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GREATER NEW YORK HEALTH CARE FACILITIES ASSOCIATION

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GNYHCFA Regulatory Updates

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AGENDA

- Medicare, Medicaid, CHIP Integrity "Enhancements"
- NY Public Health Law Requirements
- Mental Hygiene Legal Services
- Emergency Preparedness
- Coronavirus
- Other Concerns –
  - Federal Nursing Home Initiative
  - Proposed Regulations for PASRR

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New CMS Enforcement Authorities Related to Enrollment in Medicare, Medicaid or CHIP

Program Integrity Enhancements to the Provider Enrollment Process

- CMS has expanded its authority to revoke or deny enrollment in Medicare, Medicaid and CHIP.
  - Will focus on real and demonstrable histories of conduct that poses "undue risks" to taxpayers, patients, and program beneficiaries.
  - Designed to prevent continuing game of "whack-a-mole" with criminals who get booted out of programs only to re-emerge under different corporate names.
  - Effective:

November 4, 2019

Program Integrity Enhancements to the Provider Enrollment Process

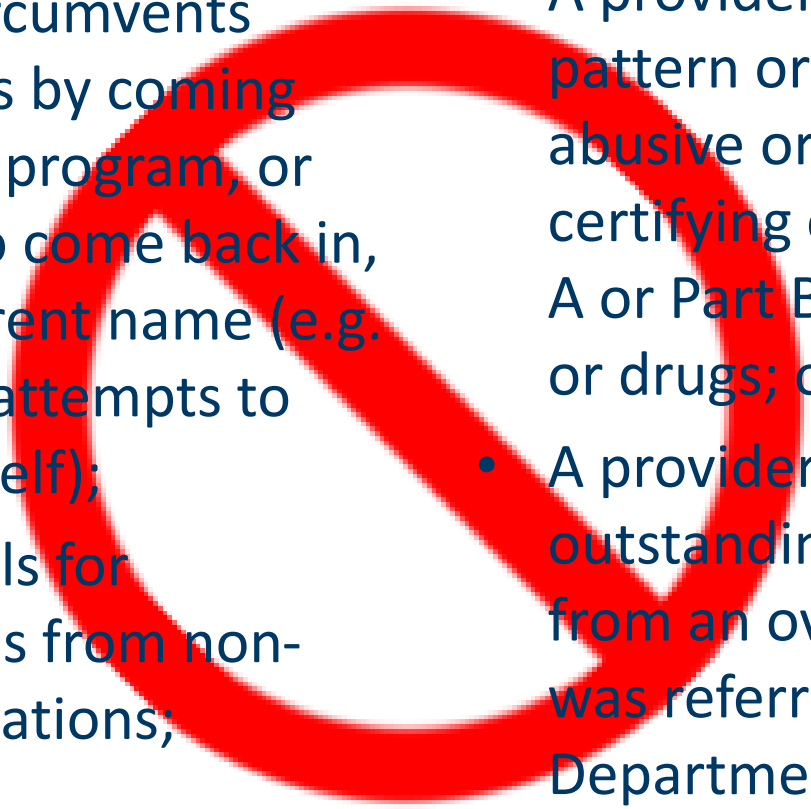
- During enrollment, must disclose to CMS any current or previous "affiliation" with a provider or supplier that:
  1. has uncollected debt of any amount;
  2. has been or is subject to a payment suspension under a federal health care program;
  3. has been excluded by the Office of the Inspector General ("OIG") from Medicare, Medicaid, or CHIP; or
  4. has had its Medicare, Medicaid, or CHIP billing privileges denied, both voluntarily or involuntarily.

Program Integrity Enhancements to the Provider Enrollment Process

- Affiliation means any of the following:
    1. A 5 % or greater direct or indirect ownership interest that an individual or entity has in another organization.
    2. A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
    3. An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization.
    4. Officer or director of a corporation.
    5. Any reassignment relationship.

CMS May Revoke or Deny Medicare Enrollment if:

- A provider circumvents program rules by coming back into the program, or attempting to come back in, under a different name (e.g. the provider attempts to "reinvent" itself);
- A provider bills for services/items from non-compliant locations;
- A provider exhibits a pattern or practice of abusive ordering or certifying of Medicare Part A or Part B items, services or drugs; or
- A provider has an outstanding debt to CMS from an overpayment that was referred to the Treasury Department.



Program Integrity Enhancements to the Provider Enrollment Process

- Increased length of penalties:
  - If false information submitted in initial enrollment application, CMS can bar enrollment for up to 3 years.
  - If enrollment is revoked, CMS can block re-enrollment for up to 10 years.
  - If enrollment is revoked twice, the ban can extend up to 20 years.

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New Public Health Law Requirements

New Public Health Law Requirements

- On December 16, 2019, Governor Cuomo signed legislation amending and adding new sections to the Public Health Law.
  - Unless otherwise noted, these amendments/additions will become effective on:

April 14, 2020

  - Some amendments/additions will require DOH to create forms or implement regulations.

New Public Health Law Requirements

- The legislative changes are a result of New York's "persistent" poor ranking in quality of care, survey and enforcement.
- They are meant to:
  - enhance transparency, accountability and enforcement efficacy; and
  - strengthen DOH's ability to regulate nursing homes.

New Public Health Law Requirements

- Why is this happening?
  - Possible result of recent explosion in sale of nursing facilities (often to for-profit and out-of-town operators).
    - Deficiencies in facilities of same or similar ownership.
    - Perception that operators are using subterfuge to get a sale through DOH/Public Health and Health Planning Council's approval process.
      - *e.g.*, it has been reported that one potential buyer who had pending violations at a facility he owned, had a manager from his company listed as the buyer instead of himself.
    - Allows DOH to more thoroughly evaluate owners' records of running other facilities.

New Public Health Law Requirements

- Why is this happening?
  - Sale of nursing facilities/conversion to non-health care related entities.
  - Complaints regarding cuts to staffing levels, persistent patterns of poor care, harm to residents.
    - New monitoring provision will allow DOH to have “eyes and ears” directly at a low-performing or troubled facility.

PHL Section **2803-x** Requirements – Transparency

- Nursing home operators must:
  - notify the DOH of any common or familial ownership of any corporation, other entity or individual providing services to the operator or the facility;
  - annually attest to the DOH to the accuracy of the information provided;
  - not enter into any arrangement to guarantee the debt or other obligation of a third party which has not received establishment approval;

PHL Section **2803-x** Requirements – Transparency

- Nursing home operators must:
  - notify the DOH at least ninety days prior to executing a letter of intent or other contractual agreement related to the sale, mortgaging, encumbrance, or other disposition of the real property of the facility;
  - refund to the DOH funds provided for capital investment through Medicaid rate adjustments or otherwise provided by the state for the purpose of improvement or transformation if the facility is sold or otherwise transferred and used for a purpose other than providing health care.

PHL Section **2803-d** Requirements – Reporting

- Revises the reporting requirements to:
  - broadly include "abuse" (*i.e.*, not just physical abuse) and "misappropriation of property" as reportable events.
    - "Abuse" now to include verbal, mental, and sexual abuse.
    - Similar to Federal regulation (42 CFR 483.12) that became effective in 2016, which requires facilities to develop and implement written policies and procedures that prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property.

PHL Section **2803-d** Requirements – Reporting

- Also revises the reporting requirements to:
  - expand the scope of persons responsible for reporting a reasonable suspicion of abuse, mistreatment, neglect or misappropriation to specifically include individuals under contract with the facility.
    - Applicable to all contractors – Not limited to contractors that provide resident care services.

PHL Section **2803-d** Requirements – Reporting

- Directs DOH to:
  - develop forms available for downloading from its website which may be used by facilities/individuals for making written reports;
    - (Facilities/individuals will not be required to use the forms)
  - contact law enforcement if it has a reasonable belief that a reported allegation may constitute a crime; and
  - seal (rather than expunge) reports that it finds to be unsubstantiated.

What are the Reporting Requirements?

- Federal (*42 C.F.R. § 483.12*):
  - All alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, must be reported immediately to the administrator of the facility.
    - Federal regulation defines "Immediately" to mean no later than 2 hours after the allegation is made, if abuse or serious bodily injury is involved, or
    - no later than 24 hours, if the events that cause the allegation do not involve abuse and do not result in serious bodily injury.

What are the Reporting Requirements?

- New York (*10 N.Y.C.R.R. § 415.4*):
  - The facility shall ensure that alleged violations involving mistreatment, neglect or abuse, including injuries of unknown source, are reported immediately to the administrator of the facility and, when required by law or regulation, to the Department of Health.
- New York (*Public Health Law § 2803-d*)
  - Reports of suspected abuse, mistreatment, neglect or misappropriation of resident property shall be made immediately by telephone and in writing within 48 hours to the department.

What are the Reporting Requirements?

- In addition, the Elder Justice Act requires that owners, operators, employees, managers, agents, or contractor of a long-term care facility report <u>any reasonable suspicion of a crime</u> against a resident of the facility to:
  - at least one local law enforcement agency and
  - the NYS DOH.
    - 2 hours if serious bodily injury is involved, or
    - no later than 24 hours, if serious bodily injury is not involved.
      - *42 U.S.C. 1320b–25.*

PHL Section **2803-w** Requirements – Independent Quality Monitor

- Permits DOH to require a facility to contract with an independent quality monitor selected by the DOH to:
  - monitor the operator's compliance with a written and mandatory corrective plan and
  - report to the DOH on the implementation of the corrective action.

PHL Section **2803-w** Requirements – Independent Quality Monitor

- DOH has authority to do this when it has determined, in its discretion, that operational deficiencies exist in the facility that show:
  - a condition or conditions in substantial violation of the standards for health, safety, or resident care that constitute a danger to resident health or safety;
  - a pattern or practice of habitual violation of the standards of health, safety, or resident care; or
  - any other condition dangerous to resident life, health, or safety.

PHL Section **2803-w** Requirements – Independent Quality Monitor

- Mandatory corrective plans must include caps on administrative and general costs that are unrelated to providing direct care (including providing at least minimum staffing levels as determined by the DOH) or care coordination.

PHL Section **2803-y** Requirements – Notices

- The operator of a residential health care facility must provide to prospective residents who inquire about admission:
  - a copy of the facility's entire approved residency agreement,
  - including the non-governmental rates charged to residents.
- The agreement must also be posted on the facility's website.

PHL Section **2803-c** Requirements – Notices

- Nursing facilities must include their policy on granting physician privileges in their statement of rights and responsibilities provided prior to the execution of an admission agreement.
  - Potential residents want to know if they will be able to continue seeing doctors with whom they have pre-existing relationships.
- To Do: develop a policy and incorporate into resident rights and responsibilities document.
  - Involve the Medical Director in developing the policy.
  - See *Dear Administrator Letter 11-13: Role of the Attending Physician in the Nursing Home* for recommendations.

    https://www.health.ny.gov/professionals/nursing_home_administrator/docs/11-13_att_phys_role.pdf

PHL Section **2803-c** Requirements – Notices

- Statement of rights/responsibilities must be given to the potential resident (or the appointed representative at the time of appointment) and to each member of the facility's staff.
  - Staff must be trained on this new element of resident rights.
  - This amendment to the PHL was enacted November 20, 2019, and became effective on:

February 18, 2020

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Other Recent Laws Affecting Residential Health Care Facilities

Mental Hygiene Legal Services

- Effective December 16, 2019, NY expanded the reach of MHLS to include:
  - patients or residents of residential health care facilities,
  - who have been admitted directly from a psychiatric unit of a general hospital or other psychiatric facility and
  - who have a serious mental illness and
  - are receiving services related to such illness.

What is Mental Hygiene Legal Services?

- MHLS is a State agency that provides legal services and assistance to patients or residents of facilities licensed by the NY State Office of Mental Health or Office for Persons with Developmental Disabilities.
- Prior to this legislation, MHLS was denied the right to access mentally ill residents of nursing homes because the facilities were not licensed by the Office of Mental Health.

The History

- In 2002, the NY Times began publishing a series of reports which claimed that patients discharged from OMH facilities and placed in discrete psychiatric units in nursing facilities were being deprived of legal protections that were available generally to patients of psychiatric wards (including the right to a lawyer).
- MHLS conducted its own investigation and sought access to nursing facility residents and their records, but the facilities denied such access.

The 2010 Ruling

- Lengthy litigation ensued.
- This prior limitation on MHLS' access to nursing facility residents was sanctioned by the NY State Court of Appeals in 2010 because of the narrow way the statute was written.
  - The Court held that MHLS could only provide services in facilities defined in Mental Hygiene Law and other places required to have an OMH operating certificate. This did not include nursing facilities.

The Legislative [In-]Action

- The State legislature attempted to amend the Mental Hygiene statute in 2010, 2012, 2014, 2016 and 2018.
  - In 2010, the bill was vetoed by the governor; all other years, it passed the Assembly only to die in the Senate.
- The 2019 amendment to the law now expands MHLS' authority to qualified residents of nursing homes.

What is MHLS' Authority?

- Broad legal authority to provide advocacy services to qualified nursing facility residents and their families, concerning:
  - Admission
  - Care and treatment, including objection to treatment
  - Discharge planning
  - Quality of care
  - Residents' rights
  - Investigations of resident abuse

MHLS' Authorized Access

- MHLS must be granted access at any and all times to the facility where a qualified resident is residing.
- MHLS may demand access to information, books and records deemed necessary by MHLS for carrying out its functions, powers and duties.

Emergency Preparedness

- Effective November 29, 2019, the Centers for Medicare and Medicaid Services (CMS) adopted revised regulations applicable to a broad spectrum of providers, including LTC providers.
  - Part of CMS' efforts to reform regulations that are identified as unnecessary, obsolete or excessively burdensome.

Emergency Preparedness - Updates

Be aware:

- The requirement that the emergency preparedness plan (EPP) be reviewed and updated annually did not change for LTC facilities.
  - Other provider types now have to do this only every 2 years.
  - CMS cited resident vulnerability, staff turnover as factors supporting its decision to keep this an annual requirement.

42 C.F.R. §483.73(a), 84 Federal Register 51732, 51755.

Emergency Preparedness - Training

Be aware:

- The requirement that training based on the EPP be conducted annually did not change for LTC facilities.
  - Other provider types now have to do this only every 2 years.
  - CMS cited staff turnover, changes in community resources, closure of receiving providers, and lack of emergency response in nursing homes following emergency events as factors supporting its decision to keep this an annual requirement.

42 C.F.R. §483.73(d)(1)(ii), 84 Federal Register at 51756.

Emergency Preparedness - Collaboration

- Certain documentation requirements were deleted.
  - The EPP must still include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation;
  - But, there is no longer a requirement to document such contact efforts.
    - Many providers found this documentation requirement overly burdensome and claimed it detracted from the focus on patient care.

42 C.F.R. §483.73(a) (4), 84 Federal Register at 51756.

Emergency Preparedness - Testing

- CMS offered some clarifications:
- The requirement that LTC facilities conduct two emergency preparedness tests annually remains.
  - One test should be a full-scale exercise that is community based.
  - If a full-scale community based exercise is not accessible, the facility may conduct an individual facility-based functional exercise.
    - ➢ It is CMS' intent that providers make an attempt to conduct a full scale exercise within their community.

42 C.F.R. 473.75(d)(2), 84 Federal Register at 51757.

Emergency Preparedness - Testing

- If a facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the facility is exempt from:
  - engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

Emergency Preparedness - Testing

- For the second required annual test, facilities have options; may choose one of the following:
  - a second full-scale exercise that is community based or an individual facility-based functional exercise; or
  - a mock disaster drill; or
  - a tabletop exercise or workshop that is led by a facilitator includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
    - ➢ These choices are not exclusive; providers may choose another option.

Coronavirus

- On March 3rd, Governor Cuomo signed into law his emergency proposal to appropriate $40 million to support DOH staffing and equipment to respond to the virus.
  - The measure also granted the Governor authority to suspend laws and local ordinances while the state is responding to certain emergencies or the imminent threat of one.
  - The Governor stated that the State's response to coronavirus would include a focus on nursing homes and congregate facilities treating senior citizens.

Coronavirus

- On Feb. 26th, DOH published emergency regulations adding Severe or Novel Coronavirus (COVID-19) to the list of communicable diseases that nursing homes, hospitals, physicians, D&TCs, and laboratories must report.
- Reporting will permit the DOH to:
  - systematically monitor for this disease, and
  - make decisions about isolation/quarantine of suspect or confirmed cases on a timely basis.

Coronavirus

- As with other communicable diseases, attending Physicians must submit specimens for laboratory examination in cases or suspected cases of coronavirus, together with data concerning the history and clinical manifestations pertinent to the examination.
  - 3/1/20: Wadsworth Laboratory was granted approval by the FDA to conduct testing in NY State.
  - NYC is awaiting approval to conduct its own testing.

Coronavirus

- DOH is set to convene conferences with local health departments and hospitals statewide to review protocols, best practices and procedures.

Coronavirus

- 2/25/2020: NYS DOH issued a Health Advisory for Health Facilities -
  - Infection Control
  - Healthcare for Asymptomatic Persons Being Monitored for COVID-19
  - Management of Healthcare Personnel with Exposure in a Healthcare Setting
  - Personal Protective Equipment (PPE) Conservation Strategies
  - Laboratory Reporting
  - Reporting criteria for persons under investigation

https://www.health.ny.gov/diseases/communicable/coronavirus/docs/health_advisory_3.pdf

One Confirmed Case in NY

Data last updated March 2, 2020

Test Results	New York State (Outside of NYC)	New York City (NYC)	Total Persons Under Investigation (PUI)
Positive Cases	**0**	**1**	**32**
Negative Results	22	8	
Pending Test Results	0	1	

Source: https://www.health.ny.gov/diseases/communicable/coronavirus/

Other concerns

DOJ: Nursing Homes are No. 1 Enforcement Target

- In remarks delivered at a conference in Washington, D.C. last week, the Assistant Attorney General for the Department of Justice's Civil Division emphasized three top areas for False Claims Act enforcement in 2020.

No. 1 = Nursing homes.
No. 2 = Medicare Advantage.
No. 3 = Electronic health records.

DOJ: Nursing Homes are No. 1 Enforcement Target

- In the DOJ's sights are SNF cases involving:
  - Subpar care,
  - Neglect, and
  - Improper prescribing of drugs to nursing home residents.
- DOJ stated it will spare no expense going after such misconduct, even if [FCA] cases don't involve huge sums of money.
  - Conference attendees were told to watch for news regarding DOJ's Elder Justice Initiative in next few days.

Source: Law 360, Overly, Jeff, *Top DOJ Atty Spotlights Main FCA Target Areas for 2020*, February 27, 2020.

The Next Day . . .

- DOJ announced a $9.5 million False Claims Act settlement agreement with a Tennessee-based provider of skilled nursing and rehabilitation services.
  - Settlement included five-year corporate integrity agreement.
- The whistleblower lawsuit had alleged false claims had been submitted for unnecessary services . . .

The Allegations . . .

- repetitive and unskilled exercises were provided that did not match plan of care goals to obtain additional minutes;
- residents were engaged in activities contraindicated by underlying medical conditions;
- ADL scores were inflated;
- resident lengths of stay were extended beyond what was medically indicated;
- services were not provided;
- budgets, goals, and quotas were used to ensure Ultra High therapy was maximized; and
- threats or adverse actions were taken against employees if they failed to meet the budgets, goals, or quotas.

DOJ Nursing Home Initiative

- On March 3rd, the DOJ announced a nation-wide initiative to "coordinate and enhance" civil and criminal efforts to pursue nursing homes that provide grossly substandard care to their residents.
  - DOJ has already initiated investigations into approximately 30 nursing facilities in 9 states.

Common Factors Cited by DOJ

- Consistent failure to provide adequate nursing staff;
- Failure to adhere to basic protocols of hygiene and infection control;
- Failure to provide residents enough food to eat;
- Withholding pain medication;
- Use of physical or chemical restraints to restrain or other wise sedate residents;
- Filthy and dangerous conditions
  - Leaking roofs
  - mold
  - rodents in residents' rooms

DOJ's Message:

Grossly substandard care will not be tolerated.

PASRR: Proposed Rules

- On Feb. 20, 2020, CMS published proposed changes to Preadmission Screening and Resident Review regulations.
  - First update since adopted in 1992!
  - Public comment will be accepted up to April 20th.

https://www.govinfo.gov/content/pkg/FR-2020-02-20/pdf/2020-03081.pdf

PASRR: Proposed Rules Highlights

- Technical updates
  - (*e.g.*, removes references to the word "annual" as, by statute, annual review has not been required since 1996).
- Updates to definitions/deletion of outdated terms
  - References to most recent versions of Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and Intellectual Disability, Definition, Classification, and Systems of Support (11th Edition).

PASRR: Proposed Rules Highlights

- Clarifying Language, *e.g.*, :
  - Level I identification screen must be completed prior to NF admission for all individuals applying for admission.
    - Including those admitted following an acute care hospitalization.
  - All positive Level I screens that identify possible MI or ID must be forwarded to the PASRR program, even if exempt from Level II determination.

PASRR: Proposed Rules Exemptions

- Hospital Discharge Exemption
  - Remains the same. Level II evaluation and determination is not required if the resident:
    - Is admitted to SNF directly from the hospital after receiving acute inpatient care;
    - requires SNF services for the condition for the which the individual received care in the hospital; and
    - is certified by attending MD to likely require fewer than 30 days of nursing services.
      - **If stay will be 30 days or more, Level II evaluation and determination will be required.**

PASRR: Proposed Rules
New - Exemptions

- Provisional Admissions: Level II evaluation and determination would not be required for short, time-limited stays:
  - Emergency stays due to emergency evacuations or protective service placements (not to exceed 14 days).
  - Individuals with delirium where the delirium prevents an accurate diagnosis at the time of entry into the nursing home but is expected to clear within 14 days.
  - Respite stays of up to 30 consecutive days to provide respite to in-home caregivers.
  - Convalescent stays of up to 30 days to recover from an acute physical illness that required hospitalization but did not meet criteria for an exempted hospital discharge.

PASRR: Proposed Rules Timelines

- Level II findings/recommendations:
  - Must be completed within 9 calendar days following notification to the PASRR program of a positive Level I identification screen or the expiration of an exemption period.
    - Timelines will vary depending on type of exemption or significant change in condition.
  - Will need to be communicated electronically or in writing (oral communications will no longer be acceptable).

PASRR: Proposed Rules
PASRR Evaluations

- Level II Evaluations and Determinations:
  - Individual must be directly involved in the evaluation activities.
  - Face-to-face person-centered interviews with the individual and his/her legal representative, family, friends or caregivers, at the individual's discretion.
- Telehealth will be permitted for Level II evaluations under certain circumstances.
  - *E.g.*, due to resource limitations, geographical distances, or other circumstances that prevent timely completion of the determination.

PASRR: Proposed Rules
Eliminate Categorical Determinations

- Level II Evaluations and Determinations:
  - CMS proposes to eliminate categorical determinations.
    - Intent is "that the PASRR process should be driven by the person's individual circumstances rather than a diagnosis."
    - This proposed change will put the focus on person-centeredness.
  - To replace categorical determinations, CMS is proposing new criteria for terminating evaluations.

PASRR: Proposed Rules
Criteria to Terminate Evaluation

- Proposed Criteria for Terminating an Evaluation:
  - The individual:
    - ➢ does not have MI or ID;
    - ➢ did not experience a qualifying significant change in physical or mental condition; or
    - ➢ Cannot be effectively evaluated because he/she is severely impaired due to (i) physical illness (such as ventilator dependency; advanced Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis; or is comatose or functioning at a brain stem level), (ii) terminal illness or (iii) dementia.

PASRR: Proposed Rules
Impact on Nursing Homes

- Ensure compliance with PASRR rules
- Ensure that residents have appropriate Level I and Level II determinations prior to admission and at other relevant times.
- Monitor exemptions and make timely notification for Level II evaluation and determination
- Comply with documentation requirements
- Ensure that recommendations are implemented and incorporated into plan of care

Questions

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