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SUBJECT

Preventable Serious Adverse Events in Nonpublic and County Nursing Facilities

BY

Bonnie L. Rose, Deputy Secretary
Office of Long-Term Living

PURPOSE:

The purpose of this bulletin is to identify Preventable Serious Adverse Events (PSAEs) for nursing facilities that are enrolled in the Medical Assistance (MA) Program and to notify those facilities how they may fulfill the obligations not to knowingly seek payment from the MA Program for PSAEs or for services required to correct or treat PSAEs.

SCOPE:

This bulletin applies to MA-enrolled county and non-public (including hospital-based and special rehabilitation) nursing facilities.

BACKGROUND/DISCUSSION:

In 2009, the General Assembly enacted legislation that imposed payment restrictions on health care providers when a PSAE occurs. See Act of June 10, 2009 (P.L. 1, No.1), codified at 35 P.S. §§ 449.91 – 449.97 (Act 1). As a general principle, a health care provider may not knowingly seek payment from a health payor or from a patient for a PSAE or for any corrective services. 35 P.S. § 449.93(a). Additionally, if the health care provider unknowingly seeks payment for the PSAE or for any corrective services and, later, discovers the issue, then the provider is further obligated to notify the health payor or patient and to pay a refund. 35 P.S. § 449.93(c). The phrase “health payor” includes the MA Program. With respect to the MA Program specifically, Act 1 directs the Department of Public Welfare (“the Department”) to issue a bulletin that contains a list of PSAEs for nursing facilities. 35 P.S. §§ 449.94(a) and 449.97(g).

Subsequent to the codification of Act 1, the Centers for Medicare and Medicaid Services (CMS) published a final rule at 76 FR 32816 (June 6, 2011) that includes, among other things, the addition of 42 CFR § 447.26 (relating to prohibition on payment for provider-preventable conditions). These new Federal regulations require that no Medical Assistance will be paid

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO: Marilyn Yocum

Office of Long-Term Living
Bureau of Policy and Regulatory Management
P.O. Box 8025
Harrisburg, PA 17105-8025
(717) 783-8412

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for “provider-preventable conditions” (PPCs) as defined in 42 CFR § 447.26. The PPCs are divided into two parts, health care-acquired conditions and other provider-preventable conditions (OPPCs). OPPCs apply to nursing facilities. The three mandatory OPPCs (wrong surgical or other invasive procedure performed on a patient; surgical or other invasive procedure performed on the wrong body part; surgical or other invasive procedure performed on the wrong patient) are included in the Commonwealth’s currently approved State Plan effective July 1, 2011. The State Plan will be amended so that all other PSAE events listed in Appendix A will be considered additional OPPCs for nonpublic and county nursing facilities for purposes of the Commonwealth’s State Plan.

This bulletin sets forth guidance for purposes of nursing facility compliance with Act 1 and 42 CFR § 447.26 as it relates to the MA Program. If an MA-enrolled nursing facility follows the guidelines in this bulletin, then the Department will consider the MA-enrolled nursing facility as having met its obligations to the Department under Act 1. However, the nursing facility should not construe satisfactions of the guidelines as compliance with other requirements under Act 1 or any other law.

PSAEs

The events listed in Appendix A qualify as a PSAE if all of the following criteria are satisfied:

1. The event was preventable. To be preventable, the event could have been anticipated and prepared for, but, nonetheless, occurred because of an error or other system failure.
2. The event was serious. The event is serious if the event subsequently results in death or loss of body part, disfigurement, disability or loss of bodily function lasting more than 7 days or still present at the time of discharge from a nursing facility.
3. The event was within the control of the nursing facility. Control means that the nursing facility had the power to avoid the error or other system failure.
4. The event occurred as a result of an error or other system failure within the nursing facility.

The Department may modify both the list of PSAEs identified in Appendix A and its payment policies and procedures in the future subject to receiving an approved State Plan Amendment. Before making any modification to the PSAEs, the Department will consult with representatives of the nursing facility trade associations, representatives of individual nursing facilities, and the Long-Term Care Delivery System Subcommittee of the Medical Assistance Advisory Committee. The Department will also provide for a 30-day public comment period.

COMPLIANCE WITH ACT 1:

1. Identification and Review of a PSAE and of the Services Required to Correct or Treat a PSAE

a. Responsibilities of the Nursing Facility

As a general principle, a health care provider may not knowingly seek payment from a health payor or from a patient for a PSAE or for any corrective services. 35 P.S. § 449.93(a). Therefore, whenever an event listed in Appendix A occurs in a nursing facility, the nursing facility must independently determine whether the event satisfies the PSAE criteria specified above and whether it has complied with the requirements of Act 1.

If the nursing facility concludes that the event constitutes a PSAE, the nursing facility may not submit a claim for payment of services associated with the PSAE or for payment of any services required to correct or treat the PSAE.

If the nursing facility discovers that payment has unknowingly been sought for a PSAE or for services required to correct or treat problems created by the PSAE, then the nursing facility shall immediately notify the MA Program. Information relating to such reports can be found on the Department's website.

In the event that the nursing facility received payment for the PSAE or for any services that were required to correct or treat the problems created by the PSAE, then the nursing facility shall refund any payment received within 30 days of discovery or receipt of payment, whichever is later.

b. Authority of the Department

The Department may identify potential PSAEs or the services required to correct or treat PSAEs and seek recovery of money through its existing claims review process, its utilization management review process, or its program integrity review process. See 55 Pa. Code §§ 1101.71, 1101.77 and 1101.83 (relating to utilization control; enforcement actions by the Department; and restitution and repayment).

With both facility-reported PSAEs and Department-identified PSAEs, the Department will determine whether the event meets the criteria of a PSAE and whether the guidelines of the bulletin have been satisfied.

In the event the Department initiates a review of an event, the Department will notify the nursing facility, in writing, that it has initiated its review. As part of its review, the Department may request medical and fiscal records, including policies and procedures, from the facility concerning the resident or the event, or both. Based on its review, the Department may recover or adjust MA payments or return money already refunded by the nursing facility. The Department's review process, including how the Department's physicians will be involved in the case review and the opportunities that a nursing facility's designated staff will have to

interact with the Department through the review process is available on the Department's website at <http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/longtermcarecasemixinformation/index.htm>.

The Department will send a written notice of its determination to the nursing facility. In the event of an adverse determination, the Department's notice to the nursing facility will outline the reasons for the determination and whether the Department will recover or adjust MA payments. If the nursing facility does not agree with the Department's determination, the nursing facility may appeal to the Bureau of Hearings and Appeals under 55 Pa. Code Chapter 41 (relating to medical assistance provider appeal procedures).

2. Guidelines: Claims Relating to PSAEs and to Services to Correct or Treat the PSAE

The Department pays MA-enrolled nursing facilities for services provided to MA-eligible persons through a prospective per diem rate and other additional payments (for example, allowable cost payment related to Pennsylvania's Nursing Facility Assessment Program and supplemental payments in accordance with the Commonwealth's Medicaid State Plan). In the context of this payment system, the Department sets forth the following minimum claims guidelines for compliance with Act 1.

a. Claims relating to PSAEs

In those instances where a PSAE occurs, the nursing facility may not submit a claim for payment of the MA per diem rate for the day of the event and shall record the day as a non-covered day on the resident census. In addition, the nursing facility shall record the day of the event as a private pay and other day on the quarterly Resident Day Reporting Form (RDR Form) related to Pennsylvania's Nursing Facility Assessment Program. Further, the nursing facility shall not seek payment from any other payor source, including the resident, for the day of the event.

b. Claims Relating to Services to Correct or Treat a PSAE

For purposes of determining the value of claims relating to services to correct or treat problems caused by the PSAE, the nursing facility must satisfy the following minimum guidelines:

i. Hospital Reserve Bed Days

If the resident is transferred to a hospital or other institution as a result of the PSAE, then the nursing facility may not submit a claim to the Department, or otherwise receive payment, to reserve the resident's nursing facility bed during the resident's absence (the nursing facility remains obligated to reserve the bed in accordance with Federal and State Medicaid participation requirements). The nursing facility shall record any PSAE-related hospital reserve bed days as non-covered days on the resident census. In addition, the nursing facility shall record those days as private pay and other days on the quarterly Resident Day

Reporting Form (RDR Form) related to Pennsylvania's Nursing Facility Assessment Program.

ii. Durable Medical Equipment

In any circumstance, the nursing facility may not seek any payment through an exceptional durable medical equipment (DME) grant for equipment or services required to correct or treat a problem created by a PSAE. In addition, the nursing facility shall report those exceptional DME costs as nonallowable costs on their cost report.

If an MA-enrolled nursing facility follows the guidelines in this bulletin, the Department will consider the nursing facility as having satisfied its Act 1-related obligations to the Department. Nonetheless, Act 1 specifically directs the health care providers to not knowingly seek payment for PSAEs and for corrective services. Therefore, the nursing facility remains obligated not to seek or to receive payments for the PSAE or for services to correct or treat problems caused by the PSAE, to provide appropriate notice and to refund applicable payments.

**Appendix A
Preventable Serious Adverse Events ("PSAEs") for
Nursing Facilities Enrolled in the Medical Assistance Program**

If an event listed below occurs in a nursing facility, then the event is a PSAE when all of the following criteria are satisfied:

1. The event was preventable. To be preventable, the event could have been anticipated and prepared for, but, nonetheless, occurred because of an error or other system failure.
2. The event was serious. The event is serious if the event subsequently results in death or loss of body part, disfigurement, disability or loss of bodily function lasting more than 7 days or still present at the time of discharge from a nursing facility.
3. The event was within the control of the nursing facility. Control means that the nursing facility had the power to avoid the error or other system failure.
4. The event is the result of an error or other system failure within the nursing facility.

1. Surgical or Invasive Procedure Events

- A. Wrong surgical or other invasive procedure performed on a patient
- B. Surgical or other invasive procedure performed on the wrong body part
- C. Surgical or other invasive procedure performed on the wrong patient

2. Product or Device Events

- A. Resident death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the nursing facility
- B. Resident death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
- C. Resident death or serious injury associated with intravascular air embolism that occurs while being cared for in a nursing facility

3. Patient Protection Events
 - A. Resident death or serious injury associated with resident elopement (disappearance)
 - B. Resident suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a nursing facility
4. Care Management Events
 - A. Resident death or serious injury associated with a medication error (such as, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
 - B. Any preventable Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a nursing facility
 - C. Resident death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results
5. Environmental Events
 - A. Resident death or serious injury associated with an electric shock in the course of a patient care process in a nursing facility
 - B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances
 - C. Resident death or serious injury associated with a burn incurred from any source in the course of a patient care process in a nursing facility
 - D. Resident death or serious injury associated with the use of physical restraints or bedrails while being cared for in a nursing facility
6. Potential Criminal Events
 - A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
 - B. Abduction of a resident of any age
 - C. Sexual abuse/assault on a resident within or on the grounds of a nursing facility
 - D. Death or serious injury of a resident resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a nursing facility