

PACE Questions and Answers

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GENERAL QUESTIONS

What is the PACE program?

The PACE program is a unique capitated managed care benefit for the frail elderly provided by a not-for-profit or public entity. The PACE program features a comprehensive medical and social service delivery system using a multidisciplinary team approach in an adult day health center that is supplemented by in-home and referral services in accordance with participants' needs.

What is a PACE organization?

A PACE organization is a not-for-profit private or public entity that is primarily engaged in providing PACE services. The following characteristics also apply to a PACE organization. It must:

- have a governing board that includes community representation;
- be able to provide the complete service package regardless of frequency or duration of services;
- have a physical site to provide adult day services;
- have a defined service area;
- have safeguards against conflict of interest;
- have demonstrated fiscal soundness; and
- have a formal Participant Bill of Rights.

What is the governing legal authority for PACE demonstrations?

For programs operating under demonstration status, the governing authority is the waiver approval and its terms and conditions. The PACE protocol is the basic standard for demonstration programs operating prior to the publication of the November 24, 1999 PACE

regulation. For PACE activity that commenced subsequent to the publication of the regulation, the PACE regulation is the governing legal authority.

What statute defines the PACE demonstration programs?

All demonstrations fall under the authority of Section 1115 of the Social Security Act. Sections 4801 and 4802 of the Balanced Budget Act (BBA) of 1997 contain the requirements that define the PACE program as a permanent provider. The BBA may be viewed at:

<http://www.hcfa.gov/regs/bbaupdat.htm>.

Where can I find publications, demographic information, and other statistics about the PACE program?

The best source for PACE demographic information is the National PACE Association. You may call, write, fax, or email the NPA at:

National PACE Association
1255 Post Street, Suite 1027
San Francisco, CA 94109
(415) 749-2686
FAX: (415) 749-2687
<http://www.natlpacessn.org/>

Is there an official government listing of sanctioned providers that the PACE organization can obtain to verify that staff and contractors are not listed?

You may find this listing at <http://www/dhhs.gov/progorg/oig/cumsan/main.htm>.

PACE APPLICATION

Does CMS require the PACE organization to build or renovate prior to submitting an application?

No, we do not require the building to be completed prior to submitting an application. However, for non-operational sites the building must be complete at the time of the State Readiness Review.

For non-operational sites, is a signed inpatient contract required?

A letter of intent will suffice for the application, but a signed contract will be required to enter into a program agreement.

How long will it take to process a PACE application?

While the circumstances contained in each application will be different, a conservative estimate of the average time needed to process a PACE application is nine months. Once CMS receives an application from the State, a determination will be made within two weeks on the completeness of the package. If the package is not complete, CMS will send a letter to the State

and the applicant notifying them of this decision. If the package is complete, a letter will be sent to the State and applicant acknowledging that the application is acceptable.

CMS has up to 90 days (retroactive to the date a complete application was received in CMS' Central Office) to determine what additional information on the application is needed, if any. A letter requesting additional information will be sent to the State and the applicant. Once all the information submitted in response to the request for additional information (which includes the information from either the State's readiness review or CMS' onsite review) is received, the second and final 90 day clock will start. CMS will render a decision on the application within this second 90 day period, and if applicable, the three party Program Agreement will be signed.

How many potential PACE sites are in the planning stages? We would like a sense of how much competition there will be for the allotted slots.

There are currently 25 approved PACE demonstration sites. We do not officially know how many potential PACE sites are in the planning stages since potential sites do not need to contact CMS. However, based on informal contact with states, we anticipate receiving approximately 60 PACE applications by the end of the 2003 fiscal year.

As of August 1, 2001, there will be 120 available program agreements for PACE programs, and 20 more available program agreements each year thereafter. Based on current expressions of interest, we do not anticipate that potential programs will exceed the limit imposed by law.

In the application should the PACE applicant describe the PACE entity or their corporate member since the PACE entity is not operational?

The PACE applicant should provide information on the PACE organization and its relationship to their corporate entity. This can be achieved by enclosing organizational charts of the entire health care system that the PACE organization is a part of. The organizational chart should show where the PACE organization relates to the other entities and the reporting structure from the governing body to the PACE organization.

Who needs to sign the State assurance, and does the Program Agreement need to be submitted with the application?

The State Administering Agency or its designee must sign the State's assurances. The application can be submitted without the Program Agreement.

In the application, is CMS requiring the potential property to be identified since the "mean travel times" on the service map are required?

Yes, CMS is requiring the prospective PACE organization to have an identified site before submitting an application.

When the PACE entity is not operational, should the PACE application describe the PACE entity or its corporate member?

The application should concentrate on the PACE entity, but it should provide information on the applicant's relationship to the corporate member.

The regulation requires position descriptions and resumes for the Program Director, Medical Director, and the Quality Assurance, Finance, and Marketing positions. Do these positions need to be filled before submitting a PACE application or will position descriptions suffice?

No, these positions do not need to be filled prior to submitting a PACE application. We recognize that the PACE site may not be operational at the time the application is submitted. However, if a PACE applicant has been operational, in the case of pre-PACE organizations or a transitioning demonstration, CMS would expect all the required positions to be filled in order to meet the needs of the organization's current participants. The application must include position descriptions for the PACE employees. Resumes should accompany the application for any staff hired. Letters of intent or employee agreements will be required before a program agreement can be signed.

How will CMS review the plan of care during the application review process and during the onsite review?

As part of the CMS review of the provider application, CMS will review a template of the provider's plan of care to ensure that it meets the requirements stipulated in the regulation. Then, during the onsite phase of the application review process, CMS will review the entire participant medical record to include all assessment data that were gathered and recorded to understand the participant's needs. Since the plan of care is based on the assessments of the team, the plan of care should reflect all of the participant's care needs. The review of the participant's medical record will be performed by experienced Registered Nurses at CMS.

PACE ELIGIBILITY

Who is a PACE participant?

To be eligible to be a PACE participant, you must be age 55 or older; meet a Nursing Facility level of care; and live in the PACE organization service area.

What is the age requirement under the regulation and can it be modified?

The age requirement in the PACE Protocol reads differently from the requirement in the Balanced Budget Act (BBA). While the Protocol states that PACE participants must be at least age 55, the BBA refers to age 55 or older. The BBA cannot be read to allow the age requirement to be set above age 55.

In addition, there is a provision in section 460.150(b)(4) of the regulation that permits additional program-specific eligibility criteria to be imposed by a PACE organization and described in the program agreement. However, this provision further states that these additional conditions may not modify the requirements of paragraph (b)(1) and (b)(3) of this section. Therefore, stricter age requirements that would restrict eligibility to dually eligible beneficiaries may not be imposed.

Is expanded Medicaid eligibility using home and community based service rules permitted under the PACE program?

Yes. Section 710 of the Omnibus Appropriations Act of 1998 permits States to cover PACE enrollees under institutional groups and rules similar to those that apply under home and community based services waivers. This means that States can elect to cover PACE enrollees under the special income level group (also known as the 300 percent group). States can also apply other institutional rules to PACE enrollees, such as spousal impoverishment and post-eligibility treatment of income.

Can States continue to require a PACE site to serve only dually eligible beneficiaries in order to remain exempt from HMO licensure?

Section 460.150(d) of the regulation specifically states that eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid recipient. A potential PACE enrollee may be, but is not required to be, any or all of the following: 1) entitled to Medicare Part A; 2) enrolled under Medicare Part B; or 3) eligible for Medicaid. This provision establishes the basic eligibility criteria for PACE participants and permits enrollment into the PACE program for individuals who are entitled to Medicare, eligible for Medicaid, or both, or neither.

The above mentioned regulatory provision would prohibit a State or a PACE organization from serving only dual eligibles. Since the regulation does not require PACE organizations to be licensed as HMOs, CMS believes this is an issue that must be resolved by the States and the providers.

PACE SERVICES

What services are provided through PACE?

PACE services include, but are not limited to, all Medicare and Medicaid services. At a minimum, there are 16 additional services that a PACE organization must provide: e.g., social work, drugs, NF care. Minimum services that must be provided in the PACE center include primary care services, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals.

Where do participants receive services?

The service delivery settings include an adult day health center, home, and inpatient facilities.

Are over-the-counter medications (vitamins, nutritional supplements, diabetic supplies, etc.) covered under the PACE program? Are there any criteria or requirements?

Over-the-counter medications are covered under the PACE program if they are authorized by the PACE multidisciplinary team and are included in the participant's plan of care.

Can participants receive hospice care while enrolled in PACE?

Since comprehensive care is provided to PACE participants, those participants who need end-of-life care will receive the appropriate medical, pharmaceutical, and psychosocial services through the PACE organization. If the participant specifically wants to elect the hospice benefit from a

certified hospice organization, then the participant must voluntarily disenroll from the PACE organization. The PACE organization would work with the State administering agency and CMS to facilitate the election of the hospice benefit.

Are PACE programs required to provide mental health services?

Yes. The PACE program is required to provide all health, medical and social services necessary to restore and preserve the participant's level of well-being. This includes mental health services. The organization can contract with mental health specialists to provide these services.

Who participates on the multidisciplinary team?

At a minimum, the multidisciplinary team is composed of a primary care physician, nurse, social worker, physical therapist, occupational therapist, recreational therapist or activity coordinator, dietitian, PACE center supervisor, home care liaison, health workers/aids, or their representatives, and drivers or their representatives.

Must members of the PACE multidisciplinary team be employed full-time?

There is no requirement that any member of the PACE multidisciplinary team be fulltime. Consequently, the PACE organization may hire staff on a part-time basis until the census is sufficient to support fulltime staff. The only requirement for the multidisciplinary team is that at least one of the members representing each discipline described in section §460.102(f) be employees of the organization. Employment means employed by either the PACE site or the parent organization.

How often must the multidisciplinary team meet?

The PACE multidisciplinary team must meet on a basis frequent enough to ensure that the comprehensive medical, health, and social needs of each participant is met. Generally, PACE teams meet daily to discuss the status of participants and recent events that may have occurred at the various locations where services are provided.

PACE ENROLLMENT

How do Participants enroll?

Enrollment in the PACE program is voluntary. If a participant meets the eligibility requirements and elects PACE, an Enrollment Agreement is signed. This contains things such as participant demographic data, description of benefits, effective date, explanation of policy regarding premiums, emergency care, etc. Enrollment continues as long as desired by the PACE participant, regardless of change in health status, until death or voluntary or involuntary disenrollment.

When must the initial comprehensive assessment be completed?

The regulations state that the initial comprehensive assessment "must be completed promptly following enrollment." Though CMS has not specified a timeframe for completion of the initial comprehensive assessment, we believe that it should be completed within a few days of a participant's enrollment into the PACE program. This is to ensure that there is no delay in

administering appropriate care to the participant. We have found that the initial assessments conducted by the PACE demonstration sites are often completed by the date of enrollment since a proposed care plan is often presented to the participant as part of the enrollment process.

When an individual meets the eligibility requirements and signs an enrollment agreement, which entity is responsible for care provision between the time of signing the enrollment agreement and the first day of the next month when enrollment becomes effective?

According to §460.158 of the PACE regulation, “A participant’s enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.”

Between the signing of the enrollment agreement and its effective date, the PACE organization may elect to provide services to the newly signed enrollee. However, any services provided are not considered “PACE” services until the effective date of the enrollment. Therefore, services would only be covered to the extent the individual’s existing health care coverage (e.g. Medicare FFS, Medicare Advantage, Medicaid Managed Care or Medicaid FFS) provides the coverage. To the extent the individual’s existing health care coverage does not provide coverage for a service furnished prior to the effective date of PACE enrollment, the PACE organization would not receive reimbursement for the provision of that service.

May enrollment be denied as a result of a change in status between the signing of the enrollment agreement and the effective date of enrollment?

If the individual experiences a major health event or change in status between the time he/she signs the enrollment agreement and its’ effective date on the first of the following month, enrollment may be denied if the individual is no longer determined to be safe to live in the community upon the effective date of enrollment.

The effective date of enrollment must be made clear to the enrollee at the time the enrollment agreement is signed. In addition, any services provided prior to the effective date of enrollment are not considered “PACE” services.

PAYMENT

How is reimbursement handled under the PACE program?

Under the Medicare program, the monthly capitation rate paid by CMS to the PACE provider equals the Adjusted Per Capita Cost (AAPCC) as calculated by CMS for HMO reimbursement with adjustment for frailty factors. Under the Medicaid program, the monthly capitation rate is negotiated between the PACE provider and the State Medicaid Agency and is specified in the contract between them. The capitation rate is fixed during the contract year regardless of changes in the participant's health status. The rates are considered payment in full.

PACE REGULATION

What does the definition of physical restraint in section 460.114(a)(1) of the regulation mean?

The definition of a physical restraint is described in the PACE regulation as any manual method, physical or mechanical device, materials or equipment attached or adjacent to the participant's body that restricts movement. As stated, any material basically becomes a restraint when used to restrict movement and participant access to their body. CMS does not limit its definition to a device or whether the material or equipment is attached to the body. For example, a geri-chair is adjacent to the participant but not attached. A geri-chair restricts movement when the lap table is secured safely in front of a person. In this situation, CMS would consider this a restraint.

What needs to be considered when identifying a physical restraint is if it restricts freedom of movement or access to the body, not the actual method used. For example, a bed sheet tucked into the patient's mattress so that the patient is covered is not a restraint. However, if a sheet were tied around an individual so that it restricts his or her freedom of movement, then CMS would consider this a restraint.

How does CMS' definition of "physical restraint" differ from the definition of the Food and Drug Administration (FDA)?

The FDA's definition refers to a device attached to the individual, such as something a patient would wear. The FDA defines a protective restraint as a device that is intended for medical purposes and that limits the patient's movement to the extent necessary for treatment, examination or protection of the patient or others.

STATE READINESS REVIEW

What type of organization applying for permanent provider status will be subjected to a Readiness Review?

An organization that is non-operational will have a Readiness Review performed by the State Administering Agency (SAA). This organization will not have any individuals to whom services or care are being provided. This type of organization could be in different phases of "readiness" to operate. However, at the time of the State Readiness Review the organization must have secured a site that will serve as the PACE center, so the SAA can inspect this facility for local, state and federal law compliance. In addition, the organization must have written policies and procedures that are pertinent to operationalize the PACE program, contracts executed in order to provide the comprehensive all-inclusive care that is required in the regulation, and employment agreements for staff described in the regulation.

Is there a specific survey tool the State will use when conducting the readiness review? If so, will the prospective provider be informed of the criteria and when will it be made available?

CMS has provided an internal review tool to the States that outlines the minimum Federal requirements to be included in the State Readiness Review; however, we expect most States will customize this tool to reflect their own individual requirements. The State Readiness Review tool can be located on the PACE Homepage, under the "[PACE Information for States and Providers](#)" link.

DATA COLLECTION, RECORD, MAINTENANCE, AND REPORTING

Is a PACE organization required to submit an Actuarially Certified Statement of Incurred, But Not Reported (IBNR), claims?

If a PACE organization is licensed as a Managed Care Organization (MCO) and required by the State Department of Insurance to submit an Actuarially Certified Statement of IBNR claims, this statement should also be submitted to CMS. If a PACE organization or its parent corporation is not licensed as an MCO and is not required by the State to have an Actuarially Certified Statement of IBNR claims completed, this information does not need to be submitted to CMS. A review and evaluation of the IBNR claims should be noted as one of the components of the audit performed to prepare the financial statements.

Are PACE organizations required to use the National Association of Insurance Commissioners (NAIC) forms to report financial information in the application or after approval as a permanent provider.

PACE organizations are not required to use the NAIC forms, known as the "orange blanks," for the submission of financial statements. If a PACE organization already completes these forms because of requirements in its state, the NAIC form would be an acceptable format. Otherwise, financial statements should be prepared on an accrual basis and in accordance with generally accepted accounting principles.

If a PACE organization is a division or department of a larger corporation, are separate audited financial statements required for the PACE organization?

A separate audited financial statement is not required for a PACE organization that is a division or department of a larger corporation. If a PACE organization is a separate entity from the parent corporation, we would like to see the consolidating schedules of the financial statement. The PACE organization is required to submit an annual income statement for PACE operations whether it is a division or separate entity. Quarterly financial statements are required throughout the trial period and at the discretion of CMS or the State Administering Agency thereafter.

If a PACE organization is licensed as a home health agency (HHA), does the PACE organization need to comply with the reporting requirements of OASIS?

No. The PACE organization only needs to comply with OASIS requirements if its state licensed and certified the organization as a Medicare/Medicaid certified HHA. The OASIS requirements relate to certified home health agencies, not PACE organizations that are merely licensed in the state.

DATA ELEMENTS FOR MONITORING

Data Element One - Routine Immunizations

For whom should I report immunization data?

Data should be reported quarterly for all participants active on the last day of the quarter. Consequently, if a participant disenrolled during a quarter, they would not be included in the data reported.

Do I report data on flu shots throughout the year or only in quarters that include months during which flu shots are given?

Data on flu shots need only be reported for quarters during which flu shots are administered, i.e., for quarters including the following months: September, October, November, December and January.

The Centers for Disease Control (CDC) makes the following recommendation regarding pneumococcal vaccines for persons aged 65 and over: “All persons in this category (65 and over) should receive the pneumococcal vaccine, including previously unvaccinated persons and persons who have not received vaccine within 5 years (and were <65 years of age at the time of vaccination). All persons who have unknown vaccination status should receive one dose of vaccine.” Consequently, some PACE participants may not have had vaccines in the previous 10-year period, but if they had received the vaccine at age 65 or later, they would be appropriately immunized. How should this be handled?

For participants who have not received a pneumococcal vaccine in the last 10 years, but are appropriately vaccinated, include them among those not immunized for pneumonia in the last 10 years and indicate they are appropriately vaccinated under reason for not immunizing.

Is it necessary to report routine immunizations for all participants every quarter? More specifically, if I report on the immunization status of all participants active on the last day of the quarter, in subsequent quarters, can I report only on those participants who are eligible for vaccines?

Yes, you may do it this way. Alternatively, you may report the immunization data for all participants active on the last day of the quarter as indicated in *Answer 1*.

Data Element Two - Grievances And Appeals

How can I report the date of resolution for a grievance or appeal that was filed in a given quarter but will not be resolved until the following quarter:

Report only on grievances and appeals that are resolved in the quarter for which you are reporting. So, “# of grievances filed” should be interpreted as “# of grievances resolved” with the same being true for appeals. This approach allows programs to report the date of resolution for grievances and appeals as indicated on the spreadsheet. For example, if a grievance is filed on March 28 and not resolved by March 31, it should not be included in the “# of grievances filed” for the quarter ending March 31. Alternatively, it should be included in the following quarter’s report at which time it can be assigned a resolution date.

Data Element Three - Enrollments

Can you provide more detail on how enrollees should be categorized by payer type since the payer types are not always mutually exclusive? For example, how should I categorize a

participant who has Medicare Part A and B coverage and pays the long-term care premium privately?

A participant should be included in only one of the following categories and the sum of participants in all categories should equal the “# of participants who enrolled.” Following are expanded definitions for each payer type:

Medicare only: includes participants with Medicare Part A and Part B coverage, Part A coverage only, or Part B coverage only. These participants do not have Medicaid coverage and pay the long-term care premium privately out-of-pocket.

Medicaid only: includes participants whose only payer is Medicaid.

Dual Eligible: includes participants who are covered by Medicare (A and B, or A only, or B only) AND Medicaid

Private Insurance: includes participants who have long-term care insurance (or other insurance) that pays, either in whole or in part, the long-term care premium

Private Pay: includes participants who pay both the Medicare and Medicaid capitation amounts privately out-of-pocket.

Data Element Four - Disenrollments

Should the number of voluntary disenrollments and involuntary disenrollments add up to the “# of participants disenrolled for reasons other than death”?

Yes, the data requested in this section are only for participants who disenrolled from PACE for a reason other than death. The number of participants who disenrolled due to death is captured elsewhere.

One of the reasons listed for disenrollment is “experience with physician.” Can you explain what this means?

These are participants who disenroll because they have a preference for a non-PACE physician, e.g., their former primary care physician.

What reasons for disenrollment might be included in “other”?

Disenrollments resulting from any reason other than “leaving the service area,” “experience with physician,” or “accessing out of network” should be included in “other.” Reasons for “other” disenrollments may include unwillingness to pay the PACE premium, dissatisfaction with some aspect of the program, etc.

Data Element Five - Prospective Enrollees

Could you further clarify the meaning of “potential pts”? We receive a substantial number of inquiries from individuals who are not eligible for our PACE program – they may be less

than 55 or live outside our service area. Should these people be included as “potential participants”?

No. Potential participants are individuals who have initiated the enrollment process and appear to meet the program’s basic eligibility requirements, i.e., age 55 or over, live in the program’s geographic catchment area and are eligible for nursing home level of care, but DO NOT enroll in PACE.

Can you elaborate a bit on the reasons for not enrolling? What is the meaning of “physician preference”? A number of the reasons given for why an individual may not meet eligibility requirements are not mutually exclusive, e.g., someone may have serious mental health issues that make it unsafe for him to remain in the community. If this situation arises, how should the person be categorized? Further, PACE program are allowed to deny enrollment only to individuals who do not meet basic eligibility requirements (55+, live in service area, certified eligible for nursing home care) or whose health and safety would be jeopardized by living in a community setting. Can you confirm that the reasons listed for why an individual may not meet eligibility requirements are intended to provide more detail as to why health and safety are jeopardized by community residence?

First, if a person chooses not to enroll due to “physician preference,” it means that he/she would prefer to retain their own community physician(s) as opposed to switch to the PACE program’s primary care physician or contracted medical specialists. In situations where more than one reason may explain why a participant did not enroll in the program, choose the one you feel describes the reason most accurately and in the greatest detail. Lastly, with the exception of “financial-to avoid cost share,” all the specific reasons listed under “doesn’t meet eligibility,” are intended to provide more detail as to why health and safety are jeopardized by community residence.

A person may still be awaiting a determination regarding financial eligibility for Medicaid or may not yet have come to a decision regarding enrollment by the end of the quarter. How should we account for individuals who initiated the enrollment process in a given quarter, but who have not completed the enrollment process by quarter’s end?

These individuals, whose status is pending, should not be included in the “# of potential pts interviewed” for that quarter. In a given quarter you should report on potential participants interviewed who have completed the enrollment process and chosen NOT TO ENROLL.

Data Element Six - Hospitalizations

When asked how many participants are admitted to the hospital in a given quarter, what should we do if the same person is hospitalized more than once in that quarter?

You should report all hospitalizations. So, if a participant is hospitalized twice in a given quarter, report two hospitalizations for that individual. In response to Question 1 under Hospitalizations, be sure to include all hospitalizations including those in which the same participant is readmitted within 31 days for the same diagnosis. In addition, you will report only the number of readmissions within 31 days in response to Question 3 under Hospitalizations.

May we report diagnoses using ICD-9-CM codes?

Yes.

Data Element Seven - Emergent Care

As in the case of hospitalizations, should we report total number of emergency room visits as opposed to number of participants seen in the ER to allow for the fact that it is possible that the same participant may be seen more than once in the ER in a given quarter?

Yes, report total number of ER visits, as opposed to number of participants seen in the ER.

If a participant is seen in the ER and then admitted to the hospital, how should this be reported?

In this situation, report a hospital admission, not an ER visit.

Data Element Eight - Unusual Incidents

Can you provide a bit more definition on the specific types of incidents you list?

The following is intended to elaborate on the definition of specific incidents:

- All participant falls should be reported, regardless of whether they result in injury. Falls that result in an injury should be reported under falls, as opposed to participant injuries.
- “falls getting into the van” also includes other unusual incidents while on the van, e.g., if something falls or tips over hitting the participant.
- “staff criminal records” refers to criminal activity that occurs after an employee is hired that might impact participants, e.g., theft, assault, drug-related incidents. It does not include traffic violations (unless they involve staff who transport program participants) or other “minor” incidents not impacting participants.
- Referring to “communicable diseases,” these include all infectious diseases required to be reported by the Centers for Disease Control.
- “food poisoning” need only be reported if the poisoning can be linked to food provided by a PACE program or contract facility; this would not include poisoning caused by food at a restaurant or from a participant’s home.
- “participant injury that required follow-up medical treatment” includes injuries requiring more than first aid, e.g., if a participant tears her skin as a result of hitting her arm on a door and it is addressed with first aid, the incident need not be reported.
- “medication errors” include those in which the wrong drug is administered; the wrong dose is administered; the wrong patient receives a drug; the drug is administered

incorrectly via the wrong route; or the drug is administered at the wrong time. In addition, if a patient makes an error self-administering a drug, this should be reported as well.

- “restraints” are defined in the PACE regulation as follows: A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant’s body that he or she cannot easily remove that restricts freedom of movement or normal access to one’s body. A chemical restraint is a medication used to control behavior or to restrict the participant’s freedom of movement and is not a standard treatment for the participant’s medical or psychiatric condition.

SANCTIONS

What type of violations trigger CMS to impose sanctions on the PACE Organization?

Section § 460.40 specifies that CMS can impose sanctions authorized by law, if CMS determines that a PACE organization has committed any of nine violations. These violations include:

1. The PACE organization fails substantially to provide to a participant medically necessary items and services that are covered PACE services, if failure adversely affected (or has substantial likelihood of adversely affecting) the participant;
2. The PACE organization involuntarily disenrolls a participant in violation of § 460.164;
3. The PACE organization discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid recipients, or both, who are eligible to enroll in PACE program, on the basis of an individual’s health status or need for health care services;
4. The PACE organization engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted under §460.150, by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicates a need for substantial future medical services;
5. The PACE organization imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted;
6. The PACE organization misrepresents or falsifies information that is furnished to HCFA, the State, or to any other individual or entity;
7. The PACE organization prohibits or otherwise restricts a covered health care professional from advising a participant of whether the PACE program provides benefits for that care or treatment, if the professional is acting within his/her scope of practice;
8. The PACE organization operates a physician incentive plan that does not meet the requirements of section 1867 (i)(8) of the Act; and
9. The PACE organization employs or contacts with any individual who is excluded from participating in Medicare or Medicaid under section 1128 or section 1128A of the Act (or with any entity that employs or contracts with that individual) for the provision of health care, utilization, review, medical social work, or administrative services.

What type of sanctions may CMS impose when a PACE program is in violation?

Based on the provisions of Section 1857(g)(2), 1857(g)(4) and 1903(m)(5)(B) of the Act, Section 460.42 of the regulation describes two types of sanctions that CMS may impose:

- 1) **Suspension of enrollment** of Medicare beneficiaries after the date CMS notifies the organization of the violation. Suspending enrollment of Medicaid recipients is an action taken by the State rather than CMS; and
- 2) **Suspension of payment**, CMS may suspend Medicare payment to the PACE organization and deny payment to the State for medical assistance for services furnished under the PACE Program agreement. Section § 460.46 specifies that CMS may also impose civil money penalties.

If CMS, after consulting with the State administering agency, determines that the PACE organization is not in substantial compliance with the PACE regulation, CMS or the State may take one or more of the following actions:

- 1) condition the PACE program agreement upon a timely execution of a corrective action plan;
- 2) withhold some or all payments under the PACE program agreement until the deficiency is corrected; or
- 3) terminate the program agreement.

Do you have a question we have not answered? Please E-mail to pace@cms.hhs.gov.