Healthcare

CAREFULLY SPEAKING®

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PACE: A Quick Guide to Program Basics and Associated Risks

Initially conceived in the 1970s, Program of All-Inclusive Care for the Elderly (PACE) refers to community-based, capitated health plans intended for older adults with chronic illnesses who qualify for skilled nursing care but wish to age at home. Due to its integrated, encompassing approach to meeting medical, social and personal care needs, the PACE concept has proven popular with often overstretched family caregivers. (See "PACE: By the Numbers," from the National PACE Association, January 2024.)

While the PACE model offers many benefits to enrollees and caregivers alike, it also presents certain risks that differ from those associated with traditional facility-based care. This edition of *CareFully Speaking*® reviews how PACE programs function, examines professional and auto liability considerations (see page 4), and offers practical risk control strategies. Also included on page 6 is a self-assessment tool designed to help PACE organizations gauge their level of exposure.

In this issue…

PACE Basics

PACE programs – which may be operated by government agencies, nonprofit organizations or for-profit companies – deliver Medicare Parts A, B and D benefits; state Medicaid-covered benefits; and all other services and support required to maintain or improve enrollees' health. After applying to and being accepted by the Centers for Medicare & Medicaid Services (CMS) and the respective state, PACE centers of care are reimbursed on a per-participant basis by CMS and relevant state agencies.

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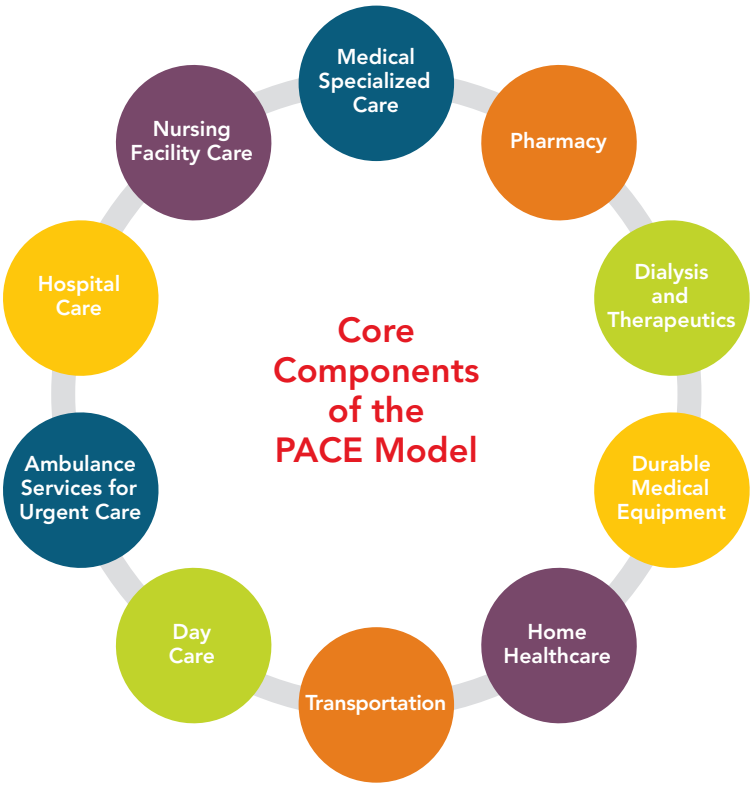
The PACE model offers an extensive range of services to enrollees, as depicted in the following diagram:



PACE Benefits

- Reduced mortality rates.
- Fewer unaddressed needs.
- Sustained independence.
- Decreased hospital and aging services facility admissions.
- Lower out-of-pocket expenses.
- Higher participant satisfaction.

Care is delivered by home healthcare agencies, contracted physicians, day health centers, non-contracted specialty physicians and family caregivers. If enrollees require hospitalization, skilled nursing services or outside specialized medical care, the PACE plan becomes the payer of record for these services. Meals are served in day health centers or at home, based upon participant needs, while durable medical equipment, medications and medical supplies are made available by the program itself or by contracted third-party vendors. (For additional information on PACE programs, see the CMS PACE manual.)

Safety and Liability Issues

As PACE participation has increased, risk management challenges have emerged related to the following operational and clinical areas, among others:

Acuity levels. Depending upon state eligibility requirements, some PACE programs – especially those that enroll individuals with cognitive deficits, wandering tendencies and a wider range of daily needs – may contend with higher acuity levels. By adopting comprehensive guidelines for enrollee assessment, screening and care planning, PACE organizations can help ensure that participants obtain the care and services they need.

Coordination of care. PACE participants are typically cared for by an interdisciplinary team of professionals. The sheer number of healthcare encounters creates the risk of miscommunication, including failure to convey test results and referral findings in a timely and accurate manner. It is therefore incumbent upon PACE programs to establish protocols and processes designed to facilitate reporting and enhance access to enrollee care data. In addition, the information systems of medical/dental clinics and diagnostic testing centers located on a PACE campus should interface with PACE record-keeping systems, in order to provide staff members with ready access to consultation findings, as well as specimen and imaging results.

Medication management. Drug-related incidents are not uncommon in home healthcare settings, which may lead to allegations of failure to prescribe or administer medications safely, monitor participants for side effects or adverse interactions, and perform proper utilization review. To minimize exposure to claims of medication mismanagement, PACE organizations should consider implementing the following safety measures, among others:

- Adoption of effective medication reconciliation techniques.
- Utilization of electronic prescribing methods and safeguards.
- Frequent quality assurance reviews of prescribing practices.
- Ongoing staff education about the risks of polypharmacy.
- Training sessions for family caregivers on medication administration techniques and safety principles.

Staffing levels. Some PACE programs, particularly those located in rural areas, struggle to recruit sufficient numbers of qualified staff. Fortunately, programs are accorded some flexibility in spending their Medicare- and Medicaid-funded capitated reimbursement rates, allowing them to invest in the areas that pose the greatest staffing challenges, such as home- and center-based personal care staff, nurses and drivers. Depending upon their particular hiring

needs, programs have utilized a variety of tactics to address workforce shortages, such as offering performance bonuses and benefit incentives, as well as by allowing staff members to train for a wider range of roles and duties.

Education and training. Most program participants have complex medical and social needs, requiring staff competence in such areas as geriatric care, chronic disease management and behavioral healthcare. By offering a combination of online courses, in-person instruction and hands-on training in relevant subjects – including falls prevention, wound care, medication management and communication strategies for older adults – organizations can help boost staff capabilities. To ensure consistency of approach and increase efficiency, staff training and performance assessment should be treated as a centralized activity overseen by a single department.

Credentialing practices. Programs have a duty to select and retain competent, properly credentialed medical providers. Potential liability associated with inadequate medical staff screening can be minimized by establishing core credentialing and assessment standards for prospective physicians and advanced practice providers, as well as by developing a well-documented process to evaluate clinical skills and performance.

Reporting and appointment follow-up. Well-designed follow-up protocols can help reduce errors related to laboratory test reporting and missed or canceled appointments. Designated PACE team members should be assigned responsibility for tracking pending diagnostic tests and flagging time-sensitive procedures. Also, written policy should dictate that no-shows be documented in the record of care, along with efforts to follow up with enrollees who miss scheduled appointments.

Changes in condition. Prompt observation and communication of changes in a participant's condition are a key risk control strategy. Since changes may occur at any time, enrollees and family members should be instructed to promptly inform staff of any new signs or symptoms. In addition, staff should undergo training sessions in how to detect warning signs of physical and mental deterioration, both upon hire and annually thereafter. (See CNA *AlertBulletin*® 2025-Issue 2, "Change of Condition in Residents: Enhancing Detection and Response.")

Emergency preparedness. Both home- and center-based care staff should be proficient at responding to medical emergencies, including cardiac arrest, diabetic insulin reactions, falls, choking and seizures. Formal response protocols should address, among other issues, medication administration, CPR guidelines, 911 notification and release of enrollee health information, as well as equipment requirements, such as portable oxygen, airways, suction and emergency drugs.

After-hour occurrences. Efficient management of after-hour occurrences is a shared responsibility of the PACE team, program participants and caregivers. Any falls, injuries, medical emergencies or other significant events that occur after normal operating hours should be swiftly conveyed by participants and/or caregivers to PACE primary care physicians and, if necessary, emergency personnel. Protocols should be in place governing management of after-hours occurrences, including reporting procedures and methods for ensuring that treating providers have access to vital information about enrollees, such as medical history, current medications and care plan basics.

(For additional risk-related information, see "A Closer Look at Professional and Auto Liability Exposures" on page 4.)

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A Closer Look at Professional and Auto Liability Exposures

Professional Liability Considerations

The following strategies, among others, can help minimize exposures related to PACE programs:

Enrollee Assessment: Documented assessments of PACE participants can help ensure that changes in condition are noted promptly, especially during periods of transition between settings.

Care Planning: When based on a thorough evaluation of enrollees' strengths, needs and preferences, participant care plans can significantly strengthen coordination of care among PACE providers, family caregivers and third-party vendors.

Hiring: PACE programs are responsible for employing competent and reliable staff. General and criminal background checks can help screen out applicants who may be unsuitable for a position. As part of the hiring process, applicants should authorize in writing an inquiry into their history, criminal and otherwise.

Agency Staffing: Before contracting with agency staff, secure written assurances from the agency that it has performed initial licensure and competency evaluations. Whenever possible, select agency personnel who are familiar with the PACE program and its participants, and ensure that job duties and insurance requirements are included in staffing agency contracts.

Drafting of Contracts: Check that all written contracts contain appropriate risk transfer language, such as hold harmless and indemnity clauses, as well as provisions governing such topics as confidentiality, terms of employment, and contract renewal and termination.

Emergency Readiness: PACE programs are required to establish an emergency preparedness program, which should be tested at least annually. In addition …

- **Train staff annually on disaster response,** including evacuation and shelter-in-place protocols.
- **Emphasize first aid capabilities,** ensuring that at least one staff member at PACE centers is trained in CPR.
- **Prominently display maps of exit routes,** as well as fire extinguisher locations.

Auto Liability Considerations

PACE programs frequently utilize both owned and non-owned vehicles for a variety of purposes, including transporting participants to medical appointments and other destinations, delivering equipment and supplies, and conveying employees and volunteers. Associated exposures include liability for collisions, participant injuries and other driving-related mishaps. For these reasons, PACE programs require auto liability coverage, coupled with a risk management program that encompasses these features:

General Preventive Measures: The following steps can help protect both program participants, employees and the organization itself from the threat of litigation and potential loss:

- Establish eligibility criteria for drivers.
- Verify proper licensing of drivers at the time of hire.
- Require proof of valid auto insurance if personal cars are used for work purposes.
- Review the motor vehicle record (MVR) for all drivers upon hire and implement an MVR monitoring system.
- Initiate a driving skills/accident prevention training program.
- Evaluate drivers' skills and knowledge on a routine basis and document results in personnel files.
- Institute and enforce a zero-tolerance policy for serious violations.

Fleet Safety: An effective fleet safety program should contain the following elements, among others:

- Driving safety protocols and procedures.
- Signed driver agreements.
- Documented MVR checks.
- A crash reporting and investigation process.
- Vehicle selection, maintenance and inspection protocols.
- Annual driver safety training.

Driver Liability: Hired and Non-owned Auto (H/NOA) refers to vehicles that do not belong to organizations but are used in connection with their operations, such as employee-owned or rental vans or automobiles. In the event of an accident, and after the vehicle's liability limits have been reached, the PACE program could be pursued to pay additional damages. To minimize this risk, permit only authorized employees to use personal vehicles for care-related purposes. (For additional strategies, see CNA Insurance, "Hired and Non-Owned Auto Exposures," 2021.)

Transportation Safeguards: During orientation and periodically thereafter, drivers should be trained to follow basic safety rules, including the following:

- **Safeguard participants in wheelchairs,** including inspecting safety straps, utilizing proper lift protocols, and checking wheelchair brakes and restraints.
- **Ensure that drivers understand safety instruction,** and that training sessions have been documented.
- **Prominently label oxygen cylinders** and secure them.
- **Maintain a written record,** including transport times, passenger names, special needs and seatbelt use checks.
- **Prohibit passengers from operating van doors or lifts** – this should be strictly the driver's responsibility.

Essential Risk Control Strategies

Quality care, both in the home environment and at PACE centers, rests upon a foundation of sound operational and clinical policies. The following suggestions are designed to spark organizational discussion on policy development:

Enhance communication and care management. Disparate operating systems and inconsistent communication protocols can result in critical care gaps and treatment delays. The following measures can help PACE providers better coordinate care:

- **Adopt a centralized care management system** featuring built-in communication platforms, in order to ensure that all providers have real-time access to enrollee care plans and other relevant information.
- **Draft formal policies** in regard to medical care, medication management, specialist referrals, transportation and other non-medical services, emphasizing communication-related responsibilities.
- **Document all communication with participants, caregivers and PACE team members,** including actions recommended to enrollees and caregivers.
- **Conduct daily weekday PACE team meetings,** in order to flag high-risk enrollees for close observation.
- **Review participant care plans on a regular basis,** as they are the chief means of communicating care provisions and service needs.
- **Instruct staff to activate the chain of command** following a sudden change in condition or behavior.

Centralize contract management. Sound, legally vetted contracts can help prevent misunderstandings in service agreements, strengthen PACE partnerships and enhance defensibility in the event of litigation. The following guidelines are intended to minimize contract-related exposures:

- **Assign specific individuals to review contracts with PACE providers** – e.g., hospitals, skilled nursing facilities and specialty medical care providers – in order to identify potential exposures associated with regulatory noncompliance, substandard documentation and other lapses.
- **Ensure that all contracts with medical providers delineate expectations concerning professional credentials** and assign responsibility for proper credentialing to one party.
- **Clearly state mutual obligations** and expectations in all service contracts.
- **Require that all contracts be reviewed by an attorney** conversant with the PACE model of care.
- **Appoint one individual to handle any contract-related grievances** that may emerge over time.

Reduce environmental health hazards. A cluttered or unclean home environment presents a number of infection control and general health challenges, including, but not limited to, mold and bacteria growth, pest infestations, poor air quality, unclean water and presence of toxic substances. The following hazard-reduction strategies can help improve sanitation:

- **Implement an infection control program,** reinforcing the importance of hand hygiene, proper disposal of medical waste, safe injection practices, and preventing clinical cross-contamination between the home environment and PACE centers.
- **Perform a documented environmental risk assessment as part of the initial screening process,** as well as ongoing home inspections, and notify PACE supervisors of any concerns that cannot be easily remedied.
- **Implement protective measures designed to minimize the possibility of cross-contamination,** focusing on the presence of rodents and other pests, such as lice, fleas, mites and bedbugs.
- **Document all infection control measures taken,** including dates of home inspection, requested cleanings and other maintenance work, and water- and air-quality tests conducted, along with results.

A formal risk management program is a vital element in minimizing PACE-related liability exposures. The self-assessment questionnaire on page 6 is designed to help organizations examine processes and programs commonly associated with liability claims, and develop a strategic plan to reduce risk exposures, strengthen defensibility and promote a culture of safety.

By providing integrated, all-around care to chronically ill seniors who wish to live at home, the PACE model has become increasingly popular within the aging services marketplace. However, as PACE has grown, associated risks – including both professional and auto liabilities – have become more visible. The suggestions contained in this article provide a starting point for PACE organizations seeking ways to protect participants from injury, strengthen coordination of care, and minimize exposure to potential litigation and consequent financial loss.

PACE Program Risk Management: A Self-assessment Questionnaire

The following sample questionnaire, which should be adapted to the organization's unique needs and circumstances, is designed to help PACE administrators and providers evaluate their progress toward creating an effective risk management program.

Administrative	Yes/No	Comments
1. **Are background checks, including sex offender records, performed on program participants** prior to their enrollment, and are findings documented?		
2. **Are contracts with third-party providers and non-employed physicians reviewed by legal counsel** for appropriate risk-transfer language, including hold harmless and indemnity provisions?		
3. **Is professional liability (PL) insurance coverage, including required limits of liability, addressed in written contracts** with non-employed physicians, nurse practitioners, physician assistants and RNs?		
4. **Is there parity in PL insurance coverage,** i.e., are the limits of liability for licensed providers who have independent PL coverage equal to CNA insurance policy limits for PACE program employees?		
5. **Is a comprehensive Quality Assurance and Performance Improvement (QAPI) program in place,** and is it regularly reviewed and updated?		
6. **Can program participants appeal treatment-related decisions** via a formal, documented process?		
7. **Is a documented emergency response plan in place,** covering both medical and non-medical disasters that occur in the home as well as at PACE day health centers?		
8. **Is the program's emergency plan tested and evaluated at least annually,** with documentation of results and corrective action plans, if applicable?		

Clinical	Yes/No	Comments
1. **Is there an orientation and onboarding program** for all licensed staff members?		
2. **Do staff undergo clinical proficiency checks** on a regular basis, including in the areas of medication safety, falls mitigation, elopement risk assessment and pressure injury (PI) prevention?		
3. **Is there a process for communicating medical orders from contracted physicians to day health center staff,** and is this process detailed in the program's written protocols?		
4. **Are written care plans prepared for program participants** and reviewed at least semi-annually, or more frequently if clinically indicated?		
5. **Are participant healthcare records stored electronically** and, if not, are there policies to protect and preserve hard-copy files?		
6. **Do contracted physicians have access to the program's electronic health record system,** if such a system is in use?		
7. **Does the PACE organization have a system-wide infection control plan** that complies with Centers for Disease Control and Prevention (CDC) guidelines for home healthcare, day health centers, clinical settings and transportation environments?		
8. **Has the PACE organization obtained a Clinical Laboratory Improvement Amendments (CLIA) waiver** from the CDC for laboratory testing performed in a day health center or a participant's home?		

Transportation	Yes/No	Comments
1. **Are newly hired drivers oriented to safety requirements,** and do they undergo annual competency checks?		
2. **If a third-party transportation vendor is utilized, do contracted drivers have the same liability limits** in their insurance policy as do PACE-employed drivers?		
3. **Are third-party drivers subject to the same orientation and annual competency requirements** as drivers directly employed by the PACE organization?		
4. **Have all potential auto-related liabilities and coverage needs been considered,** including those that do not directly involve PACE enrollees, such as delivering medical equipment and supplies, as well as transporting staff, employees and volunteers?		
5. **Are PACE drivers prohibited from transporting participants who are paraplegic** or are experiencing a medical emergency?		
6. **Is there a formal preventive maintenance and inspection program for both owned and non-owned PACE vehicles,** based upon manufacturer's recommendations, and are all inspections and repairs documented?		

Home Healthcare	Yes/No	Comments
1. **Are all home healthcare staff subject to written policies and procedures** covering both clinical care requirements and behavioral expectations?		
2. **Are staff members trained upon hire and at regular intervals thereafter in how to respond to potentially violent occurrences and other unsafe situations in home settings,** and how to report them through established channels?		
3. **Are staff members given training in how to reduce exposure to unsanitary domestic conditions** (e.g., poor air quality, bedbugs, rodent infestations) and infectious pathogens (e.g., COVID), including basic universal precautions?		
4. **Is skin integrity thoroughly assessed and documented upon enrollee admission to the program,** noting the presence of underlying PI risk factors, such as acute/chronic illness, cognitive impairment, history of PIs, malnutrition/dehydration and extended immobility?		
5. **Do enrollees have a written PI prevention plan** that is tailored to individual risk factors?		
6. **Is insurance coverage verified for all home health staff who drive their personal cars** in the course of work, and are insurance limits checked to ensure they meet state requirements?		

Behavioral Health	Yes/No	Comments
1. **Are participants screened for behavioral health (BH) conditions upon enrollment** and assessed periodically thereafter?		
2. **Do BH participants have an individualized care plan** created by an interdisciplinary team?		
3. **Does the program have a psychiatrist or a staff member trained in BH** to manage participants who require special assistance?		
4. **Are staff trained to manage participants with BH conditions,** including memory loss?		
5. **Do day health centers have a designated area for BH participants,** which can be closely monitored by staff?		

Adult Day Health Centers	Yes/No	Comments
1. **Is there a minimum staff-to-participant ratio** in day health centers?		
2. **Are onsite medications secured** and accessed according to written protocols?		
3. **Are medications brought to centers by participants secured** per written protocol?		
4. **Does a protocol govern medication changes,** i.e., type, dosage and route?		
5. **Are food service vendors licensed and certified by the state or local jurisdiction,** and are meal programs inspected annually?		
6. **Does a formal elopement prevention policy** address safety issues for offsite visits and/or day trips?		
7. **Are both electronic and mechanical anti-elopement safeguards in use,** including door alarm systems, closed-circuit television, boundary lasers and resident tracking devices?		
8. **Does a falls mitigation program emphasize staff training,** fall risk assessment, response protocols, transfer guidelines and other risk control measures?		
9. **Do centers have a secured area for participants who have memory deficits** or are habitual wanderers?		
10. **Does a written missing participant response protocol** include timeframes for notifying PACE management, family and local law enforcement?		
11. **Do centers have access to emergency resources,** e.g., oxygen, airways, suction and drugs?		
12. **Are fire and evacuation drills conducted as required by CMS and state authorities** for the type of setting in which the center is located?		
13. **Are written agreements in place with neighboring health centers** to receive participants in the event of an evacuation?		

Quick Links

- National PACE Association Annual Report, 2024
- PACE Final Rule.
- PACE Resources Page, CMS.

For more information, please visit www.cna.com/healthcare.