless separated from the facility by 2 hour fire resistant construction. However, as indicated in Answer #1, out buildings without access by nursing home residents are not required to be sprinklered for a facility to be considered fully sprinklered.
  - CMS also notes in the Letter that, between the 8/13 run of the database and the 11/13 data run, the national number of unsprinklered facilities declined from 139 to 101; and the number of partially sprinklered facilities was reduced from 1121 to 827.

Dec. 20, 2013 Revision: This Letter includes further clarification on enforcement actions and updated numbers on facilities not sprinklered/partially sprinklered [Attachment #1]. No changes have been made regarding CMS' plans to survey for compliance with the sprinkler mandate at the point of facilities' "'normally scheduled" recertification surveys. Attachment #4

also remains unchanged, i.e., specifying actions a nursing home may take to lower exposure to fire risks and reduce the scope and severity rating of a sprinkler-related deficiency to a 'level C', no more than potential for minimal harm while the system is being installed.

- **Section B, Survey and Enforcement Process On and After August 13, 2013 [paragraph 4]**
    - Revisions clarify that CMPs imposed immediately when noncompliance is found to be serious, i.e., sprinkler plans have not been completed, may be either per-day or per-instance.
        - If a per-day CMP is imposed "and the facility implements the extraordinary protections identified in Attachment Four and qualifies for a reduction in the scope and severity of the deficiency to a "C" level, the per-day CMP will end on the date that a revisit confirms that the protections in Attachment Four are in place."
    - Denial of payment for new admissions (DPNA) when a facility is found not in substantial compliance 3 months from the determination of noncompliance. CMS advises, "If a DPNA is imposed prior to three months after the date the facility was found to be out of compliance, the effective date of the DPNA will not be earlier than 30 days after CMS issues notice to the facility, and the DPNA will be removed if sprinkler status is the sole basis for the DPNA and full sprinkler status is achieved prior to the DPNA effective date, or a revisit confirms that the facility has implemented the extraordinary protections identified in Attachment Four and CMS finds that the facility qualifies for a reduction in the scope and severity of the deficiency to a "C" level."
- **Section C, Scope and Severity of Deficiency Citations, [paragraph 4]:**
    - Revisions include that DPNAs will *definitely* go into effect at 3 months if substantial compliance has not been achieved, and termination from the program will follow at 6 months, if compliance has not been achieved.
- **Attachment #1:** Provides a State-by-State listing of facilities not sprinklered and partially sprinklered as of Dec., 2013. The national total for both columns went from 928 as of Nov., 2013, to 714 as of Dec., 2013 [States not listed are fully sprinklered.

Citations at F Tag 454 – 42 CFR §483.70 Physical Environment, §483.70(a) Life Safety from Fire, S&C: 14-03-NH/LSC (Oct. 25, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-03.pdf

CMS has determined that that F-Tag 454 (§483.70 Physical Environment, §483.70(a) Life Safety from Fire) is cited primarily as a cross reference to Life Safety Code (LSC) K-Tags and that deficiencies and other findings cited at F-Tag 454 "would have been more appropriately cited

under other F-Tags or K-Tags." In order to avoid unnecessary duplication and for accurate deficiency citations, CMS has determined that the regulations at §483.70(a) are more appropriately cited under LSC requirements.

Key Changes:

- F-Tag 454 has been deleted from the Automated Survey Processing Environment (ASPEN) system.
    - Any deficiency identified under F-454 should be cited instead under the corresponding LSC K-Tag or other F-Tag as appropriate.
- The LSC survey may be conducted directly by a State Survey agency (SA), contractor or a designated State fire authority.
    - If the SA has designated a fire authority to conduct the LSC survey on their behalf, the SA must establish a process and procedures for the contracted State fire authority to notify them whether the facility is/is not in compliance with LSC requirements.
- Citations at F-454 no longer apply; the regulations at §483.70(a) are covered by Life Safety Code (LSC) requirements.
- If the health survey team observes fire hazards or other possible deficiencies in LSC, they must notify the designated LSC State Surveyors or other State survey authority and refer these concerns. When appropriate, the LSC surveyors or other State survey authority should follow up and cite the corresponding K-Tag as applicable.

Cardiopulmonary Resuscitation (CPR) in Nursing Homes, S&C: 14-01-NH (Oct. 18, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-01.pdf

Background:

- §483.10 provides that residents of a SNF/NF have the "right to a dignified existence" and "self-determination" including the right "to formulate an advance directive."
- §489.102 requires providers, including SNFs and NFs, to provide written information to residents at the time of admission about their rights to make decisions about medical care, including the right to formulate advance directives.
- The American Heart Association (AHA) publishes guidelines every 5 years for CPR and Emergency Cardiovascular Care (ECC).
- According to the AHA, reversal of clinical death is among the goals of ECC since brain death begins four to six minutes following cardiac arrest if CPR is not administered during that time. AHA guidelines urge "all potential rescuers to initiate CPR unless: (1) a

valid DNR order is in place; (2) obvious signs of clinical death (e.g., rigor mortis, dependent lividity, decapitation, transection, or decomposition) are present; or (3) initiating CPR could cause injury or peril to the rescuer."

Facility CPR Policy

- "Nursing facilities must not implement policies that prevent full implementation of advance directives and do not promote person-centered care."
- Facilities must not establish and implement facility-wide no CPR policies as this does not comply with the resident's right to formulate an advance directive under F155.
- While acknowledging research showing that CPR is ineffective in the elderly nursing home population, CMS notes that "the population in nursing homes is increasingly comprised of younger residents, residents needing short-term rehabilitation, and residents from different cultural backgrounds." Accordingly, any limits on how a facility may implement advance directives should be applied on a case by case basis, taking into consideration a resident's preferences, medical conditions, and cultural beliefs.

Survey Implications

- Surveyors are instructed to determine that "facility policy, at a minimum, directs staff to initiate CPR as appropriate."
    - Facility policy should specifically direct staff to initiate CPR when cardiac arrest occurs for residents who have requested CPR in their advance directives; who have not formulated an advance directive; who do not have a valid DNR order; or who do not show AHA signs of clinical death as defined in the AHA Guidelines for CPR and ECC.
    - Facility policy should not limit staff to calling 911 when cardiac arrest occurs. Prior to the arrival of EMS, nursing homes must provide basic life support, including initiation of CPR, to a resident who experiences cardiac arrest in accordance with that resident's advance directives or in the absence of advance directives or a DNR order.
- CPR-certified staff must be available at all times to provide CPR when needed.

Acquisitions of Providers/Suppliers with Rejection of Automatic Assignment of the Medicare Provider Agreement: Implications for Timing of Surveys and Participation, S&C: 13-60-ALL (Sept. 6, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-60.pdf

Key Provisions:

- In accordance with 42 CFR 489.18(b), an owner contemplating or negotiating a sale of a Medicare-participating provider or supplier must notify CMS. Under 42 CFR 424.516(e)(a), CMS must be notified within 30 days of a change of ownership or control of a participating provider or supplier. Both the seller and buyer provide the required notifications via submission of the Medicare enrollment form, CMS 855A or CMS 855B to their Medicare Administrative Contractor (MAC).
- CMS encourages new owners of a provider/supplier to accept automatic assignment of the seller's Medicare agreement.
    - When an acquisition has occurred, CMS automatically assigns the existing Medicare provider agreement/supplier approval to the new owner (42 CFR 489.18(c)). Automatic assignment means uninterrupted participation of the acquired provider/supplier in the Medicare program. There is no required survey of the provider/supplier as a result of the acquisition and assignment, although the Regional Office (RO) may direct the SA to conduct a survey when it has cause for concern about quality of care. In cases of deemed status providers/suppliers, automatic assignment means the new owner must notify the Area Office of the acquisition, and that accreditation continues until the AO decides whether a resurvey is necessary.
    - Acceptance of automatic assignment also means the buyer is subject to all applicable statutes and regulations and to the terms and conditions under which the assigned agreement was originally issued. These include, but are not limited to, Medicare requirements to adjust payments to account for prior overpayments and underpayments, even if they relate to a pre-acquisition period (successor liability), and to adjust payments to collect CMPs.
- New owners have the option to reject automatic assignment, resulting in termination of the prior Medicare agreement in accordance with 42 CFR 489.52.
    - If the new owner rejects assignment, the facility must be treated as an initial applicant to participate in Medicare. This means that, in addition to completing the 855 enrollment process, providers/suppliers must satisfy any other applicable Federal Medicare participation requirements, including an unannounced full survey of compliance with the applicable Medicare requirements (SNFs), Conditions of Participation (providers), Conditions for

Coverage (most institutional suppliers) or Conditions for Certification (rural health clinics).

- Rejecting assignment generally precludes the buyer from having successor liability for Medicare overpayments or underpayments. However, it also means there has been a voluntary termination of the existing Medicare provider agreement/supplier approval, including its associated CMS Certification Number (CCN).
- The voluntary termination is effective on the date acquisition is completed. There will be no Medicare payments for services to beneficiaries under the rejected/terminated provider agreement furnished on or after that acquisition date. The only exception provides for a continuation, up to 30 days, of payments for hospital or critical access hospital (CAH) inpatients, HHA or hospice patients, or SNF residents admitted prior to the acquisition date.
- If the new owner rejects the existing provider agreement/supplier approval, and that facility was deemed to meet applicable conditions based on accreditation under a CMS-approved Medicare accreditation program, the AO may not "extend" its prior accreditation to the new owner. The AO must conduct a full initial accreditation survey after the acquisition date.

- All surveys conducted for Medicare certification purposes must be unannounced in accordance with Section 2700A of the State Operations Manual (SOM).
  - If an initial survey of an applicant that rejected assignment is conducted shortly after the acquisition date, it raises doubts that the survey was unannounced. At minimum, the appearance is created that the SA or AO collaborated with the new owner on timing of the survey and CMS may refuse to accept a survey for certification purposes if the survey timing creates reasonable doubt.
  - CMS is aware that new owners have interest in having as short a gap as possible between the voluntary termination date of the seller's Medicare agreement and the effective date of the new agreement. However, this is not consistent with CMS's obligation to protect the Medicare Trust Funds by creating incentives to accept the automatic assignment of the seller's Medicare agreement. SAs and AOs must adhere to the following long-standing CMS policies for all initial certification surveys:
    - SAs and AOs must not conduct a survey for initial certification purposes until after the acquisition complete date (date of sale); the survey must be a full, standard survey and must take place under the new ownership to assess the facility's compliance under the new owner.
    - Any survey conducted prior to the completion of the acquisition is a survey of the seller, under the seller's provider agreement or supplier approval, and has no relevance once that provider agreement/supplier

approval has been terminated as a result of the new owner's rejection of assignment.

- SAs and AOs must not conduct an initial survey until the MAC has issued a recommendation for approval of the new owner's enrollment application. In cases of acquisition where new owners reject automatic assignment of the Medicare provider agreement/supplier approval, the MAC should not complete its review of the new owner's 855 and issue its recommendation until after verifying the acquisition is complete.
- The applicant must be fully operational and providing services to patients/residents before it being surveyed. At the time of survey, the facility must have opened its doors to admissions, be furnishing all services necessary to meet the applicable provider or supplier definition, and demonstrate the operational capability of all facets of operation. To be considered "fully operational," initial applicants must be serving a sufficient number of patients/residents so that compliance with all requirements can be determined.

  - Given the lead time normally required to schedule and prepare for a full survey, if an initial survey takes place shortly after the acquisition date, such timing suggests discussion with the new owner prior to the acquisition date to arrange the timing of the survey, compromising the requirement that the survey be unannounced.
  - Each case must be assessed based on the specific facts and such facts may warrant further review by the RO; however, any survey that takes place, e.g., within 14 days from the effective date of an acquisition that involves rejection of assignment warrants closer review by the RO of the circumstances and the timing of the survey.

- Unless the RO directs otherwise, SAs must not conduct initial surveys until completion of their higher priority workload. For initial applicants with an accreditation option, initial certification surveys are the lowest SA priority.
  - Longstanding CMS policy makes complaint investigations, recertifications, and other core work for existing Medicare providers and suppliers a higher priority than new/initial certification.
  - When an SA conducts an initial certification survey of an applicant that acquired a provider/supplier but rejected assignment, the RO must review the facts of the case carefully to determine whether the SA deviated from CMS workload priorities as well as the SA's typical practice for initial applicants. Such deviation may raise reasonable doubt that the survey was unannounced.
- ROs determine the effective date of each Medicare provider agreement or supplier approval in accordance with 42 CFR 489.13. While the effective date can be the last day

of an initial Medicare survey, this is not always the case. SAs and AOs must not speculate to prospective providers/suppliers on what the likely effective date will be.

2000 Edition National Fire Protection Association (NFPA) 101® Life Safety Code (LSC) Waivers, S&C: 13-58-LSC (Aug. 30, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-58.pdf

Generally:

- Under current regulations "CMS may waive specific provisions of the 2000 edition of the LSC in hospitals, critical access hospitals, long-term care facilities, ambulatory surgical centers, and inpatient hospice, which, if rigidly applied, would result in unreasonable hardship upon a provider or supplier, but only if the waiver does not adversely affect the health and safety of patients or residents."

- CMS has determined that the 2000 edition of the LSC and 1999 NFPA 99 contain several provisions that may result in unreasonable hardship for providers/suppliers, for which an adequate alternative level of protection may be achieved. CMS is making available several categorical waivers to new and existing providers and suppliers subject to the LSC.

    - The 1999 NFPA 99, Health Care Facilities Code is cross-referenced in the 2000 LSC and, as a result, it contains requirements applicable to providers and suppliers who must meet the 2000 edition of the LSC.

- Providers/suppliers wanting to take advantage of one or more of the categorical waivers identified must formally elect to use one or more of the waivers and must document their decision.

- If a provider/supplier conforms to the requirements identified for each categorical waiver elected, there will be no need to apply specifically to CMS or to wait until being cited for a deficiency to use the waiver.

- At the entrance conference for any survey assessing LSC compliance, a provider/supplier that has elected to use a categorical waiver must notify the survey team of its election, and that it meets the applicable waiver provisions. It is not acceptable to first notify surveyors of a waiver election after a LSC citation has been issued.

- The survey team will review the provider's/supplier's documentation electing to use one or more of the categorical waivers and confirm that all applicable categorical waiver provisions are being met. The waiver(s) elected must be described at Tag K000.

- Categorical waivers will not be cited as deficiencies nor do they require Regional Office approval. The applicable field on the Form CMS-2786 will be marked as "Facility Meets, Based Upon, 3. Waivers."

- If the survey team determines the waiver provisions are not being met, a deficiency will be cited.

Categorical Waivers Available:

1. Medical Gas Master Alarms

- The 1999 NFPA 99, Section 4-3.1.2.2(b)(2) requires medical gas master alarms to be located in two separate locations and Section 4-3.1.2.2(a)(9) does not allow a centralized computer as a substitute for any medical gas alarm panel.

- The use of computers to continuously monitor critical signals has increased in health care facilities and the use of computers to monitor medical gas can improve surveillance and shorten response time. As a result, the 1999 NFPA 99 provision required under the 2000 LSC is not only outmoded and unduly burdensome to providers and suppliers, but also arguably less efficient in promoting fire safety.

- The 2005 edition of NFPA 99, the NFPA began to permit a centralized computer system to be substituted for one of the master alarms, and this policy is continued in Section 5.1.9.4 of the 2012 NFPA 99.

- CMS is permitting a waiver to allow a centralized computer system to substitute for one of the Category 1 medical gas master alarms. The provider/supplier must be in compliance with all other applicable 1999 NFPA medical gas master alarm provisions, as well as with Section 5.1.9.4 of the 2012 NFPA 99.

2. Openings in Exit Enclosures

- The 2000 LSC limits opening in exit enclosures (e.g., stairwells) to doors from normally occupied spaces and corridor, and doors for egress from the enclosure, with a few exceptions.

- Existing health care facilities often have unoccupied mechanical equipment spaces that have an exit access door to an exit enclosure. Providing an alternative exit access to these areas is typically impractical and unduly burdensome with respect to the cost of the reconstruction that would be required.

- The 2003 LSC began permitting existing unoccupied openings to mechanical equipment spaces with fire-rated doors to open into exit enclosures, and continuation of this policy is reflected in Section 7.1.3.2(9)(c) of the 2012 LSC.

- CMS is permitting a waiver to allow existing openings in exit enclosures to mechanical equipment spaces that are protected by fire-rated door assemblies. These mechanical equipment spaces must be used only for non-fuel-fired

mechanical equipment; must contain no storage of combustible materials; and must be located in sprinklered buildings. The provider/supplier must be in compliance with all other applicable 2000 LSC exit provisions, as well as with Section 7.1.3.2.1(9)(c) of the 2012 LSC.

3. Emergency Generators and Standby Power Systems

- Section 9.1.3 of the 2000 LSC requires emergency generators and standby power systems to be installed, tested, and maintained in accordance with 1999 NFPA 110, Standard for Emergency and Standby Power Systems. Section 6-4.2.2 of the 1999 NFPA 110 requires diesel-powered generators that do not meet the monthly testing requirements under Section 6-4.2 to be run annually with various loads for a total of two (2) continuous hours.

- Shorter generator run times will reduce undue cost burden and negative environmental impacts. The 2010 NFPA 110, began to allow for total test duration of one hour, 30 minutes (1-1/2 continuous hours).

- CMS is permitting a waiver to allow for a reduction in the annual diesel-powered generator exercising requirement from two (2) continuous hours to one hour, 30 minutes (1-1/2 continuous hours). The provider/supplier must be in compliance with all other applicable 1999 NFPA 110 operational inspection and testing provisions, as well as with section 8.4.2.3 of the 2010 NFPA 110.

4. Doors

- Sections 18/19.2.2.2.2 through 18/19.2.2.2.5 of the 2000 LSC permit door locking arrangements where clinical needs (e.g., psychiatric units, Alzheimer units, dementia units) of the patients require specialized security measures for their safety; provided adequate provisions are made for the rapid removal of occupants by means such as remote control locks or keys carried by staff at all times.

- The need for door locking arrangements may extend to other circumstances, such as instances in which patients pose a security risk (e.g., in emergency departments) or when a patient requires specialized protective measures for safety (e.g., pediatric units, newborn nurseries).

- The 2009 LSC began to allow for door locking arrangements when patients pose a security risk or when patients require specialized protective measures for safety, and continuation of this policy is reflected in the 2012 LSC, in Sections 18/19.2.2.2.2 through 18/19.2.2.2.6.

- CMS is permitting a waiver to allow door locking arrangements where clinical needs justify them, patients pose a security risk, or where patients require specialized protective measures for their safety. The provider/supplier must be in compliance with all other applicable 2000 LSC door provisions, as well as with Sections 18/19.2.2.2.2 through 18/19.2.2.2.6 of the 2012 LSC.

- Section 19.2.2.2.4 of the 2000 LSC permits delayed-egress locks in the means of egress; provided not more than one such device is located in an egress path. However, where the clinical needs (e.g., psychiatric units, Alzheimer units, dementia units) require specialized security measures for safety, or where patients pose a security risk (e.g., emergency departments) or when a patient requires specialized protective measures for safety (e.g., pediatric units, newborn nurseries), more than one delayed-egress lock may be required along the path of egress.

- The 2009 LSC began to allow for more than one delayed-egress lock in an egress path, and continuation of this policy is reflected in Sections 18/19.2.2.2.4 of the 2012 LSC; provided that the facility also employs the compensating safety measures specified in those sections which facilitate rapid removal of occupants.

- CMS is permitting a waiver to allow more than one delayed-egress lock in the egress path. The provider/supplier must be in compliance with all other applicable 2000 LSC door provisions, as well as Section 18/19.2.2.2.4 of the 2012 LSC.

5. Suites

- Section 18/19.2.5 of the 2000 LSC requires every habitable room to have an exit access door leading directly to an exit access corridor; allows for exit access from a suite to include intervening rooms only under certain circumstances; requires suites of certain size to have two exit access doors remotely located from one another; and limits the size of sleeping room suites to 5,000 ft. The specific limitations on suite size and design in the 2000 LSC limit their efficiency and the ability for facilities to accommodate suites in their building space, which results in undue burden.

- The 2006 LSC, began to include additional provisions to further accommodate the use of suites, and continue to be reflected in sections 18/19.2.5.7 of the 2012 LSC.

- CMS is permitting a waiver to allow: (1) one of the required means of egress from sleeping and non-sleeping suites to be through another suite; provided adequate separation exists between suites; (2) one of the two required exit access doors from sleeping and non-sleeping suites to be into an exit stair, exit passageway, or exit door to the exterior; and (3) an increase in sleeping room suite size up to 10,000 ft. The provider/supplier must be in compliance with all other applicable 2000 LSC suite provisions, as well as with Sections 18/19.2.5.7 of the 2012 LSC.

6. Extinguishing Requirements

- Section 9.7.5 of the 2000 LSC requires all automatic sprinkler and standpipe systems to be inspected, tested, and maintained in accordance with the 1998 edition of NFPA 25, Standard for the Inspection, Testing, and Maintenance of

Water-based Fire Protection Systems. Sections 2-3.3 and 5-3.2 of the 1998 NFPA 25 require the quarterly testing of vane-type and pressure switch type waterflow alarm devices, and weekly testing of electric motor-driven pump assemblies. Reducing the frequency of testing requirements will reduce cost burden.

- The 2011 NFPA 25 began allowing for testing of vane-type and pressure switch type waterflow alarm semiannually and electric motor-driven pump assemblies monthly.

- CMS is permitting a waiver to allow for the reduction in the testing frequencies for sprinkler system vane-type and pressure switch type waterflow alarm devices to semiannual, and electric motor-driven pump assemblies to monthly. The provider/supplier must be in compliance with all other applicable 1998 NFPA 25 (as referenced in Section 9.7.5 of the 2000 LSC) testing provisions, as well as with Sections 5.3 and 8.3 of the 2011 NFPA 25.

7. Clean Waste & Patient Record Recycling Containers

- Sections 18/19.7.5.7 of the 2000 LSC limit the size of trash collection containers to 32-gallons when located outside of a hazardous storage area and not attended. Recycling containers used for clean waste (e.g., bottles, cans, paper) pose a lower fire risk than trash containing grease, oil, or flammable liquids. Allowing the size of container used for recycling to increase will reduce the number of trash receptacles and hazardous storage areas required, which will reduce undue cost burden.

- The 2012 LSC began allowing containers used solely for recycling clean waste or for patient records awaiting destruction outside a hazardous storage area to be a maximum capacity of 96-gallons.

- CMS is permitting a waiver to allow the increase in size of containers used solely for recycling clean waste or for patient records awaiting destruction outside of a hazardous storage area to be a maximum of 96-gallons. The provider/supplier must be in compliance with Sections 18/19.7.5.7.2 of the 2012 LSC.

Escrow and Independent Informal Dispute Resolution (Independent IDR) Process for Nursing Homes – Applicable to All Civil Money Penalties (CMPs), S&C: 13-57-NH (Aug. 30, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-57.pdf

Section 6111 of the ACA added new sections to 1819 (Medicare) and 1919 (Medicaid) of the Social Security Act (SSA) providing for "timely collection and escrow of CMPs," and allowing facilities to request an Independent IDR (IIDR) if CMS imposes a CMP and the CMP amounts are subject to collection and placement in an escrow account.

Key Provisions:

- CMS may collect and place imposed CMPs in an escrow account on whichever of the following occurs first:
    - The date the IIDR process is completed; or
    - The date which is 90 calendar days after the date of notice of imposition of the CMP.
- CMS issued a Memo on Dec. 2, 2011 phasing in the new CMP collection and escrow provisions by applying the escrow only to CMPs based on one or more deficiencies at actual harm or immediate jeopardy (scope and severity of "G" or higher).
- Effective and beginning on Oct. 1, 2013, CMPs imposed pursuant to all standard or complaint surveys resulting in deficiencies lower than a "G" will also be subject to collection and escrow (42 C.F.R. § 488.431).
    - Revisit surveys conducted on or after Oct. 1, 2013 associated with standard or complaint surveys completed prior to Oct. 1 will not be subject to escrow; IIDR will not apply to those CMPs.
    - CMPs based on surveys with deficiencies cited at "G" or higher are already subject to escrow, "accounting for about 80-85% of all CMPs."
- The offer of IIDR must be included in all CMP imposition notices. The standard IDR process remains available as an alternative. States may not charge facilities for the IIDR process (42 C.F.R. § 488.431).
- Additional instructions and guidance will be included in revisions to the State Operations Manual (SOM), Chapter 7; Survey and Enforcement Process for SNFs/NFs.

Minimum Data Set (MDS) 3.0 Discharge Assessments that Have Not Been Completed and/or Submitted, S&C: 13-56-NH (Aug. 23, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-56.pdf

This memo clarifies the steps facilities must take to address MDS 3.0 discharge assessments that have not been completed and/or submitted as required under 42 CFR § 483.20(g) and 42 CFR § 483.20(f)(1). 42 CFR § 483.20(g)-Accuracy of Assessment, requires that assessments "accurately reflect the resident's status." 42 CFR § 483.20 (f)-Automated Data Processing, requires facilities to encode the following information for each resident in the facility within 7 days from completion of a resident's assessment: (i) Admission assessment; (ii) Annual assessment updates; (iii) Significant change in status assessments; (iv) Quarterly review assessments; and (v) A subset of items upon a resident's transfer, reentry, discharge, and death. A "subset of items upon discharge" means discharge assessment.

CMS notes that failure to submit or complete MDS 3.0 discharge assessments leads to inaccurate MDS 3.0 Quality Measures (QMs) data, potentially affecting residents, facility payment, and facility liabilities, e.g., determinations of noncompliance at 42 CFR § 483.20(f) and 42 CFR § 483.20(g). A lack of completion and/or submission of discharge assessments causes errors on several reports, e.g., the MDS 3.0 Roster report; Facility Characteristics Report; and the MDS 3.0 Missing Assessment Report. As a result, this memo is intended to explain (a) what nursing homes should do to address inactive residents remaining on their resident roster due to incomplete and/or unsubmitted discharge assessments; and (b) how nursing homes can ensure compliance with discharge assessment requirements.

Relevant Provisions:

- Beginning October 1, 2013, MDS assessments older than 3 years will no longer be accepted. To minimize impact on Quality Measure data, CMS has selected a reference date of October 1, 2012.
- CMS is requiring that facilities take the following steps for not-completed discharge and/or not-submitted discharge assessments prior to September 30, 2013:
    - Identify residents appearing on the facility's current MDS 3.0 Roster report who are no longer active residents. If the resident was discharged prior to October 1, 2012, a discharge assessment must be completed indicating the actual date of discharge [Item A2000, Discharge Date].
        - The assessment must have demographic information completed in Section A.
        - Clinical information in Sections B through Z must be dash-filled.

        - Items Z0400, Signatures of Persons Completing the Assessment or Entry/Death Reporting, and Z0500, Signature of RN Assessment Coordinator Verifying Assessment Completion, must reflect the actual completion date of the assessment.

    - If the resident was discharged on or after October 1, 2012, a discharge assessment must be completed indicating the actual date of discharge in Item A2000, Discharge Date.

        - The assessment must have demographic information completed in Section A.

        - Clinical information in Sections B through Z must be completed as much as possible to reflect the actual status of the resident at the time of discharge.

        - The following coding instruction is applicable for coding BIMS, PHQ-9 and Pain interviews for these late discharge assessments:

            - In lieu of the interviews, the staff assessments should be completed if appropriate based on the available clinical record information. The gateway questions (Items C0100, D0100 and/or J0200) should be coded No (0) and the staff assessment should be completed.

            - Z0400, Signatures of Persons Completing the Assessment or Entry/Death Reporting, and Z0500, Signature of RN Assessment Coordinator Verifying Assessment Completion, must reflect the actual completion date of the assessment.

        - Facilities must complete the above steps to address the completion and submission of discharge assessments no later than September 30, 2013.

- Details about the timing requirements for discharge assessments are available in Chapter 2 of the LTC Facility Resident Assessment Instrument User's Manual, Version 3.0: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/NursingHomeQualityInits/MDS30RAIManual.html.

- A discharge assessment must be completed when the resident is discharged from the facility (whether or not return is expected).

- A discharge assessment must be completed (Item Z0500B) within 14 days after the discharge date (A2000 + 14 calendar days).

- Submission of the discharge assessment must occur within 14 days after the MDS completion date (Z0500B + 14 calendar days).

- For a discharge assessment, the Assessment Reference Date (ARD) is not set prospectively. The ARD for a discharge assessment is always the discharge date.
    - When a resident is discharged prior to the end of the prescribed ARD window, including grace days as appropriate, for a required assessment (e.g., PPS, OBRA) where the discharge assessment is to be combined with the required assessment, the ARD of that required assessment must have been set in order for the facility to adjust the ARD to equal the discharge date.
    - In the event the ARD has not been set to allow for adjustment of the PPS- or OBRA-required assessment, the stand-alone discharge assessment must be completed and the other PPS- or OBRA-required assessment is considered a missed assessment.

Notification of Facility Closure: Revisions to Tags F203 and F204 and Issuance of New Tags F523 and F524 in the State Operations Manual (SOM), Appendix PP, S&C: 13-50-NH (Aug. 2, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-50.pdf

CMS is providing advanced guidance regarding the federal requirements for Notification of Facility Closure. Any individual serving as the administrator of a skilled nursing facility (SNF), nursing facility (NF) or dually participating facility (SNF/NF) must provide written notification of an impending closure of a facility including the plan for relocation of residents at least 60 days prior to the impending closure.

Background:

- In accordance with the final rule effective on Apr. 18, 2013 (see *supra*), and under Sections 1128I(h) and 1819(h)(4) of the Social Security Act (the Act) and regulations at 42 CFR §§ 483.75(r) and (s), individuals serving as the administrator of a SNF, SNF/NF or NF must provide written notification of an impending closure of a facility, including the plan for relocation of residents, at least 60 days prior to the impending closure; or, if the Secretary terminates the facility's participation in Medicare or Medicaid, not later than the date the Secretary determines appropriate.
- Notice must be provided to CMS, the state long term care ombudsman, all the residents / representatives / responsible parties.
- An advanced copy of the revisions to Appendix PP of the SOM is attached to the Letter, revising tags F203 [§ 483.12(a)(5) Timing of the notice]; and F204 [§ 483.12(a)(7) Orientation for Transfer or Discharge] and adding new tags F523 [§ 483.75(r) Facility closure – Administrator] and F524 [§ 483.75(s) Facility closure]. CMS notes that the

"final version, when published in the online SOM may differ slightly from this interim advanced copy."

Key Provisions:

- In the event of an impending facility closure, excluding events that may result in a temporary closure resulting from a local, regional, state or national emergency such as a fire, hurricane, tornado, etc., the facility administrator must provide written notice in advance of the closure according to the requirements specified at § 483.12(a)(8).
- If CMS or the State Medicaid Agency (SMA) involuntarily terminates the facility's participation in the Medicare and/or Medicaid programs, notifications must be no later than the date specified by CMS or the SMA.
- Notice must still be given if the facility remains open but CMS or the SMA involuntarily terminates the facility's participation in the Medicare and/or Medicaid programs.
- In addition, the administrator or someone acting on behalf of the administrator should notify in writing, the:
    - Facility's Medical Director;
    - Residents' primary physician(s);
    - CMS Regional Office (RO); and
    - the SMA
- Notice of facility closure must be provided to residents and representatives in a language and manner they understand.
- The notice must include: the name, address and telephone number of the State LTC ombudsman; for residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals; and for residents with mental illness, the mailing address and telephone number of the agency responsible for the protection and advocacy of individuals with mental illness.
- The facility must have policies and procedures to ensure the administrator's duties and responsibilities involve providing the appropriate notices in the event of a facility closure.
- The administrator's duties and responsibilities include
    - Providing written notice to the SA, State LTC ombudsman, residents / representatives;
    - Providing notice to the CMS RO; and

- Determining how the residents' primary physician, SMA, and facility staff, including vendors and contractors, will be notified, to assure continuity of care and provision of necessary goods and services until closure.

- The facility will not close until all residents are transferred "in a safe and orderly manner to the most appropriate setting in terms of quality, services, and location, as available and determined appropriate by the interdisciplinary team, taking into consideration individual needs, choices, and interests.

- Each resident's complete medical record information including archived files, MDS discharge assessment, and all orders, recommendations or guidelines from the attending physician must be provided to the receiving facility or other provider at the time of discharge or relocation.

- For all impending closures, the SA must review and approve the facility's closure plans.

- At a minimum, the facility's plans and procedures must include:

    - Assurance that no new residents will be admitted to the facility on or after the date written notice of impending closure was provided to the SA [A resident who had been temporarily transferred to acute care, is on bed hold, or on a temporary leave would not be considered a new admission];

    - The primary contact(s) responsible for the daily operation and management of the facility during the closure process;

    - The primary contact(s) responsible for the oversight of those managing facility operations during the closure process;

    - Roles and responsibilities of the facility's owners, administrator, or their replacement(s) or temporary managers/monitors during the closure process;

    - Identification of any and all sources of supplemental funding, if available, to assist in maintaining the facility's daily operations until all residents are safely relocated and/or transferred;

    - The process and procedures for providing timely written notification of the facility's impending closure to the SA, Agency, LTC ombudsman, residents/representatives and the primary physician;

    - The process for providing notification of the facility's impending closure to facility staff, vendors, contractors and unions as appropriate;

    - The provisions for ongoing operations and management of the facility and its residents and staff during the closure process, including (1) payment of salaries and expenses; (2) continuation of appropriate staffing (3) ongoing assessment of residents' care needs and provision of necessary services and care; (4) ongoing

accounting, maintenance and reporting of resident personal funds; (5) the provision of appropriate resident care information to the receiving facility; and (6) the labeling, safekeeping and appropriate transfer of residents' personal belongings, such as clothing, medications, furnishings, etc.; and

- A process that provides assurance for how the closing facility will identify available facilities or other settings in terms of quality, services, and location.

- In some cases, an administrator may not have direct control over an impending closure and implementing the facility's written notice and closure plans and procedures. For example, an administrator may be hired to oversee the impending closure, or was employed less than 60 days prior to impending closure. This does not relieve the current administrator from implementing or developing plans and procedures as required; providing notifications as soon as possible; and beginning implementation of plans for closure.

- If notice requirements were not met by the previous or current administrator, the SA and CMS RO may take action against the administrator as permitted under § 488.446 (administrator sanctions: long-term care facility closures).

Office for Civil Rights (OCR) Clearance Process– Changes to State Survey Agency Responsibilities in Obtaining Information for Civil Rights Clearances for Initial Certifications and Changes of Ownership (CHOWs), S&C: 13-46-ALL (July 12, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-46.pdf

A health care provider applying for Medicare Part A participation must receive a civil rights clearance from OCR (42 CFR 480.10(b). This memo instructs that State Survey Agencies (SAs) are to include the OCR Civil Rights Certification Information Request Packet (Civil Rights Packet) with their initial enrollment package sent to a potential provider or to a provider undergoing a CHOW.

Summary of Provisions:

- SAs must now also offer the potential provider the option to answer questions and submit the entire civil rights package on line at https://ocrportal.hhs.gov/ocr/pgportal/.

    - If the provider chooses to submit the package in hard copy, the process is the same: the SA collects the completed Civil Rights Packet from the potential provider and forwards it to the appropriate CMS Regional Office (RO), with the rest of the Medicare application.

- If the provider chooses to submit the package on line, submission will be directly to the OCR intake queue; the provider will receive an e-mail from OCR with an OCR number, stating that the civil rights submission is complete. The provider must then submit a copy of the e-mail to the SA; the SA submits it to the RO in lieu of hardcopy.

- If the RO determines the potential provider does not meet Medicare Part A criteria, the RO sends the e-mail to OCR, advising "Medicare participation has been denied – no OCR clearance necessary."

- For corporate providers having Civil Rights Corporate Agreements with OCR, SAs collect and forward only the signed certification sheets, or the e-mail with the OCR number verifying the package has been submitted to OCR.

- This memo supersedes S&C: 09-57. "Obtaining Civil Rights Clearances for Initial Certifications and CHOWs" (Sept. 11, 2009) and is effective July 15, 2013.

Public Release of the Five-Star Quality Rating System Three-Year Report, S&C: 13-44-NH (June 28, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-44.pdf

CMS has posted the results of an analysis by Abt Associates that examined trends in the first three years of the Five-Star Quality Rating System. The report addresses the distribution of star ratings in each of the three individual domains (survey, staffing, quality measures) and the overall domain during 2009-2011, overall and stratified by facility characteristics. Also included are the variations in ratings across time. The report is attached to the Letter; it is also available at: **http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/FSQRS-Report.pdf**

Summary of Report:

- **Generally:** Since the implementation of the Five-Star Quality Rating System, all three independent domains, inspection, QM, and staffing, have shown improvement.

  - Due to the transition from the MDS 2.0 to the MDS 3.0 and the 'freezing' of the QM domain 3/11 to 7/12, fewer analyses of the QM component are included. CMS plans to release a new QM rating based on QMs derived from MDS 3.0 assessments conducted in 2012.

- **Inspections:** Due to the design of the Five-Star Rating System, the distribution of inspection ratings over the 3 years has remained essentially unchanged. However, with the exception of one-star facilities, there has been general improvement in the average number of deficiencies and survey scores for more recent surveys.

- The prevalence of three indicators of poor survey performance was examined: actual harm; immediate jeopardy (IJ); substandard quality of care (SQC).
    - One-star facilities were more than 100x more likely to have an actual harm (G or higher) citation on their most recent survey or in the past 12 months of substantiated complaints than five-star facilities [50.5% of one-star facilities vs. 0.4% of five-star facilities].
    - No five-star facilities had an IJ or an SQC; more than one-fifth of one-star facilities had each of these determinations. The differences between one-star and two-star facilities, for these types of survey findings, were greater than those between the other consecutive rating categories.
    - All three of these survey indicators were less common for more recent surveys, except for the one-star facilities, where each was increasingly more common for the recent surveys.
- In 2011, about 1 in 10 facilities (10.6%) received five stars; just under 1 in 5 facilities (19.4%) received one star; approximately 23% received two, three, or four stars.

- **Association of Health Inspection Rating with Staffing Levels:** "In general, the results of this analysis indicated a moderate, but consistently positive, association between inspection performance and staffing levels."

- **Staffing:** From Jan. 2009 to Dec. 2011, facilities with one-star in staffing decreased from 22.9% to 13.3%. Facilities with five stars increased slightly (7.2% to 9.0%). Facilities with four-stars increased from 30.6% to 39.3%. "Additional analyses show the greatest changes in staffing are due to increases in reported levels of RN staffing."
    - Tables 3.2 – 3.5 [p. 7] show the distributions of the Dec. 2011 ratings by ownership, type of certification, size, and affiliation (hospital-based vs. freestanding).
        - In general, non-profit and government-owned nursing homes are more highly rated than for-profit homes. Nearly twice as many non-profit as for-profit homes received five-stars overall (24.2% vs. 12.6%).
        - While this is true for all domains except QMs, where the rating distribution varies little across ownership type, the strongest trend is in staffing.
            - Less than 5% of for-profit homes received five stars and about one-sixth (16.9%) received one star.
    - 18.5% of non-profit and 23.7% of government homes received five stars in staffing, while only 5.2% of non-profits and 4.9%of government homes received one star for staffing. RN staffing ratings reflect similar differences.

- In 2011, the staffing domain had the lowest proportion in five stars – 9.0%; however, more than 1 in 3 (39.3%) received four stars; 13.3%- 21.1% received one- two- or three stars.

- Though only 15.0% of facilities have ever received five stars for staffing, two-thirds (66.5%) have received four or five stars. Across all staffing domains, more than a third of facilities have received a one star rating for staffing at some time.

- **QMs:** Facilities receiving a one-star for QMs decreased from 20.0 % to 11.0%. The proportion receiving four or five-stars increased from 34.1 % to 46.9%.

    - In 2011, 16.1% received five stars, and an additional 30.8%received four stars; slightly more received three stars (24.1%) than two stars (18.0%; approximately 1 in 9 (11.0%) received one star.

- **Overall:** In Jan. 2009, 22.7% of facilities had a one-star overall rating, while 35.2% had four- five-stars. By Dec. 2011, one-star ratings had declined to 15.6%; 43.2% had four or five stars.

    - In 2011, facilities receiving five-stars overall surpassed the number receiving one-star. Nationwide, 15.9% received an overall five-star rating; 27.3% received four stars; 41.2% received two-three stars; 15.6% received a one-star.

    - Nearly one-third (32.8%) of nursing homes have received a five-star overall rating at some time, and more than two-thirds (66.9%) have received four or five stars; only 3.3% have never received a rating higher than one star.

    - More than forty percent (41.6%) of nursing homes have received a one-star overall rating at least once, and just 2.8% have never received a rating less than five stars.

- **Examination of Rating Trends from Year 1 to Year 3:** Relatively few facilities have had no change in ratings across the full three-year period from Jan. 2009 to Dec. 2011. Fewer than 1 in 10 facilities (9.1%) had no changes in their overall rating, while a slight majority (55.6%) had a change of more than one star. The staffing domain was the "most stable," with 21.4% having no change in rating and 58.7% having a change of no more than one star. The QM domain was the "least stable" across the three-years, with 6.8% having no change in rating and more than half (59.7%) having a change of two or more stars.

    - CMS/Abt acknowledge that because other factors can affect performance, including adjustments in practice and/or reporting, it is not possible to attribute observed changes solely to the advent of the Five-Star Rating System. However, additional analyses conducted applying the rating system algorithm to data for the 11 months prior to the first reporting of the fivestar ratings reportedly showed "less evidence of improved performance found in 2008, suggesting that

recent changes may be at least partly attributable to the Five-Star Quality Rating System."

Changes to the Nursing Home Compare Website Data that is Available for Download on the Medicare.gov Website (Effective July 2013), S&C: 13-43-NH (June 28, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-43.pdf

Beginning July 2013, all users of Nursing Home Compare wanting to download data will be redirected to the data.medicare.gov website (https://data.medicare.gov/). CMS will add additional information and restructure/create new data layouts for some of the data currently available for download. Following are examples of the additional information that CMS will post:

- Expected and adjusted nursing home staffing data;
- More detailed survey data, including number of revisits; counts of substandard quality of care deficiencies; survey points calculated by the 5-Star Quality Rating System;
- QM values for the past 3 quarters and the 3-quarter average used for the QM5-Star rating; and
- National and state averages for some variables, e.g., number of health deficiencies, number and amount of CMPs, and QMs.

Reminder: Access and Visitation Rights in Long Term Care (LTC) Facilities, S&C: 13-42-NH (June 28, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-42.pdf

This memo reviews and reiterates current interpretive guidelines for 483.10(j), F-Tag 172, resident rights surrounding access and visitation.

Key Provisions:

- LTC facilities must ensure that all individuals seeking to visit a resident be given full and equal visitation privileges, consistent with resident preference and within reasonable restrictions that safeguard residents.
- Residents must be notified of their rights to have visitors on a 24-hour basis, including, but not limited to, spouses (including same-sex spouses), domestic partners (including same-sex domestic partners), other family members, or friends.

- Surveyors are instructed to inquire during resident and family interviews if all understand that visitors are allowed 24-hrs a day and whether the facility has restricted or limited any visitors.

- If interviews indicate that residents do not understand visitation policies or that the facility has limited or restricted visitors against resident wishes and outside of any reasonable restrictions, the surveyor should review the circumstances around those restrictions/limitations, interview facility staff, and evaluate the facility's visitation policies.

Rollout of Quality Assurance and Performance Improvement (QAPI) Materials for Nursing Homes, S&C: 13-37-NH (June 7, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-37.pdf

This letter announces the rollout of the CMS QAPI website, including "introductory materials to help nursing homes establish a foundation to implement and sustain QAPI."

QAPI at a Glance - QAPI at a Glance is a detailed guide illustrating "QAPI in action;" it describes the five elements of QAPI; the action steps for implementing the QAPI principles; and provides tools and resources nursing homes may use as they further develop their systems.

QAPI Tools:

- QAPI Self-Assessment: evaluates the extent to which components of QAPI are in place within an organization and identifies areas requiring further development.
- Guide for Developing Purpose, Guiding Principles, and Scope: identifies principles to guide decision making and help set priorities.
- Guide for Developing a QAPI Plan: guides the organization's quality efforts and serves as the main document to support implementation of QAPI.
- Goal Setting Worksheet: helps set goals that are specific, measurable, attainable, relevant, and time-bound.

QAPI News Brief - CMS created a newsletter that describes some of the basic principles of QAPI. The newsletter "may be printed and posted for review by caregivers, and nursing home residents and their families."

Video – Nursing Home QAPI – What's in it for you? - An introductory video "which provides insight into what quality means to residents, their families, and advocates, and presents a 'business case' for what is in it for nursing homes that embrace QAPI."

Nursing Home Quality Improvement Questionnaire - The Nursing Home Quality Improvement Questionnaire administered by Abt Associates to 4200 randomly selected nursing homes during

the summer of 2012, resulted in a 71% response rate. Detailed results from the questionnaire, "designed to identify baseline information related to quality systems and processes in nursing homes" will be posted to the QAPI website "in the near future."

Visiting the Website

- The QAPI website: http://go.cms.gov/Nhqapi.
- Questions may also be emailed to: Nhqapi@cms.hhs.gov.

Next Steps - CMS will expand QAPI by developing resources to "empower residents and their families to be engaged in the quality efforts in their nursing home." These materials will be posted to the QAPI website as they become available.

Advance Copy - Changes for Sub-Task 5E, Medication Pass Observation Protocol for Long Term Care (LTC) Facilities, S&C: 13-36-NH (June 7, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-36.pdf

This memo details changes made to the Traditional LTC Facility Survey, Sub-Task 5E-Medication Pass Observation.

Medication Pass Sample Size Change

- The number of observations required to calculate a facility's medication error rate is changed to a minimum of 25 medication administration opportunities.
    - A minimum number is specified "because it is acceptable to include more than 25 observations to capture multiple routes, times, and caregivers."
- This revision eliminates the requirement to extend the medication pass for another 20-25 opportunities if errors are detected in the first 20-25 observations.
    - Additional guidance specifies that surveyors will watch and document all of the resident's medications being administered at the time of observation.
    - Surveyors will not stop the observation in the middle of a resident's medication pass.
    - If surveyors reach 25 medication observation opportunities when there are medications remaining for that resident, they are to observe all medications being administered and add those opportunities to the total medication administration sample.

Rationale

- Between 2009 and 2011, F332 citations for the standard QIS ranged from 7 - 9%; from 9 - 10% for the standard Traditional Survey.

- In March, 2013, the QIS Medication Administration Observation sample size was changed to a minimum of 25 observations. These changes to the Traditional Survey process provide CMS with consistent data collection procedures and align the two survey processes.

Forms

- CMS–20056 (2/2013), Medication Administration Observation, replaces CMS Form-677, Medication Pass Worksheet, and will be used to document the Medication Administration Observation [**see Attachment B**].
- CMS-20056 is available for download from the QIES Technical Support Office/QIS/QIS Forms: https://www.qtso.com/download/qis/forms/CMS-20056_MedAdmin_03062013.pdf. The printed version will be available via the existing CMS LTC Survey forms ordering process.

State Operations Manual (SOM)

- **Attachment A** is an advance copy of the interim Survey protocol guidance.
  - *Please note: CMS remains in process of updating the SOM to reflect these revisions, as well as further clarifications on the Medication Administration Observation procedure. The final version of this document as published in the SOM may differ slightly from the advanced copy*.

Attachment A

- All changes to the SOM are italicized. Only the revised sections are highlighted below:

Advance Copy Appendix P/Sub-Task 5E - Medication Pass and Pharmacy Services
(Rev. XX, Issued: 05/24/2013, Effective/Implementation: 7/1/2013)

A. Objectives: No revisions

B. Use: No revisions.

C. General Procedures

1. **Medication *Administration Observation***
   Use *form CMS-20056 (2/2013),* Medication *Administration Observation.*

   Observation Instructions:
   - *Make random observations of a minimum of 25 medication opportunities; a minimum number is specified because it is acceptable to include more than 25*

observations in a medication observation to capture multiple routes, times, and caregivers.

- *Observe several staff over different shifts and units to capture a review of the facility's medication distribution system.*
- *Observe for multiple routes of administration including*: intravenous (IV), intramuscular (IM), or subcutaneous (SQ) injections; transdermal patches; inhaler medications; eye drops; and medications provided through enteral tubes;
- Be as neutral and unobtrusive as possible;
- *Watch and document all of the resident's medications being administered. Do not stop the observation in the middle of a resident's medication pass. If the surveyor reaches 25 medication observation opportunities when there are medications remaining for that resident, observe all medications and add those opportunities to the total medication administration sample.*
- Observe how the staff confirmed the resident's identity prior to giving medications;
- Confirm that the medication can be identified by the staff administering the medication after being removed from the packaging.
- Observe whether staff immediately documented the administration and/or refusal of the medication after the administration or the attempt. Note any concerns.

NOTE: If the surveyor has reason to believe that a medication may be given to the wrong resident or that the wrong medication and/or dose may be given to a resident, the surveyor will intervene as appropriate. The surveyor will continue to observe the staff person until the point where the error is actually going to occur, allowing the staff administering the medication to catch their mistake before the surveyor brings it to their attention. If the staff person catches the mistake, this would not be considered an error. However, if a surveyor must intervene, this observation would be counted as a medication error.

Record the following, including:

- *T*he name and dose/concentration of each medication administered, *obtained from the label;*
- *The* route of administration;
- *The time of medication administration;*
- *If the medication is expired, note the expiration date*;

- Record all multiples, such as 2 drops or 2 tablets. For liquids, record actual volume, or in the case of items such as psyllium, record number of "rounded teaspoonfuls" and the amount of liquid. In the absence of a number, it is assumed to be one;
- Record the techniques and procedures that staff used to handle and administer medications, such as proper hand hygiene, checking pulses, flushing gastric tubes, crushing medications, route and location of administration (e.g., sub-Q or IM injection, eye, ear, inhalation, or skin patch), shaking and/or rotating medication, giving medications with or between food or meals, whether medications are under the direct control/observation of the authorized staff;

Medication Reconciliation

- *Following the medication administration observation, compare your findings with the prescribers' orders.* Review to assure that medication records, including prescriber's orders and the Medication Administration Record (MAR) are accurate and complete. Determine whether there was an error(s) in medication administration. A medication error is the preparation or administration of medications or biologicals that is not in accordance with any of the following:
- The prescriber's order (whether given incorrectly or omitting an ordered dosage);
- Manufacturer's specifications (not recommendations) regarding the preparation and administration of the medication or biological;
- Accepted professional standards and principles that apply to professionals providing services;

Calculating Facility Medication Error Rate - If no errors are found after reconciliation of the observation with the prescriber's orders, the medication observation is complete. *I*f one or more errors are found, calculate the medication error rate.

Step 1. Combine all surveyor observations into one overall calculation for the facility. Record the Total Number of Errors. Record the number of Opportunities for Errors (doses given plus doses ordered but not given).

Step 2. Medication Administration Error Rate (%) = Number of Errors divided by Opportunities for Errors multiplied by 100. A dose of medication that was ordered but not given (by omission) is considered an error to be added to the number of opportunities.

Step 3. After the overall error rate is determined, the team will determine whether a facility citation is appropriate during the team meetings. If the Medication Administration Error Rate is 5% or greater, cite F332. If any medication error is

Step 4. determined to be significant, cite F333.

NOTE: If a **significant** medication error has been identified during the course of a Resident Review, including a revisit or a complaint investigation, it is not necessary to have observed a medication pass in order to cite a deficiency at F333.

2. **Medication Storage (includes labeling): No revisions.**
3. **Controlled Medications: No revisions.**
4. **Pharmaceutical Services: No revisions.**
5. **Provision of a Licensed Pharmacist: No revisions**

Attachment B: Form CMS 20056 (2/2013) Medication Administration Observation

- Surveyor Observation Instructions: Make random medication observations of:
- Several staff over different shifts and units,
- Multiple routes of administration (oral, enteral, intravenous, intramuscular, subcutaneous, topical, optical, etc.),and
- A minimum (not maximum) of 25 medication opportunities.
- Residents are not to be pre-selected for observation.
- Includes a list of potential 'error situations' that may be observed during medication administration; Observation Findings / Calculation process.

Advanced Copy: Dementia Care in Nursing Homes: Clarification to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309 – Quality of Care and F329 – Unnecessary Drugs, S&C: 13-35-NH (May 24, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-35.pdf

This memo clarifies Appendices P and PP related to nursing home residents with dementia and unnecessary drug use. The revised CMS guidance and surveyor training highlight and re-emphasize many of the dementia care elements/key principles already required under the Social Security Act and/or current regulations: Person–Centered Care; Quality and Quantity of Staff; Thorough Evaluation of New or Worsening Behaviors; Individualized Approaches to Care; Critical Thinking Related to Antipsychotic Drug Use; Interviews with Prescribers; Engagement of Resident and/or Representative in Decision-Making.

Appendix P

- Changes to resident sampling for the traditional survey are intended to ensure inclusion of an adequate number of residents with dementia receiving an antipsychotic (changes to QIS were included in the 10.1.3 release).

- Task 1 – Off Site Preparation

    - Use of the Facility QM Report to pre-select concerns for any QM that flagged at the 75th (or greater) national percentile.

    - Use of instructions in Tasks 2 & 4 to include a resident with dementia receiving an antipsychotic in the sample.

- Task 2 – Entrance Conference/Onsite Preparatory Activities

    - Entrance Conference

        - 3. The team coordinator should:

        - Request the names of residents with a diagnosis of dementia who are receiving, have received, or presently have PRN orders for antipsychotics over the past 30 days.

        - If the facility population includes residents with dementia, ask the administrator or DoN to describe how the facility provides individualized care and services for these residents and to provide policies related to use of antipsychotics in residents with dementia.

- Task 4 – Sample Selection for Traditional Survey

    - Phase 1 - Use the [above] list of names of residents; Compare to the off-site Phase 1 sample and determine if a resident from the list is already included; Ensure that, at minimum, at least one of the residents on the list is in the Phase 1 sample for a comprehensive or focused record review.

    - If at least one resident on the facility-provided list is not included, consider replacing 1 resident with 1 resident from the facility-provided list or adding a resident from the list.

    - Reference the "Review of Care and Services for a Resident with Dementia Checklist" while conducting this review.

- Sample Selection for QIS - Surveyors will not have to make adjustment to the selection; the software will automatically identify the required sample.

Appendix PP
F309 – §483.25 Quality of Care

- **Review of Care and Services for a Resident with Dementia**

- Use for residents with dementia - There is no specific investigative protocol for care of a resident with dementia. For the traditional survey, surveyors may use the checklist, "Review of Care and Services for a Resident with Dementia"; For the QIS, surveyors use the general CE pathway and may use the checklist as a guide to completing that pathway.
- Definitions
  - Behavioral interventions - Individualized approaches provided as part of a supportive physical and psychosocial environment.
  - Person-Centered or Person-Appropriate Care - Care tailored to all relevant considerations for the individual, including physical, functional, and psychosocial aspects.
  - Behavioral or Psychological Symptoms of Dementia (BPSD) - Term used to describe behavior or other symptoms in individuals with dementia that cannot be attributed to a specific medical or psychiatric cause.
- Overview of Dementia and Behavioral Health
  - What is Behavior?
  - What is Dementia?
  - What is Delirium?
  - Therapeutic Interventions or Approaches
    - Examples of techniques /environmental modifications that may prevent certain behavior related to dementia
- Medication Use in Dementia (see also F329)
  - Must only be used if the care process [below] and at F329 have been followed
- Resident and/or Family/Representative Involvement
  - Resident and family/representative involvement expected to the extent possible in helping staff understand potential underlying causes of behavioral distress and to participate in development and implementation of the resident's care plan (PoC).
- Care Process for a Resident with Dementia
  - Includes an interdisciplinary team (IDT) approach that focuses holistically on needs of the resident as well as needs of the other residents; Facility systems and procedures are in place to assure assessments are timely and accurate;

interventions described and consistently implemented, monitored, and revised as appropriate in accordance with current standards of practice.

- Residents' records reflect implementation of the following care processes:
  - Recognition and Assessment
  - Cause Identification and Diagnosis
  - Development of PoC
  - Individualized Approaches and Treatment
  - Staffing and Staff Training
  - Involvement of Medical Team
  - Monitoring, Follow-up and Oversight
  - Quality Assessment and Assurance (QAA)

- **Criteria for Compliance (F309)**
  - DEFICIENCY CATEGORIZATION (Part IV, Appendix P)
    - Examples illustrate differences between compliance / non-compliance at levels 4, 3 and 2 for F309 Review of a Resident with Dementia. Includes explanation of noncompliance; Decision-Making Grid with Components of IJ.
    - Additional clinical resources that identify the challenges and basic principles of dementia care.

F329 - §483.25(l) Unnecessary Drugs

- Amends indications for use: Antipsychotic Medications
  - Conditions Other than Dementia
  - Behavioral or Psychological Symptoms of Dementia (BPSD)
  - Inadequate Indications, i.e., if the only indication is one or more of the identified conditions; diagnoses alone do not warrant use unless the following criteria are also met:
    - The behavioral symptoms present a danger to the resident or others AND one or both:
      - The symptoms are identified as due to mania or psychosis; OR

- Behavioral interventions have been attempted and included in the PoC, except in emergency.

- Additional Criteria: Acute Situations/Emergency
  - Use must meet the criteria and all of the following requirements:
    - Acute treatment period is limited to 7 days or less; AND
    - A clinician in conjunction with the IDT must evaluate and document within 7 days to identify and address any contributing and underlying causes of the acute condition and verify the continuing need for an antipsychotic.
    - If the behaviors persist beyond the emergency, pertinent non-pharmacological interventions must be attempted, unless clinically contraindicated, and documented following resolution of the acute psychiatric event**.**
- Additional Criteria: Enduring Conditions (non-acute; chronic; or prolonged) if meets the criteria above.
  - Target behavior/s must be clearly/specifically identified and documented. Monitoring must ensure the behavioral symptoms are:
    - Not due to a medical condition or problem that can be expected to improve or resolve as the underlying condition is treated or the offending medication(s) are discontinued; AND
    - Not due to environmental stressors alone that can be addressed to improve the symptoms or maintain safety; AND
    - Not due to psychological stressors alone, anxiety or fear stemming from misunderstanding related to his or her cognitive impairment that can be expected to improve or resolve as the situation is addressed; AND
    - Persistent. There must be clear documented evidence that the situation/condition continues or recurs over time and that other approaches attempted have failed to adequately address the behavioral/psychological symptoms and that the resident's quality of life is negatively affected.
- New Admissions:
  - Residents admitted already on an antipsychotic. The facility is responsible for:

- Preadmission screening for mentally ill and intellectually disabled individuals, and;
- Obtaining physician's orders for the resident's immediate care.

▪ Residents not requiring PASRR screening and admitted on an antipsychotic. Use of the antipsychotic must be reevaluated at the time of admission and/or within 2 weeks (initial MDS) to consider whether the medication can be reduced or discontinued.

o Dosage. Treatment should be at the lowest possible dose to improve the target symptoms being monitored. [Includes a table as a general guide for residents with dementia who meet all of the [above] criteria.]

o Duration. Refers to Guidance Section V–Tapering of a Medication Dose/Gradual Dose Reduction (GDR).

o Monitoring. Periodic evaluation of ongoing effectiveness and potential adverse consequences; use of any other psychopharmacological medications given to the resident.

o Potential Adverse Consequences. The facility assures residents are adequately monitored for adverse consequences, e.g., anticholinergic effects, falls, excessive sedation; cardiovascular; metabolic; neurologic.

- F329 - Investigative Protocol - Provides additional example(s) regarding the differences between compliance/non-compliance at severity levels 4, 3 and 2 (no level 1 included).

Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.43, Discharge Planning, S&C: 13-32-HOSPITAL, May 17, 2013

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-32.pdf

While this Letter pertains to hospitals, revising the guidance for the hospital discharge planning Condition of Participation (CoP), it includes expectations for outreach and/or communication with post-acute care settings**.**

Advisory Boxes: Included throughout the guidelines are "blue boxes" that "display advisory practices to promote better patient outcomes." The advisory boxes provide resource information and/or references for process improvement, but do not comprise required practice and are not used for determining compliance. Examples pertaining to post-acute care include the following:

"For Information – Not Required/Not to be Cited
It would be advisable for the hospital to develop its discharge planning policies and procedures with input from the hospital's medical staff prior to review and approval by the governing body. Hospitals are also encouraged to obtain input from:

- Other healthcare facilities and professionals who provide care to discharged patients, including but not limited to: nursing homes/skilled nursing facilities, home health agencies, primary care physicians and clinics, etc.; and
- Patients and patient advocacy groups.

For Information– Not Required/Not to be Cited

- Although not required under the regulations, hospitals would be well advised to develop collaborative partnerships with post-hospital care providers to improve care transitions of care that might support better patient outcomes. This includes not only skilled nursing facilities and nursing facilities, but also providers of community-based services. For example, Centers for Independent Living (CIL) and Aging and Disability Resource Centers (ADRC) are resources for community-based services and housing available to persons with disabilities and older adults."

Key Provisions:

§ 482.43(c)(3) -The hospital must arrange for the initial implementation of the patient's discharge plan.
§ 482.43(c)(5) -As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

Interpretive Guidelines §482.43(c)(3) & §482.43(c)(5) - The hospital is required to arrange for the initial implementation of the discharge plan. This includes providing in-hospital education/training to the patient for self-care or to the patient's family or other support person(s) who will be providing care in the patient's home. It also includes arranging:

- Transfers to rehabilitation hospitals, long term care hospitals, or long term care facilities;
- Referrals to home health or hospice agencies;
- Referral for follow-up with physicians/practitioners, occupational or physical therapists, etc.;
- Referral to medical equipment suppliers; and
- Referrals to pertinent community resources that may be able to assist with financial, transportation, meal preparation, or other post-discharge needs.

- It is not acceptable to only advise a patient to "return to the ED" whenever problems arise. Tools and techniques focused on improving the support provided to patients discharged to their homes include:
    - Improved education) to patients and support persons regarding disease processes, medications, treatments, diet and nutrition, expected symptoms, and when and how to seek additional help;
    - CMS does not prescribe specific methodologies; examples include the teach-back, repeat-back approach and simulation laboratories;
    - Written discharge instructions in the form of checklists when possible, that are legible, in plain language, culturally sensitive and age appropriate;
    - Providing supplies that are needed immediately post-discharge; and
    - A list of all medications the patient should be taking after discharge, with clear indication of changes from pre-admission medications.
- It is also necessary to provide information to patients and their support persons when the patient is being transferred to rehabilitation or a long term care hospital, or to a long term care setting, such as a SNF or NF. The information should address questions such as the goal of treatment in the next setting and prospects for the patient's eventual discharge home.
- The hospital must document in the patient's medical record the arrangements made for initial implementation of the discharge plan.

§ 482.43(c)(6) - The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and post-hospital extended care services through individuals and entities that have a contract with the managed care organizations.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.

§ 482.43(c)(7) The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of

post-hospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

§ 482.43(c)(8) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of this chapter.

Interpretative Guidelines §482.43(c)(6), §482.43(c)(7) & §482.43(c)(8)

- The hospital must include a list of Medicare-participating home health agencies (HHAs) and skilled nursing facilities (SNFs) in the discharge plan for those patients for whom the plan indicates home health or post-hospital extended care services are required.

- "Extended care services" are defined at Sections 1861(h) and (i) of the Social Security Act as items or services furnished in a SNF. SNFs included on the list must be located in a geographic area that the patient or patient's representative indicated he/she prefers.

- For HHAs, the list must consist of Medicare-participating HHAs that have requested the hospital to be listed and which serve the geographic area where the patient lives. Hospitals may expect the HHA to define its geographic service area when it submits its request to be listed.

- During the discharge planning process the hospital must inform the patient of his/her freedom to choose among Medicare-participating post-hospital providers and must not direct the patient to specific provider(s) or otherwise limit which qualified providers the patient may choose among.

- Hospitals have the flexibility either to develop their own lists or to print a list of skilled nursing facilities and home health agencies in the applicable geographic areas from the CMS websites, Nursing Home Compare (www.medicare.gov/NHcompare) and Home Health Compare (www.medicare.gov/homehealthcompare). If hospitals develop their own lists, they are expected to update them at least annually.

Blue Box Guidance - For Information – Not Required/Not to be Cited

- Hospitals may also refer patients and their families to the Nursing Home Compare and Home Health Compare websites for additional information regarding Medicare-certified SNFs and HHAs, as well as Medicaid-participating nursing facilities.

- The data on the Nursing Home Compare website include an overall performance rating, nursing home characteristics, performance on quality measures, inspection results, and nursing staff information.

- Home Health Compare provides details about every Medicare-certified HHA in the country. Included on the website are quality indicators such as managing daily activities,

managing pain and treating symptoms, treating wounds and preventing pressure sores, preventing harm, and preventing unplanned hospital care.

- The hospital might also refer the patient and their representatives to individual State agency websites, Long-Term Care Ombudsmen Program, Protection and Advocacy Organizations, Citizen Advocacy Groups, Area Agencies on Aging, Centers for Independent Living, and Aging and Disability Resource Centers for additional information on long term care facilities and other types of providers of post-hospital care.

- If the patient is enrolled in a managed care insurance program that utilizes a network of exclusive or preferred providers, the hospital must make reasonable attempts, based on information from the insurer, to limit the list to HHAs and SNFs that participate in the insurer's network of providers.

- If the hospital has a disclosable financial interest in an HHA or SNF on a patient's list, or an HHA or SNF on the list has a disclosable financial interest in the hospital, these facts must also be stated.

- When the patient or patient's family has expressed a preference, the hospital must attempt to arrange post-hospital care with an HHA or SNF, as applicable, which meets these preferences. If the hospital is unable to make the preferred arrangement, e.g., there is no bed available, it must document the reason the patient's preference could not be fulfilled and must explain that to the patient.

§ 482.43(d) Standard: Transfer or Referral - The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

Interpretive Guidelines § 482.43(d)

- The hospital must take steps to ensure patients receive appropriate post-hospital care by arranging, as applicable, transfer to appropriate facilities or referrals to follow-up ambulatory care services.

- "Appropriate facilities, agencies, or outpatient services" refers to entities such as SNFS, NFs, HHAs, hospice agencies, mental health agencies, dialysis centers, suppliers of durable medical equipment, suppliers of physical and occupational therapy, physician offices, etc. which offer post-acute care services that address the patient's post-hospital needs identified in the patient's discharge planning evaluation. The term does not refer to non-healthcare entities, but hospitals are encouraged to make appropriate referrals to community-based resources that offer transportation, meal preparation, and other services that can play an essential role in the patient's successful recovery. "Appropriate facilities" may also include other hospitals to which a patient is transferred for follow-up

care, such as rehabilitation hospitals, long term care hospitals, or even other short term acute care hospitals.

- The "medical information" necessary for transfer or referral includes, but is not limited to:
    - Brief reason for hospitalization (or, if hospital policy requires a discharge summary for certain types of outpatient services, the reason) and principal diagnosis;
    - Brief description of hospital course of treatment;
    - Patient's condition at discharge, including cognitive and functional status and social supports needed;
    - Medication list (reconciled to identify changes made during the patient's hospitalization) including prescription and over-the-counter medications and herbal. Note: an actual list of medications needs to be included in the discharge information, not just a referral to an electronic list available somewhere else in the medical record;
    - List of allergies (including food as well as drug allergies) and drug interactions;
    - Pending laboratory work and test results, if applicable, including information on how the results will be furnished;
    - For transfer to other facilities, a copy of the patient's advance directive, if the patient has one; …
        - The regulation requires transfer or referral "along" with necessary medical information. In the case of a patient being transferred to another inpatient or residential health care facility, the necessary information must accompany the patient to the facility. In the case of a patient discharged home, transmittal of the information to the patient's physician may take place up to 7 days after discharge or prior to the first appointment, whichever comes first.
- It is recognized that hospitals have certain constraints on their ability to accomplish patient transfers and referrals:
    - They must operate within the constraints of their authority under State law;
    - A patient may refuse transfer or referral; or
    - There may be financial barriers limiting a facility's, agency's, or ambulatory care service provider's willingness to accept the patient. In such cases the hospital does not have financial responsibility for the post-acute care services. Hospitals are expected to be knowledgeable about resources

available in their community to address such financial barriers. This includes Medicaid services, availability of Federally Quality Health Centers, Area Agencies on Aging, etc. Hospitals are also expected to take steps to make those resources available to the patient.

Report of the National Background Check Program (NBCP) Long-Term Care (LTC) Criminal Convictions Work Group, S&C: 13-24-NH (Apr. 12, 2013, rev. July 3, 2013)

Survey and Certification Letter: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-24-Memo.pdf

Attachment: Report of the National Background Check Program (NBCP) Long-Term Care (LTC) Criminal Convictions Work Group: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-24-Attachment-.pdf

Summary of Key Findings:

- Section 6201 of the ACA established the National Background Check Program to identify efficient, effective, and economical procedures for LTC facilities or providers to conduct background checks on prospective direct patient access employees on a national basis.
- According to the OIG's March, 2011 interim report, based on FBI-maintained criminal history records, "92% of nursing facilities employed one or more individuals with a history of criminal conviction." In that report, OIG recommended that CMS define the classifications for direct patient access employees and work with participating States to develop a list of convictions that disqualify an individual from nursing facility employment, including periods for which each conviction bars the individual.
- In response, a work group of CMS employees and volunteers from 11 State Agencies (SAs) developed options for CMS to consider:
    - Common definitions for "direct access employee;"
    - A list of State convictions that should disqualify individuals from direct access employment in LTC; the conviction types that should be considered for mitigation or rehabilitation, and the time period for which each conviction should disqualify individuals.
- The work group considered all LTC facilities and providers identified in Section 6201 of the ACA, including: SNFs/NFs; home health agencies; hospice; LTC hospitals; personal care services; adult day care; residential care; Intermediate Care Facilities for the Intellectually Disabled (ICF/IID); and any other facility or provider of LTC services as determined by the State.

- The Work Group developed a "Consolidated Option: for defining a direct access employee:
    - An individual who has direct access to a resident or beneficiary through ownership, employment, or a contract/agreement with a LTC facility or provider. This does not include volunteers or students, unless they perform regular or unsupervised functions equivalent to those of direct access employees. Also excluded are contractors performing repairs, deliveries, installations, or similar services only for the facility or provider.
    - Direct access is having, or expecting to have, duties that involve one-on-one contact with a resident or beneficiary, or access to the resident or beneficiary's property, personally identifiable information, or financial information.
- Because of wide variance across States regarding definitions of specific crimes, the work group suggested utilization of categories for disqualifying convictions versus lists of individual crimes. Suggested categories included: (1) crimes against care-dependent or vulnerable individuals, (2) crimes against the person, (3) crimes against property, and (4) crimes related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.
- The work group elected to follow the rehabilitation factors contained in Section 6201 of the ACA including:
    - Passage of time;
    - Extenuating circumstances;
    - Demonstration of rehabilitation; and
    - Relevancy of the particular disqualifying information with respect to the current employment of the individual.
- Minimum disqualification times were based on whether the charges were felonies or misdemeanors; violent or non-violent; and the amount of time that had elapsed from time of conviction or release from prison.
- CMS will consider the work group's findings and options and formulate a plan for future action.

Life Safety Code (LSC) Short Form Survey for Nursing Homes – Limited Option, S&C: 13-22-NH (Apr. 5, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-22.pdf

CMS stated that its intent for this procedure is to "allow surveyors to spend more time with facilities whose life safety code compliance poses greater risk to residents, and less time with those above-average facilities where life-safety code compliance is superior." Improving targeting of surveyor time is important to "(a) meet the resource limitations of the recent sequester-required budget reductions;" (b) respond to the challenge of enforcing the Aug. 13, 2013 deadline for all nursing homes to be fully sprinklered; and "(c) ensure that Medicare and Medicaid funds are used in the most efficient and effective manner."

State Option

- CMS will permit States--at the States' option--to implement a Short Form Fire Safety Survey for a limited number of specified facilities that have demonstrated superior compliance with LSC requirements and are fully sprinklered.
- These facilities will be identified on a confidential list that, beginning in FY13 and at the beginning of each year thereafter, CMS will make available to the respective State Survey Agencies (SAs).
- Only facilities that are considered fully sprinklered, do not have any significant waivers of LSC requirements, and are not certified by the use of the Fire Safety Evaluation System (FSES) will be considered for use of the short form survey. CMS is not eliminating the use of the longer LSC survey process or the FSES in implementing this Short Form.

CMS Selection Criteria and Process

- For the selected nursing homes, the Short Form may be used to collect data on a specific set of K tags.
- These identified K tags will give a core indication of the facility fire safety status. If initial survey findings indicate there are serious problems, the survey must be expanded to cover additional K tags.
- The Short Form already contains more than the initial set of K tags, so the survey may easily be expanded while the survey team is onsite, or a full survey may be scheduled.

Eligibility Requirements – To be eligible, a facility must:

- Be fully sprinklered;

- Generally not have any waivers or use the Fire Safety Evaluation System – Health Care (FSES/HC) to be certified;
- Have not been cited for K0062 Sprinkler Maintenance, K0054 Smoke Detector Maintenance, K0050 Fire Drills, K0104 Smoke Barriers and 0051 Fire Alarms in the last two years.
- Not have more than 2 survey cycles since the last Long Form survey was conducted.

- CMS advises these criteria may be subsequently modified based on the results of LSC surveys over time.
- The SA may determine who completes the Short Form survey process, provided every surveyor who conducts the survey first completes the CMS Short Form survey training, expected to be available via webinar.
- Short Form surveys might be completed by health surveyors who have participated in a webinar in which specific K tags are reviewed; or by surveyors who ordinarily complete fire safety surveys (such as State Fire Marshals or other Health Department staff who may conduct LSC surveys on a regular basis).

Attachment A

The Letter includes Attachment A: Life Safety Code – Targeted LSC Short Form - Special Survey Instructions

- The process uses the existing Short Form 2786R (June 2007 edition).
- Use of the existing form will expedite the process as it is already available and is part of the current data system.
- The 2786R has been used in the past as a screening tool to determine if a more detailed LSC survey is required.
- The K tags selected for Short Form review are concentrated in the maintenance of fire protection systems in the facility, fire drills for staff, means of egress availability and emergency electrical power where installed.

Key K Tags for the Short Form Survey

- The following K tags are proposed to be reviewed by surveyors on-site:
  - K38 - Exit access:
  - K39 - Exit corridor width
  - K47 - Exit signs operational:
  - K50 - Fire drills:

- K52 - Fire alarm system properly maintained
- K62 - Automatic sprinkler system properly maintained
- K72 - Means of egress unobstructed by furnishings and decorations
- K144 - Emergency generator properly maintained
- K211 - Alcohol based hand rubs properly used

Access to Statements of Deficiencies (CMS-2567) on the Web for Skilled Nursing Facilities, Nursing Facilities, Hospitals, & Critical Access Hospitals, S&C: 13-21-ALL (Mar. 22, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-21.pdf

In July 2012, CMS began posting Statements of Deficiencies (CMS-2567s) for skilled nursing facilities and nursing facilities on Nursing Home Compare. In March 2013, CMS initiated posting of CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaint investigations. This memo describes the contents and location of these files.

Nursing Homes:

- Since July, 2012, users of Nursing Home Compare have been able to view final CMS-2567s for the most recent standard health survey and the most recent 15 months of complaint surveys. In July, 2012, CMS also began posting in an electronic database the same CMS-2567 deficiency data on the Five-Star Nursing Home Quality Rating System. Both websites are updated monthly.
- In April 2013, CMS will expand access to CMS-2567s from the current single survey cycle to the preceding three standard health surveys and three years of complaint surveys.
- To "improve the public's ability to interpret CMS-2567 findings," CMS also plans to add indicators for the scope and severity of each deficiency cited.
- CMS-2567 reports are publicly releasable upon request and do not require release through a Freedom of Information Act (FOIA) request.
- Current posted CMS data do not contain any Plan of Correction (POC) information.
    - Facility POCs may be requested from either the facility or the State Survey Agency (SA). Section 1902(a)(9)(D) of the Social Security Act (SSA) requires each State to maintain a consumer-oriented website that includes the nursing home

CMS-2567 and the facility POC. Links to the State websites may be found on Nursing Home Compare.

- CMS advises that "the above-referenced CMS web pages may help alleviate the workload involved in fulfilling requests for [these] documents, especially beginning in April 2013, when more nursing home CMS-2567s become available on the webpage."
- CMS notes that at least two additional private websites, ProPublica and the Association for Health Care Journalists, publish information based on CMS-2567 data.

F tag 155 - Advance Directives - Revised Advance Copy, S&C: 13-16-NH (Mar. 8, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-16.pdf

This memorandum replaces a previous version of S&C: 12-47-NH, 9/27/12.

Key Provisions:

- Additional revisions have been made to Surveyor Guidance at F tag 155 in Appendix PP of the SOM and the associated Power Point. The revisions include:
    - Removal of the term "right to accept" when referring to medical and surgical treatment to correlate with § 483.10(b)(4).
    - Addition of guidance specific to experimental research.
        - "The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experimental research (e.g., medication, other treatment) and the possible consequences of participating. The resident must give informed consent in order to participate. If the resident is incapable of understanding the situation and of realizing the risks and benefits of the proposed research, but a legal representative gives proxy consent, the facility has a responsibility to ensure that the proxy consent is properly obtained and that essential measures are taken to protect the individual from harm or mistreatment. The resident (or his/her legal representative if the resident lacks health care decision-making capacity) must have the opportunity to refuse to participate both before and during the experimental research activity.

A facility participating in any experimental research involving residents must have a process for committee (e.g., an Institutional Review Board) approval of this research and mechanisms in place for its oversight. In this regard, § 483.75(c), Relationship to Other HHS Regulations, applies (i.e., research conducted at a facility must adhere to 45 CFR Part 46, Protection of Human Subjects of Research)."

- Clarification that § 483.10(b)(8) applies only to adult residents and not all residents regardless of age.
  - "NOTE: While the language of 42 C.F.R §483.10(b)(8) applies only to adults, states may have laws that govern the rights of parents or legal guardians of children to formulate an advance directive. The CMS believes that this is an important issue for the parents/guardians of terminally ill or severely disabled children. Therefore surveyors are encouraged to refer to state law in cases where concerns arise regarding advance directives in non-adult populations. The regulatory language found under § 483.10(b)(4) applies to all residents, regardless of age."
- Addition of definition for "Investigational or experimental drugs."
  - "Investigational or experimental drugs" refer to new drugs that have not yet been approved by the FDA or approved drugs that have not yet been approved for a new use, and are in the process of being tested for safety and effectiveness."
- Updating the Investigative Protocol.
  - 'Use' - no longer used for all residents in the sample; to be used for:
    - "Complaints from residents, family members or other resident representatives concerning services related to a resident's right to refuse medical or surgical treatment, participate in experimental research, formulate an advance directive, or provide written information, policies and procedures related to advance directives;
    - All sampled residents identified with orders or a condition (e.g., neuromuscular diseases, exacerbation of COPD, temporary swallowing or gastrointestinal tract issues) potentially related to provision of life-sustaining treatments such as artificial nutrition/hydration, artificial ventilation, dialysis, blood transfusions, or cardiopulmonary resuscitation. (NOTE: For the QIS, this review would be conducted during Stage 2…);
    - Residents who refused medical or surgical treatment; or
    - Is participating in an experimental research activity or project.

- Guidelines specific to experimental research and record review relative to a physician's basis for conscientious objection and/or need for additional information related to a resident's decisional capacity.

- Updating the Power Point training slides.

Physician Delegation of Tasks in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), S&C: 13-15-NH (Mar. 8, 2013)

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-15-.pdf

This Letter replaces the Survey and Certification memo from Nov. 13, 2003, addressing physician delegation of tasks in SNFs and NFs. It clarifies Federal guidance for physician delegation of certain tasks in SNFs and NFs to non-physician practitioners (NPPs; formerly "physician extenders") such as nurse practitioners, physician assistants, or clinical nurse specialists. It also implements Section 3108 of the ACA, which adds physician assistants to the list of practitioners that can perform SNF certifications and re-certifications; and clarifies policy on co-signing orders in SNFs and NFs.

Generally - Section 483.40(e)(2) provides that, "A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies."

SNF

- Section 483.40(c)(3), mandates that all required physician visits be made by the physician personally and not be delegated.

    - A required physician visit includes the initial comprehensive visit and every alternate required visit thereafter.

- The initial comprehensive visit in a SNF is the initial visit, no later than 30 days from admission, "during which the physician completes a thorough assessment, develops a plan of care and writes or verifies admitting orders for the resident."

    - The physician may not delegate the initial comprehensive visit. Non-physician practitioners may perform other medically necessary visits prior to and after initial comprehensive visit.

- Alternate visits may be delegated to a Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) licensed by the State and performing within the scope of practice.

- Alternate visits, as well as medically necessary visits, may be performed and signed by the NPP--physician co-signature is not required.

- Section 424.20(e)(2) states that NPs and CNSs who are not employed by the facility and are working in collaboration with a physician may sign the required initial certification and re-certifications when permitted under the State scope of practice.

- Effective with services furnished on or after January 1, 2011, in accordance with section 3108 of the ACA, PAs who are not employed by the facility may perform the required initial certification and periodic re-certifications of a SNF beneficiary.

NF

- Similar to SNFs, the initial comprehensive visit in a NF is the initial visit, no later than 30 days from admission, "during which the physician completes a thorough assessment, develops a plan of care and writes or verifies admitting orders for the resident."

- Section 483.40(f) provides that "At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician."

- At the option of the State, NPs, PAs, and CNSs who are employees of the facility, while not permitted to perform visits required under § 483.40(c)(1), are permitted to perform other medically necessary visits and write orders based on these visits.

- The physician is not required, other than under State law, to verify and sign orders written by NPPs employed by the facility for other medically necessary visits.

    - Medically necessary visits may not take the place of physician required visits, and may not count towards meeting the required physician visit schedule.

- In contrast to the initial SNF visit, NPPs may provide initial NF visits and other required visits under §§ 483.40(c)(3) and (f) if the State permits.

- Required physician tasks, such as verifying and signing orders in a NF, may be delegated to a PA, NP, or CNS who is **not** an employee of the facility but is working in collaboration with a physician.

- Orders written by an NPP employed by the NF during visits that are not required visits, and are "other medically necessary visits," do not require physician co-signature except as mandated by State law.

- The Federal requirements restricting NPPs employed by the NF from performing a *required visit*, do not apply to *other medically necessary visits*.

SNF/NF

- In dually-certified facilities, the facility must determine the payment source. For a Part A Medicare stay, the NPP must follow the guidelines for services in a SNF. For residents in a Medicaid stay, the NPP must follow the provisions outlined for care in NFs.

Other Developments

CDC National Safety Network – Long Term Care Facilities Infection Control Website (Jan. 24, 2014)

http://www.cdc.gov/longtermcare/

The Centers for Disease Control and Prevention's (CDC) long term care facilities (LTCF) infection control website was developed in partnership with the Advancing Excellence in America's Nursing Homes Campaign (AE). Long-term care providers can use the site to access information and resources to prevent infections. The new CDC website is geared to SNFs/NFs and assisted living facilities, and offers information for clinical staff; infection control coordinators; and residents/consumers. The site addresses:

- Clinical Staff Information - Includes guidance documents and web links to resources, e.g., CDC presentations, reports, on common infections that occur in long-term care facilities and how to prevent them.

- Resident Information

    - Contains links to information and resources about infections that can be found/acquired in nursing homes and assisted living facilities, i.e., Carbapenem-resistant Enterobacteriaceae (CRE); C. difficile; Influenza; Methicillin-Resistant Staphylococcus aureus (MRSA); Norovirus; Catheter-associated Urinary Tract Infections.

    - Also includes the link to Nursing Home Compare.

- Prevention Tools

    - Intended to assist clinicians, administrators, and health department personnel with infection prevention, includes links to the Advancing Excellence in America's Nursing Homes Campaign (AE) C. difficile Infection Prevention Assessment Checklists and to CDC toolkits, i.e., Long-term Care Infection Prevention Toolkit; C. difficile Toolkit; Carbapenem-resistant Enterobacteriaceae (CRE) Toolkit; Norovirus Toolkit; MRSA Toolkit; Catheter-Associated Urinary Tract Infection (CAUTI) Toolkit

- Providers can also use this site to access the infection tracking system for long-term care facilities in the CDC's National Healthcare Safety Network, and other CDC Links for LTC Settings, including:
    - Antibiotic Stewardship, including the Fact Sheet: Antibiotic use in nursing homes
    - [http://www.cdc.gov/getsmart/healthcare/learn-from-others/factsheets/nursing-homes.html]
    - Guidelines for Infection Prevention and Control in Healthcare Settings and:
    - Viral Hepatitis and LTCF
    - Influenza Outbreak Guidance for LTCF
    - Other Influenza Resources for Healthcare Providers
    - Tuberculosis Infection Control in Healthcare
    - Healthcare Preparedness Resources
    - Safe Water for Healthcare Facilities
    - Addressing Falls in Nursing Home

OIG Advisory Opinion No. 14-01 (Jan. 13, 2014)

http://www.healthlawyers.org/News/Advisory%20Opinions/Documents/2014/AO14-01.pdf

In this Opinion, OIG concluded that while an arrangement involving payments to a senior living placement agency would potentially generate prohibited remuneration under the Anti-kickback Statue (AKS) if the requisite intent to induce or reward referrals of Federal health care program business were present, parties to the arrangement had taken sufficient steps to adequately reduce that risk. As a result, OIG concluded that it would not subject the parties to administrative sanctions.

Facts:

- Requestor is a non-profit parent company to subsidiaries involved in senior housing and geriatric care, including 11 residential communities (Communities), 2 SNFs and a management company.
- The Communities and SNFs are largely private pay, although a few residents receive some funding through a State Elderly Medicaid Waiver Program.
- Requestor contracts with a private placement agency and pays the agency for each new resident that the agency places at two of the Communities. The fee is based on a percentage of the resident's charges for the first and/or second month of residency at the Community. The contract does not permit the agency to refer residents that rely in whole or in part on Federal or state funding.

- None of the residents at the two communities in question have access to services provided at any of the other Communities or the SNFs that would be reimbursable by Federal health care programs.

Analysis:

- Residents at the two Communities served by the referral agency may eventually receive Federally-reimbursed services if he/she enters the Elderly Waiver Program while residing at a participating Community, or he/she moves to an affiliated SNF or a Community where Federally-payable services provided by SNF staff are available to residents. As a result, there is remuneration under the referral contract that implicates the AKS. However, the issue becomes whether remuneration is *likely* to be an improper payment to generate Federal health care program business for the Requestor and its affiliates.
- OIG concludes, based on the facts and circumstances of the arrangement, taken together, adequately reduce the risk that the remuneration provided under the arrangement could be an improper payment for referrals or the generation of Federal health care program business. Specifically, OIG cited the following four factors:
    - The placement fee is calculated only on the initial rent and services provided by the two Communities to the referred residents. It does not include any charges to Federal health care programs. This factor, in combination with others, serves to reduce the risk of fraud and abuse posed by the arrangement.
    - The contracts underlying the arrangement expressly prohibit placement by the agency, and acceptance by the two Communities, of potential residents who are known to rely, in whole or in part, on state or Federal funding sources.
    - The placement agency refers potential residents only to Communities that provide housing and services not reimbursable by Federal health care programs, and residents at the participating Communities do not have access to services at other Communities affiliated with the Requestor that would be reimbursable by Federal health care programs. That residents of the participating Communities may, at some point in the future, receive Federally-reimbursable housing or services from an affiliated Community (i.e., by moving there) is "substantially speculative and outside the control of the referral agency.
    - The Requestor certified that the Communities do not track referrals or common residents/patients among them, nor do they limit their residents' choice of providers, practitioners or service suppliers, in order to steer them to affiliated providers.

Conclusion:

- Although the arrangement could potentially generate prohibited remuneration under the AKS if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will not impose administrative sanctions in this case.

CMS Manual Updates to Clarify Skilled Nursing (SNF), Inpatient Rehabilitation Facility (IRF), Home Health (HH), and Outpatient (OPT) Coverage Pursuant to *Jimmo vs. Sebelius*, MLN Matters Article #MM8458 (Jan. 14, 2014, rev. Jan. 15, 2014)

Article: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8458.pdf

Change Request 8458: http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R179BP.pdf

This document reflects changes to the Medicare Benefit Policy Manual (MBPM) in response to the settlement agreement in the case of *Jimmo v. Sebelius* regarding the so-called "Improvement Standard" for therapy services. It applies to Skilled Nursing Facilities (SNFs); Inpatient Rehabilitation Facilities (IRFs); Home Health Agencies (HHAs); providers and suppliers of therapy services under the Outpatient Therapy (OPT) Benefit–including Critical Access Hospitals (CAHs), hospitals, rehabilitation agencies, SNFs, HHAs, physicians, certain non-physician practitioners, and therapists in private practice.

Key Provisions:

- **No "Improvement Standard" is to be applied in determining Medicare coverage for maintenance claims in which skilled care is required.** Medicare has long recognized that even in situations where no improvement is expected, skilled care may nevertheless be needed for maintenance purposes (i.e., to prevent or slow a decline in condition).
    - Restorative/Rehabilitative therapy - In evaluating a claim for skilled therapy that is restorative/rehabilitative (i.e., whose goal and/or purpose is to reverse, in whole or in part, a previous loss of function), it would be entirely appropriate to consider the beneficiary's potential for improvement from the services. CMS notes that such a consideration must always be made in the IRF setting, where skilled therapy must be reasonably expected to improve the patient's functional capacity or adaptation to impairments in order to be covered.
    - Maintenance therapy - Even if no improvement is expected, under the SNF, HH, and OPT coverage standards, skilled therapy services are covered when an individualized assessment of the patient's condition demonstrates that skilled care is necessary for the performance of a safe and effective maintenance program to maintain the patient's current condition or prevent or slow further deterioration. Skilled maintenance therapy may be covered when the particular patient's special medical complications or the complexity of the therapy procedures require skilled care.
- **Coverage depends upon an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the skilled treatment, care, or services**

in question. When such assessment demonstrates that skilled care is needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, the care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively through the use of *nonskilled* personnel.

- **Enhanced guidance on appropriate documentation -** Portions of the revised manual provisions now include additional material on the role of appropriate documentation in facilitating accurate coverage determinations for claims involving skilled care. While the presence of appropriate documentation is not, in and of itself, an element of the definition of a "skilled" service, such documentation serves as the *means* by which a provider would be able to establish and a Medicare contractor would be able to confirm that skilled care is, in fact, needed and received in a given case.
    - An example of this material appears in a new Section 30.2.2.1 of the MBPM's revised Chapter 8, in the guidelines for SNF coverage under Part A.

FDA Guidance for Providers and Consumers: Bed Rail Safety

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/default.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

The Food and Drug Administration (FDA), working in coordination with the Consumer Product Safety Commission (CPSC) and the Administration for Community Living, recently posted new guidance for providers and consumers related to bed rail safety.

The site addresses safety concerns, recommendations for providers, and suggestions for filing complaints. Included are sections on:

- Bed Rail Safety
- Safety Concerns about Bed Rails
- Recommendations for Consumers and Caregivers about Bed Rails
- Recommendations for Health Care Providers about Bed Rails
    - This section includes the links to FDA Guidance, "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment," for health care facilities and manufacturers, and the "Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings" developed by the Hospital Bed Safety Workgroup (HBSW), the FDA partnership with representatives from the hospital bed industry, national

healthcare organizations (including LeadingAge), patient advocacy groups, CMS, and other federal agencies.

- Information for Manufacturers of Bed Rail Products
- How to Report a Problem or Complaint
- FDA and CPSC Activities
- Additional Resources

OIG Report, Medicare Nursing Home Resident Hospitalization Rates Merit Additional Monitoring, OEI-06-11-00040 (Nov., 2013)

http://oig.hhs.gov/oei/reports/oei-06-11-00040.pdf

OIG states that this report was necessitated by the risk to nursing home residents and high Medicare costs associated with high rates of hospitalizations by individual nursing homes.

Objectives

- To determine the percentage of Medicare nursing home residents hospitalized in fiscal year (FY) 2011 and the associated costs to Medicare.
- To identify the medical conditions most commonly associated with these hospitalizations.
- To determine the extent to which these hospitalization rates varied across nursing homes.
- To determine the extent to which these hospitalization rates varied according to select nursing home characteristics [geographic location; CMS NH Five-Star Rating System scores; size/number of beds; type of ownership].

Methodology:

- OIG used administrative and billing data for nursing homes and hospitals to identify all Medicare residents in Medicare and/or Medicaid-certified facilities transferred to hospitals for inpatient stays in fiscal year (FY) 2011.
- OIG collected and combined assessment data from the MDS; beneficiary information from the Enrollment Database (EDB); and hospital claims data from the National Claims History (NCH).
    - For this study, a Medicare 'nursing home resident' was defined as any Medicare beneficiary who stayed in a Medicare or Medicaid-certified nursing home for at

least 1 day in FY '11; a hospitalization was defined as when a Medicare resident went to a hospital for a Medicare-reimbursed inpatient stay within 1 day of discharge from a nursing home.

- All Medicare nursing home residents were included, i.e., those in Medicare-paid skilled nursing and rehabilitative (SNF) stays and those in stays not paid by Medicare, including 'long-term' stays.
    - The percentage of Medicare nursing home residents that each nursing home hospitalized was calculated.
    - OIG identified the diagnoses associated with these hospitalizations via submitted Medicare claims; calculated Medicare reimbursements for the hospital stays; calculated the rates and costs of hospitalizations of nursing home residents; and examined the extent to which annual rates of resident hospitalizations varied among individual nursing homes (facilities with 30 or more Medicare residents in FY '11).

Findings:

- In FY 2011, nursing homes transferred 1/4 of their Medicare residents (825,765 of 3.3 million) to hospitals for inpatient admissions.
    - 67.8% had one transfer; 20% had two transfers; 7.2% had 3 transfers; 5% transferred 4 or more times.
- Medicare spent $14.3 billion on these hospitalizations (1.3 million stays; 33% more per stay than for average Medicare hospitalizations).
- Nursing home residents were transferred to hospitals for a range of conditions, with septicemia, pneumonia, and congestive heart failure being the most common.
- Annual rates of Medicare resident hospitalizations varied widely, ranging from 1% to 69.7%, with an average of 25%.
    - Nursing homes with the following characteristics had the highest annual rates of resident hospitalizations: homes in Arkansas, Louisiana, Mississippi, or Oklahoma; homes with 1, 2, or 3 stars in 3 of the 4 domains (overall; inspection; staffing) of the CMS Nursing Home Five-Star Rating System.
    - Large (120+ beds) and medium (80–120 beds) nursing homes had higher annual hospitalization rates.
- For-profit nursing homes had the highest annual hospitalization rates (1.5%) compared to government-owned (-1.5%) and not-for-profits (-3.8%).

OIG Recommendations for CMS:

- Develop a quality measure (QM) that describes nursing home resident hospitalization rates and consider public reporting on Nursing Home Compare; and
- Instruct State survey agencies to review the proposed quality measure/resident hospitalization rates as part of the survey and certification process.

CMS Response: CMS concurred with both recommendations.

- CMS advised it will develop and implement a nursing home hospitalization QM in accordance with the rulemaking process and that it is also developing a SNF readmission measure to be submitted to the National Quality Forum (NQF) for endorsement in late 2013.

- CMS indicated that surveyors should consider measures of hospitalization during their nursing home reviews.

CMS Q & A Document re: Aligning Nursing Home Quality Initiatives (Oct. 22, 2013)

http://www.leadingage.org/uploadedFiles/Content/Members/Nursing_Homes/Survey_and_Certification/FAQ_Aligning_NH_Quality_Initiatives_10_2013.pdf

This document was created to clarify how some of the national nursing home quality initiatives relate to and are aligned with each other. It addresses/describes the various national quality initiatives via a set of common questions and answers for nursing homes (see below), to clarify how the initiatives relate to and are aligned with each other. Specifically, it describes Quality Assurance and Performance Improvement (QAPI), the National Nursing Home Quality Care Collaborative (NNHQCC), the National Partnership to Improve Dementia Care in Nursing Homes, Advancing Excellence in America's Nursing Home's Campaign**.**

CMS Memorandum re: Impact of United States v. Windsor on Skilled Nursing Facility Benefits for Medicare Advantage Enrollees (Aug. 29, 2013)

http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/SNF_Benefits_Post_Windsor.pdf

CMS advised that, effective immediately, Medicare Advantage (MA) organizations must cover services in a skilled nursing facility (SNF) in which a validly married same sex spouse resides to the extent that they would be required to cover the services if an opposite sex spouse resided in the SNF. The memorandum comes as a result of the U.S. Supreme Court's ruling in *United States v. Windsor*, which invalidated the Federal Defense of Marriage Act (DOMA).

OIG Report: Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI-02-12-00040 (July 29, 2013)

http://oig.hhs.gov/oei/reports/oei-02-12-00040.asp

This report describes hospitals ' use of observation stays and short inpatient stays in 2012.

Background:

- "Observation services are short-term treatments and assessments provided to outpatients to determine whether beneficiaries require further treatment as inpatients or can be discharged. CMS policy states that observation services are usually needed for 24 hours or less."
    - Physicians are directed to consider whether beneficiaries are expected to need at least 24 hours of hospital care.
    - "During observation stays, treating physicians use short-term treatments and assessments to determine whether a beneficiary should be admitted as an inpatient or discharged. Observation stays can occur anywhere in the hospital, including the emergency department, a separate observation unit, or an inpatient unit." In accordance with CMS policy, "the decision to admit or discharge can usually be made within 24 hours, and should rarely take longer than 48 hours."
- CMS, Congress, and others have raised concerns about hospitals' use of observation stays and short inpatient stays.
- Concerns include beneficiaries spending long periods of time in observation stays without being admitted as inpatients and that beneficiaries may pay more as outpatients than if they were admitted as inpatients.
- Beneficiaries not admitted as inpatients may not qualify under Medicare for skilled nursing facility (SNF) services following discharge.
- CMS is also concerned about improper payments for short inpatient stays when beneficiaries should have been treated as outpatients, i.e., a significant portion of payments for these stays were improper because the services should have been provided in the outpatient setting.
- Under CMS' Notice of Proposed Rulemaking (NPRM) (79 Fed. Reg. *27485, 27644-27650 (May 10, 2013)*, CMS contractors would presume that inpatient hospital stays lasting 2 nights or longer were reasonable and necessary and would qualify for payment as inpatient stays. Conversely, CMS contractors would presume that stays lasting less than 2 nights would not qualify for payment as inpatient stays and instead would be paid for as outpatient stays. CMS proposed that time spent in any outpatient area of the hospital would not count towards this 2-night presumption.

Methodology:

- OIG based this study on analysis of Medicare Part A and Part B hospital claims from 2012 and SNF Part A claims for beneficiaries who received these hospital services.

- The number and characteristics of observation stays, long outpatient stays (Part B hospital claims that lasted at least 1 night) and were not coded as observation stays, and short inpatient stays (Part A hospital claims that were 1 night or less) were determined. OIG then determined the number of hospital stays in which beneficiaries spent at least 3 nights in the hospital but did not qualify for SNF services.

Findings:

- Medicare beneficiaries had 1.5 million observation stays in 2012; these beneficiaries commonly spent 1 night or more in the hospital.
    - Observation stays were most often chest pain; 2nd was digestive disorders; and 3rd and 4th were fainting and "signs and symptoms," which includes general pain or malaise.
    - 78% of observation stays began in the ER. 92% of beneficiaries spent at least 1 night (2 calendar days) in the hospital: 55% spent 1 night; 26% spent 2 nights; and 11% spent at least 3 nights.
- Beneficiaries had an additional 1.4 million long outpatient stays, some of which may have been observation stays. Beneficiaries had 1.1 million short inpatient stays, often for the same reasons as observation stays.
- On average, Medicare paid nearly 3X more for a short inpatient stay than an observation stay; beneficiaries paid almost 2X more.
- Some hospitals were more likely to use short inpatient stays, whereas others were more likely to use observation or long outpatient stays.
- Beneficiaries had over 600,000 hospital stays that lasted 3 nights or more but did not qualify them for SNF services.
    - These stays included observation and long outpatient stays, and stays in which the beneficiary began as an outpatient and was eventually admitted into a short or 2-night inpatient stay.
    - 4% of these beneficiaries, or 25,245, of the 617,702 hospital stays, received SNF services following their discharge from the hospital, even though they did not qualify for these services under Medicare.
    - For 23,148 of these hospital stays, Medicare inappropriately paid for the SNF services, for a total of $255 million.

- Beneficiaries paid a total of $63 million in copayments, for an average of $2,735 for the SNF services following each hospital stay.

- OIG's results indicate that "under the NPRM, the number of short inpatient stays would be significantly reduced; however, the number of observation and long outpatient stays may not be reduced if outpatient nights are not counted towards the proposed 2 night presumption."

- Under the NPRM, "some hospitals would likely follow the provisions and continue to bill these as outpatient stays; other hospitals—given strong financial incentives and few barriers—would likely not follow the provisions and would admit beneficiaries as inpatients as soon as possible to meet the 2 night presumption."

- Findings raise concerns about SNF services for beneficiaries in observation stays, long outpatient stays, and short inpatient stays. CMS should consider how to ensure that beneficiaries with similar post-hospital care needs have the same access to and cost sharing for SNF services.

- This report contains no formal recommendations. OIG does state, however that:

  - "Allowing nights spent as an outpatient to count toward the 3 nights needed to qualify for SNF services may require additional statutory authority. Ensuring that controls are in place so that Medicare does not inappropriately pay when beneficiaries do not qualify for SNF services is also critical."

  - OIG "will refer to CMS in a separate memorandum the SNFs that received $255 million in inappropriate payments so that CMS can look into recoupment."

Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013)

http://oig.hhs.gov/exclusions/files/sab-05092013.pdf

The updated Special Advisory Bulletin describes the scope and effect of the legal prohibition on payment by Federal health care programs for items or services furnished by (1) an excluded person; or (2) at the medical direction or on the prescription of an excluded person. The updated Bulletin describes how exclusions can be violated and the administrative sanctions OIG can pursue against those who have violated an exclusion; and provides guidance on the scope and frequency of screening employees and contractors to determine whether they are excluded persons. OIG originally published a Special Advisory Bulletin in September 1999 on the effect of exclusion from participation in Federal health care programs. The 1999 Bulletin has been the primary source of published guidance from OIG in this area, i.e., for excluded persons and for providers seeking to ensure compliance with the restrictions on employing or contracting with excluded individuals or entities.

Generally:

- The updated Bulletin:
    - Iterates earlier guidance on the scope and effect of an OIG exclusion,
    - Provides additional guidance on the scope of the payment prohibition and potential CMP liability,
    - Provides guidance on best practices for screening against the LEIE to ensure that providers do not employ or contract with an excluded individual; and
    - Directs providers to use OIG's SDP to self-disclose the employment of or contracting with an excluded person.

OIG Exclusion / Penalties:

- An OIG exclusion means that no Federal health care program payment may be made for any items or services furnished (1) by an excluded person; or (2) at the medical direction or on the prescription of an excluded person. The exclusion and the payment prohibition apply to an individual even if he/she changes from one health care profession to another while excluded.
- If a health care provider arranges or contracts (by employment or otherwise) with a person that the provider knows or should know is excluded by OIG, the provider may be subject to CMP liability if the excluded person provides services payable, directly or indirectly, by a Federal health care program.
- OIG may impose CMPs of up to $10,000 for each item or service furnished by the excluded person for which Federal program payment is sought, as well as an assessment of up to three times the amount claimed, and program exclusion.
- Providers that identify potential CMP liability on the basis of the employment of, contracting with, or arranging with an excluded person may use OIG's Provider Self-Disclosure Protocol (SDP) to disclose and resolve the potential CMP liability.

LEIE:

- OIG program exclusion information is found in the LEIE on the OIG Web site: http://oig.hhs.gov/exclusions
- The online database currently includes: (1) name of the excluded person at the time of exclusion; (2) provider type; (3) the authority under which the person was excluded; (4) the State where the excluded individual resided at the time of exclusion or the State where the entity was doing business; and (5) a mechanism to verify search results via Social Security Number (SSN) or Employer Identification Number (EIN). OIG will soon

update the LEIE to include a National Provider Identifier (NPI), for individuals and entities excluded after 2009.

- To avoid potential CMP liability, providers should check the LEIE prior to employing or contracting with persons and periodically check the LEIE to determine the exclusion status of current employees and contractors.

- Providers are not required by statute or regulation to check the LEIE. Because there is no statutory or regulatory requirement to check the LEIE, providers may decide how frequently to check the LEIE. However, OIG updates the LEIE monthly, so screening employees and contractors each month best minimizes potential overpayment and CMP liability.

OIG Advisory Opinion Process

- The OIG Advisory Opinion process is available to offer formal binding guidance on whether an employment or contractual arrangement may constitute grounds for the imposition of sanctions under OIG's exclusion and CMP authorities at Sections 1128 and 1128A of the Act.

    - The process and procedure for submitting an advisory opinion request may be found at 42 CFR § 1008, or on the OIG Web site at: http://oig.hhs.gov/compliance/advisory-opinions.

OIG Report: Skilled Nursing Facilities Often Fail To Meet Care Planning and Discharge Planning Requirements, OEI-02-09-00201 (Feb., 2013)

http://go.usa.gov/2CDC

Rationale:

Several OIG studies and investigations found that SNFs had deficiencies in quality of care, did not develop appropriate care plans, and failed to provide adequate care to beneficiaries.

- In fiscal year 2012, Medicare paid $32.2 billion for SNF services.

- This study is part of a larger body of work about SNF payments and quality of care.

Objectives:

- To determine the extent to which SNFs met Medicare care planning requirements.

- To determine the extent to which SNFs met Medicare discharge planning requirements.

- To describe instances of poor quality care.

Methodology:

- OIG based this study on a medical record review of a stratified simple random sample of SNF stays from 2009.
- Using CMS' national Claims History File, OIG identified Part A SNF claims from 2009; identified stays that ending in 2009, further defined by length of stay and number of claims; and selected a stratified random sample of 245. A focus on stays 21 days or longer resulted in a sample of 190, projected to 1,104,692 stays in the population.
- Reviewers (RNs, with consultations as needed from PT, OT, Speech) determined the extent to which SNFs developed care plans that met Medicare requirements; provided services in accordance with care plans; and planned for beneficiaries' discharges as required.
- Reviewers also identified examples of poor quality care.

Findings:

- For 37% of stays reviewed, SNFs did not develop care plans that met requirements or did not provide services in accordance with care plans.
    - 25% did not meet at least 1 of the care planning requirements;
    - 19% did not address 1 or more RAPs triggered / problem areas identified in the resident assessment.
    - 7% did not include measureable objectives.
    - 2% were not completed by interdisciplinary teams.
    - 15% did not provide at least 1 service as contained in the care plan(s), i.e., more or fewer.
- For 31% of stays reviewed, SNFs did not meet at least 1 of the discharge planning requirements.
    - 16% lacked summaries
    - 23% lacked post-discharge plans of care.
- Medicare paid approximately $5.1 billion for stays in which SNFs did not meet these requirements.
- Reviewers found examples of poor quality care related to wound care (3), medication management (5), and therapy (2 at inappropriately high levels).

Recommendations:

- OIG recommended that CMS:
    - Strengthen the regulations on care planning and discharge planning;
        - Require SNFs to document why services were not provided in accordance with the care plans, similar to the requirement that SNFs document why a care plan does not address certain triggered RAPs/identified problem areas.
        - Required that discharge planning be conducted by an interdisciplinary team, including a physician.
    - Provide guidance to SNFs to improve care planning and discharge planning;
    - Increase surveyor efforts to identify SNFs that do not meet care planning and discharge planning requirements and to hold these SNFs accountable;
    - Link payments to meeting quality-of-care requirements; and
    - Follow up on the SNFs that failed to meet care planning and discharge planning requirements or that provided poor quality care.
        - OIG will provide CMS with a list of the SNFs reviewed that did not meet one or more of the care planning or discharge requirements or were identified re: the examples of poor quality of care.

CMS Response:

- CMS concurred with all five of the OIG recommendations, citing current efforts, e.g., QIO/NH Quality Care Collaborative, and considerations for future directives, e.g., incorporating care planning and discharge planning in future nursing home demonstrations.