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ACRONYMS

ADE .................................................. Adverse Drug Event
CBPCP .................................................. Community-Based Primary Care Physician
CMMI .................................................. Center for Medicare and Medicaid Innovation
CMS .................................................. Centers for Medicare & Medicaid Services
CO .................................................. Central Office
CQI .................................................. Continuous Quality Improvement
DHHS .................................................. Department of Health and Human Services
DP2 .................................................. DataPACE2
DP3 .................................................. DataPACE3
DRG .................................................. Diagnosis-Related Group
EMR .................................................. Electronic Medical Record
EOC .................................................. Environment of Care
ER .................................................. Emergency Room
FWA .................................................. Medicare Part D Fraud, Waste and Abuse Requirements
HCBS .................................................. Home and Community-Based Services
HOS-M .................................................. Health Outcomes Survey-Modified
HPMS .................................................. Health Plan Management System
IDT .................................................. Interdisciplinary Team
IRE .................................................. Independent Review Entity (Contracted by Medicare)
MTM .................................................. Medication Therapy Management
NH .................................................. Nursing Home
NP .................................................. Nurse Practitioner
NPA .................................................. National PACE Association
PA .................................................. Physician Assistant
PAC .................................................. Participant Advisory Committee
PACE .................................................. Program of All-Inclusive Care for the Elderly
PBM .................................................. Pharmacy Benefit Manager
PCP .................................................. Primary Care Provider
PDAC .................................................. PACE Data Analysis Center
PDE .................................................. Prescription Drug Event
PO .................................................. PACE Organization
QAPI .................................................. Quality Assessment and Performance Improvement
QD .................................................. Quality Director
QI .................................................. Quality Improvement
FOREWORD

This is the first PACE Quality Director’s Handbook. The National PACE Association (NPA) thanks all the authors who contributed to the handbook by sharing their valuable insights and recommendations to assist PACE organizations’ quality improvement efforts and development of a robust quality program. The handbook is intended to serve as a resource and ongoing reference for all quality staff.

Following are important disclaimers for your attention:

➢ The PACE Quality Director’s Handbook contains information relevant to all quality staff (quality coordinator, quality manager, etc.) and is not limited to quality directors.

➢ Given that the PACE proposed rule seeks to transition the Quality Assessment and Performance Improvement (QAPI) terminology to Quality Improvement (QI), an effort was made to utilize “QI” rather than “QAPI” in the handbook when possible.

➢ Several chapters were adapted from the PACE Medical Director’s Handbook.

➢ Narratives related to any CMS document (e.g., PACE Manual, Level I and II Guidance) and PACE regulations are paraphrased and/or excerpted directly from the source.

➢ Not all content may be applicable to your PACE organization (PO) or required by the Centers for Medicare & Medicaid Services (CMS), your State Administering Agency, etc. We recommend that you reach out to your account manager with any questions.
CHAPTER 1
The History of PACE

Authors: Jessica Burt and Janet O’Connor
The PACE model of care can be traced to the early 1970s, when the Chinatown-North Beach community of San Francisco saw the pressing needs of families whose elders had emigrated from Italy, China and the Philippines for long-term care services. For these families, the option of placing their elders in nursing homes was not a culturally acceptable solution. In order to meet this community need, William Gee, DDS, a public health dentist, headed the committee that hired Marie-Louise Ansak in 1971 to investigate solutions. They, along with other community leaders, formed a nonprofit corporation, On Lok Senior Health Services. (On Lok is Cantonese for “peaceful, happy abode.”) In 1973 On Lok created a community-based system of care and an innovative way to offer a comprehensive array of medical supervision, physical and occupational therapies, nutrition, transportation, respite care, socialization and other needed services using home care and an adult day setting.

**Timeline for the Creation of PACE**

<table>
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<th>Event</th>
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<tr>
<td>1971</td>
<td>William Gee, DDS, and two others execute articles of incorporation for the nonprofit Chinatown-North Beach Health Care Planning and Development Corporation (later renamed On Lok Senior Health Services) and retain Marie-Louise Ansak to study the feasibility of building a nursing home in the community. She finds a nursing home would be financially infeasible and culturally inappropriate. Instead, she obtains funding to train health care workers in cooperation with University of California San Francisco and outlines a comprehensive system of care combining housing and all necessary medical and social services based on the British day hospital model.</td>
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<td>1973</td>
<td>On Lok opens one of the nation’s first adult day centers in San Francisco.</td>
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<td>1974</td>
<td>On Lok begins receiving Medicaid reimbursement for adult day health services.</td>
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<tr>
<td>1975</td>
<td>On Lok adds a social day care center and includes in-home care, home-delivered meals and housing assistance in its program.</td>
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<tr>
<td>1978</td>
<td>The On Lok model of care expands to include complete medical care and social support of nursing home-eligible older individuals.</td>
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<td>1979</td>
<td>On Lok receives a four-year Department of Health and Human Services grant to develop a consolidated model of delivering care to persons with long-term care needs.</td>
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<tr>
<td>1983</td>
<td>On Lok is allowed to test a new financing system that pays the program a fixed amount each month for each person in the program.</td>
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<tr>
<td>1986</td>
<td>Federal legislation extends the new On Lok financing system and allows 10 other organizations to replicate its service delivery and funding model in other parts of the country.</td>
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<td>1987</td>
<td>The John A. Hartford Foundation, Robert Wood Johnson Foundation and Retirement Research Foundation provide funding to On Lok and the first replication centers to support its efforts.</td>
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<td>1990</td>
<td>The first Programs of All-Inclusive Care for the Elderly (PACE®) receive Medicare and Medicaid waivers to operate the program.</td>
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<td>1994</td>
<td>The National PACE Association (NPA) is formed.</td>
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<td>1997</td>
<td>The Balanced Budget Act of 1997 establishes the PACE model as a permanently recognized provider type under both the Medicare and Medicaid programs.</td>
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<tr>
<td>Year</td>
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<tr>
<td>2000</td>
<td>The John A. Hartford Foundation and Robert Wood Johnson Foundation fund the PACE Expansion Initiative to assist NPA in expanding the benefits of the PACE model of care to more families in need.</td>
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<tr>
<td>2001</td>
<td>Alexian Brothers Community Services, in St. Louis, MO, becomes the first PACE provider to become a full, permanently recognized part of the Medicare and Medicaid programs.</td>
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<td>2006</td>
<td>CMS publishes the final PACE Regulation in November. Congress awards grants of $500,000 to 15 organizations for rural PACE expansion.</td>
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<td>2007</td>
<td>Forty-two PACE programs are operational in 22 states.</td>
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<td>2010</td>
<td>The Veterans Affairs (VA) Central Office awards funds for a pilot program for seven VA medical centers to contract for PACE services with 11 PACE organizations.</td>
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<tr>
<td>2011</td>
<td>Eighty PACE programs are operational in 28 states.</td>
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<tr>
<td>2015</td>
<td>The PACE Innovation Act of 2015 is passed by Congress and signed into law by President Obama. It provides CMMI the authority to develop PACE pilots for new populations. A total of 116 PACE programs are operational in 32 states.</td>
</tr>
<tr>
<td>2017</td>
<td>A total of 122 PACE programs are operational in 31 states serving over 40,000 participants.</td>
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The Robert Wood Johnson Foundation provided funding for six centers in 1986, in addition to On Lok, to develop PACE demonstration programs, which were made possible by congressional authorization of additional Medicare and Medicaid waivers. Based on the success of these programs, PACE was able to make the rare transition from demonstration to permanent provider type. The Balanced Budget Act of 1997 approved the granting of provider status to PACE organizations (POs) under Medicare and gave state Medicaid agencies the option to include PACE as a Medicaid benefit.

There have been recent initiatives to expand the availability of PACE to new markets and populations. In April 2006 CMS issued the Rural PACE Provider Grant Program Solicitation Announcement. The grant, titled “Establishing PACE As a Community Care Option for Rural Elders,” was made to NPA to provide support for several activities that were designed to leverage a separate $7.5 million federal grants program administered by the Centers for Medicare & Medicaid Services (CMS) to 15 rural PACE applicants (of which 14 were awarded full PACE program status by the end of the grant from the John A. Hartford Foundation). The grant program provided 14 grantees with $500,000 each to support the development of a rural PACE program for some of the most vulnerable Medicare, Medicaid and dually-eligible beneficiaries in 13 states across the country. CMS awarded all of the possible funds and the maximum number of grants available to expand patient-based care to a greater number of people with Medicare and Medicaid who live in rural areas.

Another initiative to expand the availability of PACE was forged through a partnership between NPA and the Department of Veterans Affairs (VA) to secure VA payment for PACE. In early 2009 this effort focused on implementing a pilot with the Philadelphia VA Medical Center (VAMC) and the LIFE UPenn PACE program. In November 2009 the VA Central Office issued an RFP to encourage patient-centric care as an alternative to institutional care. PACE was one type of program that was solicited as part of the RFP, especially in rural areas. In January 2010 the VA Central Office awarded funds for a pilot program for seven VAMCs to contract for PACE services with 11 PACE organizations, which allowed for 80 veterans to be enrolled at any given time across all the participating POs. Moving forward, the plan is to advocate for this contract arrangement to be expanded to all VAMCs wishing to contract with PACE.
What Is PACE?
The Program of All-Inclusive Care for the Elderly (PACE®) was designed to provide a multitude of delivery services to the frail elderly. By delivering all needed medical and supportive services, the program is able to provide the entire continuum of care and services to seniors with chronic care needs while maintaining their independence in their home for as long as possible.

The program includes the following care and services:

➢ adult day care that offers nursing, physical therapy, occupational therapy, recreational therapy, meals, nutritional counseling, social work and personal care;
➢ medical care provided by a PACE physician or nurse practitioner familiar with the history, needs and preferences of the participant;
➢ home health care and personal care;
➢ all necessary prescription drugs;
➢ social services;
➢ medical specialties, such as audiology, dentistry, optometry, podiatry and speech therapy;
➢ respite care;
➢ hospital and nursing home care, when necessary;
➢ institutional nursing home long-term care; and
➢ transportation.

These programs are innovative because they provide continuous care and services offering individuals eligible for nursing home care the option of continuing to live in the community. Because these health care costs traditionally are paid for through the Medicare and Medicaid programs and out of people’s pockets, access to a comprehensive system of care that encompasses preventive, primary, acute and long-term care is usually not possible. One key to the PACE model is the combining of dollars from different funding streams in order to deliver a comprehensive set of services focused on the health and well-being of the individual.

PACE delivers care differently than traditional long-term care providers, so it can be difficult to understand how all of the elements of the program work together. For example, the public primarily may be aware of the vans that PACE organization use to provide transportation to their participants. Policy-makers may view PACE as a program that integrates Medicare and long-term care funding in a way that saves taxpayer dollars while providing more effective care. PACE participants and their family members might see the PACE center as the central part of the program.

PACE organizations receive a monthly capitated payment – a lump sum from Medicare combined with Medicaid or a participant’s private pay resources that is used to pay for a variety of comprehensive services. They are responsible for the care their participants need. As such, the financial interests of the organizations and the care needs of the people they serve are aligned in a unique way. Regardless of whether needed services would be reimbursed under traditional fee-for-service Medicare and Medicaid, PACE provides a comprehensive set of preventive, primary, acute and long-term care services specifically tailored to the needs of each participant to avoid hospital or nursing home placement to the greatest extent possible.
PACE is designed to monitor participants closely for even subtle changes in needs that, if left unattended, could lead to costly acute care episodes. For example, if a Medicare beneficiary goes to an emergency room every month to be treated for skin infections caused by flea bites, the traditional, fragmented care delivery system would have trouble addressing the root cause of her condition and might continue to just treat the bites. For a PACE enrollee in that situation, an interdisciplinary team (IDT) – with input from social workers, home health aides and drivers who have been in the participant’s home – may decide to fumigate the home and provide a flea dip for her pet. This flexibility can produce more cost-effective solutions and a higher quality of life than prescribing costly medications or continually hospitalizing an individual.

The various components of the PACE model, including the work of the IDT, result in care and services that are tailored to the individual needs of each PACE participant.

The ability to coordinate the care of each participant enrolled in PACE is key to the model. PACE organizations coordinate and provide needed preventive, primary, acute and long-term care services so their participants can continue living in the community. To understand how PACE works, it is important to learn about the components that enable the program to respond to the unique needs of each participant. The PACE organization is comprised of IDTs, capitated payment arrangements, PACE centers and transportation.

The IDTs are comprised of physicians, nurse practitioners (NPs), nurses, social workers, therapists, van drivers, aides and others who meet regularly to exchange information and solve problems as the conditions and needs of PACE participants change. Through IDTs, the viewpoints of different disciplines are brought together, and information is shared that is gained through interaction with the PACE participant over time and in different settings. This approach empowers those involved and allows more information to be available at the critical points when decisions are being made about the participant’s needs for care and services and how best the team can provide the care and services approved by the IDT.

PACE participants can attend the PACE center, or not, at a frequency scheduled to meet their individual needs. PACE centers operate Monday through Friday during regular business hours. Some centers are open before and after business hours and on weekends. A PACE center includes a health clinic with a primary care physician. Some PACE organizations have NPs, physical and occupational therapy facilities, a kitchen or food delivery service to provide one daily meal at the center, and at least one common room for social and recreational activities. Unlike fee-for-service Medicare and Medicaid programs, PACE has the flexibility to provide services like occupational and physical therapies even when the goal is to maintain or slow the decline of an ability rather than to have measurable improvement in function. PACE participants have regular contact with primary care professionals who know them well, so slight changes in their health status or mood can be addressed immediately.

Transportation for PACE participants is another covered benefit. Transportation is critical to the implementation of the care plan and a key way PACE supports families who are providing care for their loved ones. Transportation is not only to and from the day center but to other appointments as well. Providing transportation also places a driver, who has been trained to observe cues, in the home of the PACE participant. Drivers can report cues that may signal a change in health status or other changes that should be monitored.

The PACE Population
To qualify for PACE, a person must be age 55 or over, live in a PACE service area, and be certified by the state to need nursing home-level care. Like nursing homes, PACE tends to attract participants who are older and have very high care needs. The average PACE participant is 77 years old and female. (Seventy percent of
participants are female.) The average PACE participant who is Medicare-eligible has 5.4 medical conditions. Although extremely frail, most PACE participants live alone in the community. Only 5 percent live in nursing homes. When participants need nursing home care, they do not disenroll from PACE; the PACE organization pays for nursing home care. The IDT follows them through all care settings, including hospital stays and nursing home placements. PACE helps arrange supportive housing when appropriate.

Considering the needs of those it serves, PACE has good outcomes. Overall, the number of hospital inpatient days (acute covered days) per thousand Medicare fee-for-service (FFS) beneficiaries was 1,529 in 2009. For the same time period, the number of hospital days per thousand for Dual FFS members (not all of whom would have met the nursing home eligibility criterion set by PACE) was 3,327. In contrast, the number of hospital days per thousand for Institutional FFS members, to which a PACE enrollee comes closest in terms of having need for long-term care, was 7,497. During the same period of time, the number of hospital days per thousand for PACE enrollees was 3,500.

It is important to note that the information for PACE enrollees was derived from data submitted by 25 out of 60 PACE organizations and represents nearly 10,000 participants out of a total of approximately 20,000.

Other indicators of the good outcomes in PACE were highlighted in two studies. Research conducted by Abt Associates concluded that PACE participants have improved health status and quality of life, lower mortality rates, increased choice in how time is spent, and greater confidence in dealing with life’s problems than non-PACE individuals with comparable health needs. A study conducted by the secretary of the Department of Health and Human Services in 1997, which compared PACE enrollees to individuals receiving home and community-based waiver services (HCBS), found higher quality of care and better outcomes among PACE enrollees. Compared to HCBS clients, PACE enrollees reported better preventive care, better self-rated health status, less pain and likelihood of depression, and better management of health care.

Housing and the PACE Model

While housing is not a covered benefit or service under PACE, most PACE organizations find that strong relationships with accessible, affordable housing providers are important. As PACE organizations mature and their participants continue to age, arranging appropriate housing will become key to maintaining participants in the least restrictive and often most cost-effective environments.

Income Levels in PACE

There is no income eligibility requirement for participating in PACE. However, during the PACE demonstration process, many providers and state policy-makers were interested in how the PACE model could be used to provide care to hard-to-serve populations. PACE has been a successful model of care because it integrates across the full continuum of care and services possible, regardless of who is paying. In the future, payment sources for PACE enrollees likely will be more mixed as programs seek to serve many different income levels. PACE participants already use a variety of payment sources, including Medicare, Medicaid, VA, long-term care insurance benefits and out-of-pocket resources.

References

2. Dual FFS
3. Institutional FFS
4. Adjusted for partial year enrollment.
CHAPTER 2
Quality Director: Roles and Responsibilities

Author: Lori Trotter
Note: Many of the citations in this chapter have been abstracted from the CMS PACE Manual, last updated as Revision 2 on June 9, 2011. Since CMS PACE regulations currently are being updated, the PACE Manual may not reflect the most recent updates. PACE organizations may want to reference the updated Electronic Code of Federal Regulations to ensure they are complying with current requirements.

PACE regulations and PACE guidance from the PACE Manual may be of interest to the quality director to better understand the role and scope of responsibilities, particularly Chapter 6 (section 50.8), Chapter 7 (Section 20.9), Chapter 9 (Sections 20.0-20.4), Chapter 10 (Sections 10, 20.0-20.4, 30), and Chapter 12 (Section 50), as well as Sections 50.2.1 and 50.3-50.3.2 of the Prescription Drug Benefit Manual, Chapter 9: Compliance Program Guidelines and Medicare Managed Care Manual, Chapter 21: Compliance Program Guidelines also may be of interest.

Under the direction of the medical director and executive director, the quality director develops and implements the annual quality improvement (QI) plan, oversees QI activities and teams, oversees all required quality reporting to CMS (including via the Health Plan Management System), the State Administering Agency (SAA), the board of directors (board), the Participant Advisory Committee (PAC), staff, participants, providers, and other federal and state agencies. The quality director participates as a fully contributing member of the senior management team.

Quality directors collaborate with the medical director and executive director to plan, organize, direct, and lead the personnel and work processes of the QI program. Additionally, they help to develop performance improvement targets for the quality, service and efficiency of the organization. This is achieved through the application, teaching and skillful use of techniques for system design, reengineering, QI, outcomes measurement and statistical analysis. The quality director is responsible for the efficient and effective coordination and implementation of the QI plan and related QI activities.

The quality director supports continuous quality improvement (CQI) in the quality of care and service provision. This is accomplished by assisting all key stakeholders to develop and maintain quality initiatives that are focused on the continuum of care processes, which aim to maximize the outcomes for all PACE participants.

The quality director’s approach to CQI is fostered by a process that includes the following key components: identification, investigation, implementation, improvement and monitoring. Implementation of these basic concepts will lead to the successful development and execution of a quality plan that not only meets regulatory requirements but supports the efforts of the PACE organization toward implementing a formalized and systematic approach to CQI.

The quality director plays a significant role and engages leadership, staff, providers and other key stakeholders in QI efforts. A collaborative approach to QI, along with the use of a QI model (i.e., PDCA), ensures the involvement of individuals who are responsible for the work to be measured; identification of critical work processes and requirements; identification of critical results desired, with alignment to regulatory requirements; development of measurements for the critical work process or results; and establishment of performance goals, standards or benchmarks.

The quality director provides guidance in establishing and monitoring strategy to set and achieve quality goals. That strategy, supported by the development of an annual QI plan, should include specific quality measures and metrics to evaluate progress and guide necessary adjustments. Data collection and analysis are at the heart of quality improvement. Ongoing tracking and analysis of data is imperative to identify performance trends, significant results, and opportunities for performance improvement based on sound methodology. Data will help quality directors understand how well their systems work, identify potential
areas for improvement, set measurable goals, and monitor the effectiveness of change.

The quality director takes the lead in the follow-up and monitoring of outcomes and the development of correction plans for identified risk areas. This includes identifying the most cost-effective actions that can be implemented to correct errors and improve processes or methods so outcomes are more effective and efficient.

1. Prevention Programs
   ➢ Develop proactive risk assessments, which can include the use of failure mode and affects analysis, system analysis and other tools.
   ➢ Develop systems to oversee adverse events, near-misses and potentially unsafe conditions.
   ➢ Develop and implement event reporting policies and procedures.
   ➢ Ensure the collection and analysis of data to monitor the performance of processes that involve risk or may result in serious adverse events (e.g., medication use processes).

2. Continuous Development of the Risk Management Program
   ➢ Monitor the data collection and processing, information analysis, and generation of statistical trend reports for the identification and monitoring of adverse events, claims, finances, and effectiveness of the risk management program.
   ➢ Analyze data collected on adverse events, near-misses and potentially unsafe conditions; provide feedback to providers and staff; and use this data to facilitate systems improvements to reduce the probability of the occurrence of future related events. Root-cause analysis and systems analysis can be used to identify causes and contributing factors in the occurrence of such events.
   ➢ Ensure compliance with data collection and reporting requirements of regulatory agencies.
   ➢ Facilitate and ensure the implementation of patient safety initiatives, such as improved tracking systems for medication safety systems and falls prevention programs.
   ➢ Facilitate and ensure provider and staff participation in educational programs on patient safety and risk management.

3. Compliance
   ➢ In collaboration with the executive management team, maintain compliance with all applicable regulatory standards, including the health department, PACE, HHA, OADLC, OSHA and HIPAA.
     • include interdisciplinary and ancillary staff and management representation;
     • develop compliance measures, which may include those related to Part D, claims review, coding accuracy, and measures from the Office of Inspector General (OIG) Work Plan;
     • monitor the plan, analyze outcomes, and implement actions for improvement; and
     • report findings through the quality reporting process.

4. Communication
   ➢ Improvement occurs through leadership support and the communication of results:
     • establish leadership commitment to improving care;
     • include quality issues as part of regular discussions and meetings; and
     • engage staff and participants in improvement work to review data and plan changes.
5. **Education**
   - Integrate QI into orientation and training for new staff.
   - Train managers and supervisors in essential monitoring methods and measurement techniques specific to quality indicators.

6. **Reporting**
   - Performance improvement and QI activities are reported to participants, staff, contractors, administration, the Participant Advisory Committee (PAC), the board, and CMS and the state as required.
   - Periodic/quarterly reporting includes establishing a timetable within the QAPI plan to communicate the QI activities through the quality process.
   - Level I Events are defined by CMS in the Level I Guidance (February 2016). Refer to the publication for specific reporting information.
   - Level II Events are defined by CMS in the Level II Reporting Guidance (July 2015). Refer to the publication for specific reporting information.
   - Additional reporting:
     - state-specific reporting may be required (refer to the SAA for more information);
     - reporting may be required as a result of events or issues resulting from care, service or assessments of participants, including abuse reports to the Area Agency on Aging, state or law enforcement, and infection reports to the local and/or state health department.

In addition, a quality director may have oversight over compliance/fraud, waste and abuse and infection control and may serve as the privacy officer and/or training coordinator for the PACE organization, among other responsibilities. Refer to the PACE Manual and regulation for more information.
Purpose of the Quality Improvement Program

PACE programs help frail, nursing home-eligible older adults who wish to remain in their own homes to achieve a quality of life consistent with their own personal goals. The IDT, made up of health professionals from various disciplines and non-clinical support personnel, manages the care with the participant, family and caregivers. The IDT works with participants and their families to manage chronic disease, prevent new health problems, and support the participants’ highest level of physical, mental, social and emotional functioning. This occurs through health promotion, disease prevention, disease and disability management, and self-management techniques. PACE enhances the quality of life of frail, older adults by addressing their medical and psychosocial needs so they can enjoy continued autonomy and remain in their home and community safely.

To ensure the highest level of quality care to its participants, PACE programs will understand each participant’s goals of care, effectively manage the available resources to meet the goals of care, and actively involve all employees, as well as contract providers and consumers, in ongoing improvement efforts. PACE sets forth guidelines for the evaluation of all aspects of program operations, incorporating structure, process and outcome criteria. The intent of the plan is to meet the goal of the program by providing quality services to the frail elders. Appropriate and efficacious services should be provided in an organized, effective, safe and efficient manner to improve participant health outcomes and environmental safety. The program-wide, collaborative process is intended to design, measure, assess, and improve performance for all participant care, services and program functions.

PACE organizations (POs) submit a QI plan as part of their PACE application, which must meet certain requirements (§460.132). CMS and the state already will have approved a QI plan prior to its inclusion in the program agreement, and auditors will review the plan during monitoring visits. The plan must be written and reviewed annually by the governing body of the PACE organization. A formal evaluation each year will guide the required annual plan revision. The QI plan must specify how a PO will identify areas for improving or maintaining service delivery and patient care, develop and implement plans of action to improve or maintain quality of care, and document and disseminate the results of the QI activities to the PACE staff and contractors. Most auditors also expect that QI activities are communicated to participants and caregivers.

QI Program Goals

The goals of the QI program are as follows:

➢ to enhance operating efficiency, integration and effectiveness through the principle of continuous quality improvement;
➢ to monitor the appropriateness of documenting the interdisciplinary care planning process;
➢ to reduce the number of preventable occurrences and identify a clear process across the continuum of services where these occurrences are reported, trended, and reviewed for opportunities in process/performance improvement to reduce participant and program risk;
➢ to support the adherence and compliance of the program to regulatory standards;
➢ to utilize the care continuum to meet participant needs at the most appropriate and cost-effective level of care within the program;
➢ to promote an environment where each discipline of the interdisciplinary care team plays an integral part in the quality improvement process;
➢ to improve satisfaction with services that the participants, family members, representatives and referral sources receive; and
➢ to monitor and maintain an appropriate and adequate provider network.

Responsibilities of the Quality Director

In addition to being a member of all quality committees, the quality director is administratively responsible for the QI plan (with oversight from the medical director) and its yearly evaluation. This includes the following:

➢ Providing advice and direction in the development of the plan.
➢ Documenting the QI plan and any changes or updates to it or any of its components.
➢ Ensuring that the QI plan meets state and regulatory requirements.
➢ Ensuring that the QI plan is implemented as designed.
➢ Coordinating the activities of the QI committee.
➢ Monitoring, educating and communicating regulatory issues among the PO directors and staff to ensure compliance.
➢ Developing clinical and non-clinical performance indicators, including utilization review and subcontractor and participant satisfaction performance indicators.
➢ Directing data analysis in the development of systems to collect quality-related data and information.
➢ Working with the data analyzed, the information technology system utilized, and the IDT in conducting periodic focused studies and chart reviews, as well as collecting data to evaluate if the QI plan has been implemented as designed.
➢ Analyzing related data and information.
➢ Analyzing complaints, grievances, appeals and utilization management data and reporting such findings to the QI committees.
➢ Developing recommendations to address clinical and non-clinical quality problems and ensure ongoing quality.
➢ Working closely with the medical director in identifying, reporting, and resolving any potential or actual quality care problems or concerns.
➢ Providing reports and service utilization data to the medical director regarding subcontractors’ performance.
➢ Assisting the medical director in the completeness of credentials verification for new and renewing network providers. (PO-dependent.)

Regulatory Requirements

The regulatory requirements for QI programs, which are delineated in Subpart H – Quality Assessment and Performance Improvement, are organized into six sections:

1. General Rule (§460.130)
2. Quality Assessment and Performance Improvement Plan (§460.132)
3. Minimum Requirements for Quality Assessment and Performance Improvement Program (§460.134)
4. Internal Quality Assessment and Performance Improvement Activities (§460.136)
5. Committees with Community Input (§460.138)
6. Additional Quality Assessment Activities (§460.140).

For additional details and clarification, refer to the PACE Regulations and PACE Manual (Chapter 10).

Language from the CMS PACE Regulations is paraphrased or excerpted below.

**General Rule**

PACE organizations must develop, implement, maintain, and evaluate their QI program and assure the program is effective and data-driven, reflecting the full range of services furnished and showing improvements in all types of care. The expectation is that POs will operate a continuous QI program that does not limit activity to selected kinds of services or types of patients, using as much flexibility as is necessary to fully meet obligations of participant care. CMS does not require the use of a common quality assessment tool or a set of specific outcome measures beyond the data elements for monitoring as established in the program agreement (though some states will expect other specific elements, such as DataPACE3). Thus, POs have the flexibility to develop the program that best meets their needs. The desired outcome of the QI requirement is that data-driven quality assessment serves as the engine that drives and prioritizes continuous improvements for all PO services.

To support the data-driven QI process, POs must maintain a health information system (§460.202) that collects, analyzes, integrates, and reports data necessary to measure their performance and develop their QI program. This system is not required to be electronic, but it must have the capability to measure the performance of a PO, including outcomes of care.

**Minimum Requirements for a QI Program**

The quality assessment and performance improvement program of a PACE organization must use objective measures to demonstrate improved performance in the following areas:

- **Utilization of PACE Services**: Analysis of utilization data such as hospitalizations, ER visits and SNF admissions allows the PO to evaluate the effectiveness of the services provided to participants and identify opportunities to improve care outcomes.

- **Caregiver and Participant Satisfaction**: Continually gauging participant and caregiver satisfaction with services provided by the PO and using the feedback to build on quality improvement initiatives demonstrate a commitment to patient-centered care and will improve the overall health care experience.

- **Outcome Measures Derived from Data Collected During Assessments**: Outcome measures derived from participant assessment data is important to monitor as part of the ongoing quality improvement efforts of a PO to evaluate if participant outcomes are achieved as expected. This includes physiological well-being, functional status, cognitive ability, social/behavioral functioning, and participants’ quality of life assessment data. The outcome measures selected must be based on current clinical practice guidelines and professional practice standards that are applicable to the care of PACE participants.

- **Effectiveness and Safety of Staff Provided and Contracted Services**: The effectiveness and safety of PACE services provided by PO staff or contractors must be evaluated to ensure that PACE participants achieve the outcomes intended through the services provided. Areas of evaluation should include the competency of clinical staff, promptness of service delivery, and achievement of goals and measurable outcomes.
➢ Non-Clinical Areas: The evaluation of non-clinical outcomes such as grievances and appeals, life safety and environmental issues provides the PO with a broader perspective and analysis to identify improvement opportunities.

Additionally, the PO is expected to meet a minimum level of performance on specific quality measures as established by CMS and the SAA and must ensure that all data utilized to evaluate performance is accurate and complete.

Internal QI Activities

A PACE organization must use a set of outcome measures to identify areas of good or problematic performance and take actions targeted at maintaining or improving care based on outcome measures. The PO is expected to incorporate actions resulting in performance improvement into standards of practice for care delivery and periodically track performance to ensure that any performance improvements are sustained over time. Performance improvement priorities should be based upon the prevalence and severity of identified problems, with priority given to improvement activities that affect clinical outcomes. POs are expected to correct immediately any identified problem that directly or potentially threatens the health and safety of a PACE participant.

An individual must be designated to coordinate and oversee the implementation of QI activities. While the medical director is ultimately responsible for the oversight of the quality program, the quality director ensures that all IDT members, PACE staff and contract providers are involved in the development and implementation of quality assessment and performance improvement (QAPI) activities and are aware of the results of these activities. The quality director also encourages participant and caregiver participation in PO improvement activities.

Committees with Community Input

With community input, a PACE organization must establish one or more committees to do the following:

➢ evaluate data collected pertaining to quality outcome measures;
➢ address the implementation of and results from the quality improvement plan; and
➢ provide input related to ethical decision-making, including end-of-life issues and implementation of the Patient Self-Determination Act.

See Chapter 17 of the PACE Manual for more information.

Additional Quality Assessment Activities

A PACE organization must meet external quality assessment and reporting requirements as specified by CMS or the SAA in accordance with §460.202.

QI Plan and Work Plan Components

An effective QI plan will include a detailed annual QI Work Plan (QWP). The QWP clearly identifies what quality indicators will be tracked during the year, as well as priorities for QI projects. The QWP is developed from the annual evaluation of the QI plan from the previous year, with additional suggestions from the quality improvement committee.

A suggested approach is to start developing the QWP in October by preliminary evaluation of the previous year’s quality data. The quality committee may consider this draft in November, with staff assigned to
each indicator. Staff will develop the method to track and report the data and submit recommendations to the committee, which will make final decisions on what to focus on for the coming year. This process does not preclude the inclusion of ad hoc QI projects throughout the year. Areas to analyze for possible QI indicators or projects can come from many sources.

The quality committee should utilize sound methodology for the selection of QI priorities. The PACE regulations state that quality initiatives must have objective measures, so the proposed indicators must be measurable. Quality indicators may be triaged by identifying which issues are high in cost, risk, profile, security or volume. CMS considers clinical outcomes as high-priority issues.

Once the QWP is finalized, the implementation begins. A good QWP will have established time frames for collection and clear assignments for reporting the performance data of each indicator. The quality director will be responsible for holding staff or contractors accountable for these reports. For each indicator, a brief narrative must be developed outlining the rationale behind the indicator selection, purpose and measurable outcome target. Ideally, the reporting will include a graphic display with corresponding explanatory narrative.

An annual evaluation of the QI program is required and may be reviewed by state and federal regulators at routine audits. This evaluation should be a detailed, results-oriented written report. Quarterly updates are useful in keeping stakeholders aware of quality initiatives and progress. The distribution of updates should include front-line staff, all organizational leaders, the IDT, participants, the Participant Advisory Committee, contracted providers, the governing board and possibly broader distribution via a newsletter or website.

**Quality Improvement Process**

The key to a successful QI program is the implementation of a sound, systemic approach – a QI model for improvement. As you work with any QI method, the key is to choose strategies carefully that have the best chance to improve how your PO interacts with participants and caregivers.

**Prioritization**

Balancing the ongoing desire for improvement in multiple areas with the reality of limited resources requires criteria for determining which initiatives to prioritize. As you begin to determine and prioritize potential areas for improvement, you need to identify and understand the ways in which the PO could improve. Start with an examination of the participant population and aspects of care, which includes the following:

- program satisfaction (participants, caregivers, contracted providers, alternate care sites);
- functional status (physical and cognitive);
- nutrition;
- quality of life;
- psychological well-being;
- social activity;
- continuity of care;
- access to care;
- diagnostic accuracy;
- appropriateness of services;
➢ patient compliance;
➢ organizational performance; and
➢ treatment plan interruptions.

The identification of improvement opportunities arises from program measures, staff suggestions, QI committee suggestions, medical record audits and other sources. It may be triggered by the following:

➢ Level II events or target goals/thresholds not achieved;
➢ deviation from benchmarked data that vary from that of other PACE programs and/or recognized standards;
➢ satisfaction surveys that include participants, family members and contracted providers; and
➢ trends identified through utilization reports/reviews and CMS Data Element reports.

Intensive assessment should be done when statistical analysis detects an undesirable variation in performance as compared to pre-established criteria or recognized standards, control limits or Level II events. Examples are as follows:

➢ significant adverse drug events;
➢ participant injury or unexpected death;
➢ incorrect medication/dosages that caused injury to the participant or have the potential to cause injury; and
➢ participant complaints related to personnel misconduct that may have serious consequences for the participant, especially as it relates to allegations of abuse, neglect, or actual/potential harm.

When multiple opportunities for improvement are identified but cannot be addressed all at once, the quality committee may recommend priorities. The leadership team makes all final determinations for delaying or discontinuing improvement activities. However, if no actions are taken in response to an identified opportunity to improve care or service delivery, the process that resulted in the lack of action should be documented. This documentation is the action taken.

**Performance Measures and Indicators**

Measuring performance can help you understand how well your PO is accomplishing its QI goals. It allows for an analysis of where and what changes need to be made to improve performance and the quality of care provided. Performance measures are designed to measure systems of care and are derived from clinical or practice guidelines. Data defined into specific measurable elements provide an organization with a meter to measure the quality of its care.

Hundreds of quality measures are used in health care. They generally fall into four broad categories:

1. **Structural**: Measures the capacity of the organization and the conditions in which care is provided by looking at factors such as staff, facilities and health IT systems. Example: Does the hospital have an EHR system?
2. **Process**: Measures if the services provided to patients are consistent with routine clinical care. Example: Percentage of patients who received the influenza immunization.
3. **Outcome**: Measures the results of health care from the care received. Example: Rate of emergency department visits.
4. **Patient Engagement/Experience**: Provides feedback on patients’ experiences of care. Example: Rate of grievances.

Indicators are to be objective, measurable, and based on knowledge and clinical experience. They may be derived from national PACE statistics, standards of practice, professional guidelines, practice parameters, or other applicable patient care or service benchmarks derived from guidelines, including Health Outcome Survey-Modified (HOS-M) data and state-specific assessment and outcome data.

Consider the following characteristics when selecting performance measures:

➢ Align with the goals of the organization.
➢ Demonstrate a relationship to positive health outcomes.
➢ Are under the control of the health care system.
➢ Are reliable, valid and standardized in that they result in the same reading regardless of who does the measuring or when and where the measurement is taken, they measure what it is intended, and the definitions of data elements, collection process and analysis are precise and comprehensible so they can be understood and applied in the same way regardless of who refers to or applies them.

The following factors also should be considered:

➢ Relevance: Does the performance measure relate to a frequently occurring condition or have a great impact on patients of the organization?
➢ Measurability: Can the performance measure be quantified realistically and efficiently given the finite resources of the facility?
➢ Accuracy: Is the performance measure based on accepted guidelines or developed through formal group decision-making methods?
➢ Feasibility: Can the performance rate associated with the performance measure be improved realistically given the limitations of the clinical services and patient population?

**Ongoing Measurement and Assessment**

Once potential performance indicators have been selected, the feasibility of collecting meaningful and reliable data on the indicators needs to be assessed. Ongoing data measurement and assessment is the foundation for all performance improvement activities. Data assessment is systematic, interdisciplinary and collaborative.

General subjects for ongoing measurement within a service may include the following:

➢ participants, families, employees, regulators, contracted providers, and/or community needs and expectations and the degree to which these are met;
➢ staff views on current performance and opportunities for improvement;
➢ high-volume, high-risk, high-cost and problem-prone processes associated with patient rights, assessment, care, treatment and services, continuum of care, education, surveillance, prevention of infection, equipment management, environment of care, and performance improvement;
➢ risk management and safety activities, and/or
➢ quality control issues.
Threshold Development

Thresholds for evaluation are numbers used to determine when processes/outcomes of care need further evaluation. Failure to meet thresholds should trigger an organizational response relative to the event monitored by the indicator. Thresholds should be determined statistically if appropriate data are available. They may include the following:

➢ control limits,
➢ specification limits,
➢ trends,
➢ benchmarks derived from NPA/Clinical Practice Guidelines (national and regional)/health care literature,
➢ staff experience,
➢ past organizational performance,
➢ customer expectations and
➢ HOS-M outcome data.

Process Improvement Tools

QI staff should utilize a process improvement model with relevant statistical process control tools and teamwork techniques and tools, including the following:

➢ Plan-Do-Study-Act (PDSA)
➢ Cause and Effect Diagram
➢ Failure Modes and Effects Analysis (FMEA)
➢ Flowchart
➢ Histogram
➢ Pareto Chart
➢ Project Planning Form
➢ Run Chart and Control Chart
➢ Scatter Diagram

Problem Resolution

It is the responsibility of both the QI committee and leadership team to create a framework for problem-solving within the organization. Based on the results of quality review and analysis, those individuals involved in the analysis of the monitoring activities/processes should be responsible for recommending to leadership (through the quality director) the best action plan for a given problem or improvement opportunity.
The plan of action will include the following:

➢ an explanation of what is to occur,
➢ identification of who is responsible for implementing the plan of action,
➢ a time frame in which this action will occur,
➢ the evaluation of plan effectiveness, and
➢ follow-up reports.

Re-Evaluation and Follow-Up

Monitoring activities will be conducted to determine the effectiveness of plans of action. The timeliness of follow-up depends on the following factors:

➢ severity of the problem,
➢ frequency of occurrence, and
➢ impact of the problem on patient outcomes.

If follow-up shows the desired results have been achieved, the issue will be re-evaluated on a periodic basis to ensure continued improvement. Develop a schedule for re-evaluation and update it at the quarterly meeting with the leadership team.

If follow-up indicates that the desired results are not being achieved, a more in-depth analysis of the problem and further determination of the source of variation are needed. A subcommittee of the leadership team or other workgroup may be established. All quality assessment and improvement steps and follow-up results should be shared with appropriate PACE staff for discussions and suggestions.
Introduction

§460.130(a)(b) General rule.

§460.134(a)(5) Minimum requirements for quality assessment and performance improvement program.

Given the scope of their quality oversight responsibilities, PACE organizations tend to focus resources on quality in clinical areas. However, PACE regulations §460.130 and §460.134 reference oversight of certain PACE operations functions as well. Although the current CMS PACE audit protocol does not specify operations areas other than service requests, grievances and appeals, there is still an implicit expectation of the quality director that these areas demonstrate compliance with the PACE regulations.

For example, the governing body remains nominally accountable for the QI plan and quality oversight of the organization; POs are responsible for meeting the requirement to orient, train, credential, and oversee competencies of contracted providers; and transportation services remain a crucial venue for potential participant infection control and safety issues. Thus, the quality director has a responsibility to ensure quality oversight and maintain participant safety standards and compliance.

Transportation

§460.76(a), §460.76(b), §460.76(b)(1), §460.76(b)(2), §460.76(c), §460.76(d), §460.76((d)(1), §460.76(d)(2), §460.76(e) Transportation services.

Though transportation is not deemed to be a clinical service, four aspects of transportation service affect participant safety and service quality: vehicles, drivers, scheduling and IDT input. These four areas, their impact on participants, and the role of the quality director are depicted in the table below.

Table: PO Responsibilities for Transportation Services and Quality Director Roles

<table>
<thead>
<tr>
<th>Transportation Component</th>
<th>Relevant Considerations and PO Responsibilities</th>
<th>Role of Quality Director or Transportation Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vehicles</td>
<td>Van maintenance</td>
<td>Periodic or random audits of maintenance logs, inspection dates</td>
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<tr>
<td></td>
<td>Safety features (e.g., seatbelts, wheelchair anchors, oxygen tank safety, lift operations)</td>
<td>Periodic audits of van safety</td>
</tr>
<tr>
<td></td>
<td>Communication capabilities with PO</td>
<td>Episodic van rides to oversee van safety and participant experience</td>
</tr>
<tr>
<td></td>
<td>Oversight of contractor</td>
<td>Documentation of contractor oversight requirements</td>
</tr>
<tr>
<td>Drivers</td>
<td>Licensure and security</td>
<td>Periodic or random audits of driver personnel records to ensure requirements are met</td>
</tr>
<tr>
<td></td>
<td>Experience with the elderly and/or the disabled Knowledge of and training for emergency procedures</td>
<td>Documentation of oversight of contractor requirements</td>
</tr>
<tr>
<td></td>
<td>Assistance in participant safety</td>
<td></td>
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<td></td>
<td>Infectious disease clearance</td>
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<tr>
<td></td>
<td>Completed PACE orientation</td>
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<tr>
<td></td>
<td>Oversight of contractor</td>
<td></td>
</tr>
</tbody>
</table>
Scheduling
- Timeliness of pick-up and drop-off times
- Participant satisfaction with transportation services
- Timeliness, safety for medical, dental and other appointments
- Delivery of medications and food, if relevant
- Development of policy regarding food safety and medication “chain of custody”
- Training regarding above policy
- Review of transportation grievances

IDT Input
- Completion of initial, annual and periodic assessments
- Participation in IDT meetings
- Periodic or random medical record audits to ensure assessments are timely, comprehensive, and up to date

Oversight of these components may be best accomplished by developing indicators in collaboration with the transportation department and grievances and appeals staff. A review of participant satisfaction surveys also reveal issues and concerns important to participants. Metrics for completeness of personnel records, competencies and participant assessments help assemble a complete assessment of transportation services for presentation to the governing board and other stakeholders.

### Involuntary and Voluntary Disenrollments

§460.164(a), §460.164(a)(1), §460.164(a)(2), §460.164(a)(3), §460.164(a)(4), §460.164(b), §460.164(b)(1), §460.164(b)(2), §460.164(c), §460.164(c)(1), §460.164(c)(2), §460.164(d)(1), §460.164(d)(2), §460.164(e)

Involuntary disenrollment.

§460.172(a), §460.172(b), §460.172(c) Documentation of disenrollment.

Involuntary disenrollment is a potentially problematic area for POs, falling at the intersection of participant rights and potential fraud, waste and abuse (FWA). The PACE regulations, as codified above, strictly limit the reasons for involuntary disenrollment to failure to pay premiums, extended absence from the service area, disruptive or threatening behavior, or sustained noncompliant behavior if a participant is deemed mentally competent and willfully in control of his or her compliance decisions.

As viewed through the lens of participant rights, involuntary disenrollment carries risks because participants, by virtue of enrollment in PACE, retain their prerogative to share in medical decision. Therefore, they cannot be compelled to undergo any test, medication, or course of treatment. The FWA lens is important as well. Since a PO receives capitated payments for each participant, FWA concerns may arise if a participant who is made aware of his or her rights and obligations remains out of the service area for more than 30 days while the PO continues to receive the capitation payment. Also for this reason, a participant whose health conditions require the use of extensive health care resources cannot be involuntary disenrolled since the PO previously agreed to accept the capitation as complete payment.

A participant is subject to disenrollment each year if the State Administering Agency (SAA) determines her or she no longer qualifies for the level of care provided by a PO. In practice, however, most SAAs waive this recertification requirement on the assumption that disenrollment from the PACE program might lead to a decrease in functional status that would warrant re-enrollment in PACE. Quality directors should review the SAA agreement and be familiar with state regulations and processes for voluntary and involuntary disenrollments.

Finally, participants are entitled to voluntarily disenroll for any reason at any time.

The documentation requirements for disenrollments are stated robustly in Section §460.172, the only PACE regulation wholly dedicated to documentation of another regulation. The emphasis on documentation, particularly of involuntary disenrollment, speaks to the importance of building a strong case for
disenrollment for reasons of potential liability, acknowledgment of participant rights, and FWA protections. (POs also are encouraged to review their SAA agreement for any additional requirements that may need to be adhered to.)

For most disenrollments the PO has the responsibility to inform the participant of alternative Medicare programs and to create discharge documents for use by a subsequent provider. These include a clinical summary of the participant’s problem list, care, medications, and IDT plan of care. Individual states may have additional SAA requirements that the quality director needs to understand in order to maintain and monitor compliance.

§460.172 contains the explicit requirement that the PO, through the quality director or other staff member, records and makes available the reasons for all voluntary disenrollments and includes that information in the quality program. The safest interpretation of this requirement is that the quality director maintains the responsibility to ensure the existence of a systematic process for documentation of all disenrollments—including tracking, trending, analysis, and reporting of the reasons for disenrollment—and for organizational root-cause analyses to better understand and explain the reasons.
CHAPTER 5
Intersection of Medical and Quality Leadership Drive QI

Authors: Tina Stallings and Priscilla Millan
Overall Roles

PACE Regulation 42 CFR Part 460 states, “The organization must employ, or contract with, in accordance with §460.70, a medical director who is responsible for the delivery of participant care, clinical outcomes, and the implementation, as well as oversight, of the quality assessment and performance improvement program.” Under the leadership of the medical director, a PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program; must reflect the full range of services furnished by the PACE organization; and must take actions that result in improvements in its performance in all types of care (42 CFR § 460.130). Similarly, CMS believes the designation of a dedicated quality director is imperative to conduct continuous performance improvement activities that inform the PACE organization (PO) leadership ultimately responsible for care delivery, including ambulatory, home health, adult day care, long-term, acute, emergency and restorative services. Within these domains of care, leaders oversee multiple disciplines internally, such as medical, nursing, social, mental health, recreation therapy, dietary, restorative therapies and transportation, as well as specialized services in the community.

A PO must designate an individual to be the quality director, whose function is to coordinate and oversee the implementation of QI activities. The quality director is responsible for handling day-to-day quality issues, collecting and analyzing data, detecting trends, and coordinating IDT members, PACE staff and contract providers in planning QI activities, disseminating reports on activities to them, and compiling comments related to participant/caregiver satisfaction and concerns. The quality director must encourage PACE participants and their caregivers to be involved in QI activities, including providing information about their satisfaction with services.

(42 CFR §§ 460.134, 460.136, 460.202(a))

Below are examples that operationalize the collaborative relationship of medical and quality directors, as well as the distinct role of medical directors in promoting quality improvement.

General Expectations

A quality director proactively should develop a solid working relationship with the medical director. Regular meetings should be scheduled to review the QI program with the medical director, who will use the meetings to monitor progress on projects, assist in developing a system for data collection and analysis, and provide direction for further quality activities or corrective actions. The medical director often will chair or co-chair the quality committee and may present reports to the governing body. The mission of the sponsoring organization may filter down to the PACE administration and quality program with variable intensity and commitment. By identifying unifying themes or priorities, the leaders of the administration and QI program set the focus for QI efforts. Building upon momentum and values that already are driving the staff and processes will ease the disruptions that sometimes are associated with QI.

Participation in Committees

Through the development of committee(s) with community input, PACE organizations will be able to receive guidance regarding their QI program and the ethical issues they face. A medical director should promote a healthy ethics committee with appropriate community representation. Besides having regular meetings to review specific ethics issues and cases, this committee should be supplied with meaningful quality data (e.g., copies of quality committee minutes and reports) for review and comment. The input from this committee should be forwarded to the quality committee for inclusion in the agenda and minutes.
of the next meeting. Some medical directors serve as chair of the ethics committee, but this is neither necessary nor even desirable in most cases. The medical director should be on the distribution list for minutes of the Participant Advisory Committee to be aware of issues that impact quality of care or may require advocacy or action in the quality committee.

**Role in the QI Plan**

Organizational philosophies toward QI are highly variable. Most will embrace QI precepts on paper, but resource allocation may not match the words. Thus, the medical director plays a key role in obtaining operational buy-in to the QI plan. QI plans as originally developed for the PACE application tend to be somewhat generic. In collaboration with the quality director, program director and governing body, the medical director should strive to adapt the plan to be particular to his or her organization and circumstances. Make sure that it is a real plan, with enough specificity that a PACE organization can use it as a guide during the year. The medical director will be held accountable to the QI plan. As a result, plans should not be overly general or prescriptive to a degree that the PO cannot keep its promises. Be enthusiastic, but recognize that others may not share that enthusiasm.

**Use of Data for QI Activities**

The quality director should work collaboratively with the medical director, drawing on the medical director’s understanding of data management and statistics to choose reasonable data elements and define their calculations. The medical director has an important role in providing guidance for additional standards of clinical practice within the organization, such as using NPA Model Practice guidelines or physiological outcome measures.

In collaboration with the medical director, the quality director must ensure the following quality initiatives routinely are implemented and tracked internally by the PO for performance improvement opportunities (according to §460.136):

- use a set of outcome measures to identify areas of good or problematic performance;
- take actions targeted at maintaining or improving care based on outcome measures;
- incorporate actions resulting in performance improvement into standards of practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time;
- set priorities for performance improvement, considering prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes; and
- immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant.
QI Program Evaluation

An annual evaluation of the QI program is required and will be reviewed by state and federal regulators at routine audits. This evaluation should be detailed and result in a written report. The quality director, in collaboration with the medical director, will identify areas in the approved work plan to improve or maintain service delivery and patient care. QI committee members communicate and approve the evaluation of the annual work plan and escalate it to internal corporate entities (i.e., corporate quality committee, quality board of directors) for review, approval, and opportunity for feedback to the PACE QI committee. The evaluation feedback encompasses the following:

➢ evaluating care and services when thresholds are reached to identify opportunities to improve care and services or problems;
➢ assessing the effectiveness of the actions and documenting the improvement; and
➢ communicating the results of the monitoring and evaluation process to relevant individuals, departments or services and to the organization-wide quality management programs.
CHAPTER 6
PACE QI and Utilization Management

Authors: Tracey Cook and Kumar Vengadabady
PACE organizations should co-manage utilization and quality. Utilization Management (UM) is inextricably linked practically and philosophically to quality management. UM and quality improvement (QI) support that the highest quality of care is usually the most cost-effective care in the long run. UM and QI use data identification, collection, analysis and reporting at the core of understanding utilization. Some situations, such as institutional care, require real-time assessment and management of utilization in both UM and QI.

**Quality Improvement**

Quality improvement is defined as systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted groups.

**Utilization Management**

Utilization management is defined as an ongoing system of monitoring, evaluation and education of the appropriateness and medical need of health care services, procedures and facilities according to evidence-based criteria or guidelines and under the provisions of a health plan. UM addresses PACE clinical activity or admissions and the ongoing provision of care through benefits analysis of qualifiable and quantifiable data and attributes of resources and outcomes to identify absolute results. This system of evaluation is compared to its own results over time and/or to other PACE organizations (POs) for outcomes.

**Interrelationship of UM and QI**

Using this outcome data to evaluate and manage processes that produce different results ties UM to quality to demonstrate internal improvements and to identify areas that require improvement. Concurrent review involves screening for medical necessity and the appropriateness/timeliness of care delivery.

UM gains efficiency in an effective health care delivery system and should evaluate the cost and quantity of services delivered to the PACE participant.

QI utilizes the data acquired through UM processes to identify patterns and monitor the use of services (such as quality of services, overuse, underuse, or inappropriate use of services and/or resources), fair and consistent utilization decision-making, and preservation or resources to continuously improve care and outcomes of care provided within the PO.

Note that UM in PACE is substantially different from its employment in typical managed care organizations (MCOs), which utilize UM criteria to determine the medical necessity and appropriateness of clinical decisions. In PACE that function is taken on by the IDT, whose decisions, in the absence of a designated UM department, are driven primarily by the assessment of participant needs with an awareness of costs. In addition, the PACE regulations require a consideration of medical necessity, as well as participant/caregiver preferences. §460.98(e) states, for example, that “the frequency of a participant’s attendance at a center is determined by the IDT, based on the needs and preferences of each participant.” Similarly, §460.101(a)(4)(iii) states, “The comprehensive assessment must include…participant preferences for care.” Therefore, the UM function and its relationship to QI occur in the context of the IDT’s responsibility for utilization decisions.

**Data Collection and Sources: How Quality Metrics Impact Utilization**

Data must be collected consistently or it will not reflect correctly the reality of utilization or outcomes. Organizations that have well-defined processes for data collection will be best suited to collect meaningful data. Two complementary and sometimes interchangeable domains of care are use of resources and both positive and negative outcomes.
The PACE program has some control over medications, errors (such as medication errors and errors in care delivery), wounds and wound care, participant and staff infection control, participant behaviors, PACE center immunization rates of participants and staff, care encounters (such as nursing, social services, PT and OT), hours of care and operation, and PACE PCA hours in the home.

The PACE program has some influence over falls, admissions and disenrollment/discharges per month, satisfaction surveys and follow-up, staffing, physician encounters, specialist encounters, institutional use (such as hospitals and nursing homes), and use of community-based resources such as home health care and hospice.

The PACE program also should track the trends concerning participant death at the facility, institutions and home and whether hospice was consulted. Staffing ratios, employee turnover, Worker’s Compensation claims and employee illnesses are other areas to monitor. The PACE program should define its organizational structure to identify the data, who collects the data, who ensures the data are correct and relevant, what the data mean to the PACE center and its operations, who evaluates and trends the data (how the data are measured), and who reports the data to whom.

Every item to be reviewed and analyzed should consider the following:

➢ Underutilization: Should more have been done by PACE to prevent harm or illness? Should an outside resource have been contacted and consulted (inadequate care, readmission for a problem the PACE center could have better treated/handled)?

➢ Overutilization: What could the PACE center have done to prevent utilization of another resource or service (e.g., avoidable hospital admission)?

➢ Administrative Issue: Evaluate if all resources are available and appropriately utilized (e.g., not having a BSC commode in the home when a fall could have been prevented by eliminating a walk to the bathroom in the middle of the night).

➢ Non-Adherence/Barriers with Care Plan: Were all things considered, and could the non-adherence have been prevented with education or intervention? Is the non-adherence an ongoing issue that potentially could cause great harm? What barriers exist that prevent adherence? Will the participant voluntarily disenroll from PACE? Is an involuntary disenrollment imminent?

➢ Tracking and Trending of Appropriate Utilization/Unnecessary Care or Service Vs. Inappropriate Utilization of Care or Service: Was the care or service truly necessary (e.g., giving medication such as an antibiotic to appease the caregiver, not for a medical issue requiring antibiotics)? Did things go as planned (appropriate care, treatment and/or utilization of services)?

Following are examples of tracking tools used for data collection:

➢ Wound Log: Tracks and trends wound progression and care

➢ High-Risk Skin Assessment Tracking: Tracks the documentation of participants with a Braden Scale score of less than 12 or those who use a wheelchair or are at nutritional risk.

➢ Diabetic Foot Inspection Tool: Tracks the documentation of foot inspections for participants with diabetes.

➢ Infection Control Log: Tracks and trends all infections for participants and employees.

➢ Antipsychotopic/Antidepressant Medication Tool: Tracks participants on medication for dementia, mood enhancers.

➢ Orders and Medication Error Log: Tracks and trends errors.
➢ Fall Log: Tracks the documentation of reasons for falls and interventions.
➢ Death and Death Review Log: Why did death occur? Was a non-biased MD review completed post-death?
➢ ER Visit and Hospitalization Logs: Documentation of institutionalizations, readmits, and ER visits and revisits.

Other tracking tools include a grievance log, a service requests and appeal log, PCA logs, specialist visit logs, Level I and II reporting logs, pharmacy reviews and pharmacy costs, admission and disenrollment logs, satisfaction survey results, referrals to home health or hospice, DME logs to track equipment in the center and at home, and capitation income and cost of care per participant.

Table: Examples of Services and Measures Conducive to UM/QI Oversight

<table>
<thead>
<tr>
<th>Care/Service/Event</th>
<th>Examples of Quality/Utilization Management Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications</td>
<td>Review use of high-volume or high-cost medications</td>
</tr>
<tr>
<td></td>
<td>Routine reviews counting the same items each month</td>
</tr>
<tr>
<td>Orders Review</td>
<td>Ordering trends (for medications, diagnostics, specialist visits, etc.)</td>
</tr>
<tr>
<td></td>
<td>Correct execution of orders</td>
</tr>
<tr>
<td></td>
<td>Appropriateness of orders</td>
</tr>
<tr>
<td>Polypharmacy</td>
<td>Review all medications for rationale and diagnosis, necessity, efficacy, effectiveness</td>
</tr>
<tr>
<td></td>
<td>Review by MD and/or PharmD</td>
</tr>
<tr>
<td>Pharmacy Outcomes and Evaluation</td>
<td>Pharmacy medication reviews at time of participant enrollment</td>
</tr>
<tr>
<td></td>
<td>Medication review after each participant fall</td>
</tr>
<tr>
<td></td>
<td>Monitoring of fraud, waste and abuse in medication prescribing</td>
</tr>
<tr>
<td>Pain Management</td>
<td>Evaluation of medication effectiveness</td>
</tr>
<tr>
<td></td>
<td>Prescribing trends (evolution from conservative analgesic prescribing to NSAIDs to narcotics and other scheduled medications)</td>
</tr>
<tr>
<td>Psychotherapeutic Agents, Anxiolytics, Sedatives and Hypnotics</td>
<td>Evaluation of medication effectiveness</td>
</tr>
<tr>
<td></td>
<td>Prescribing trends</td>
</tr>
<tr>
<td></td>
<td>Beers criteria for potential for participant harm</td>
</tr>
<tr>
<td>Wound Care/ Integument Issues</td>
<td>Evaluation of wound types for proper identification, interventions in place for wound/ulcer prevention (e.g., pressure-relieving devices, nutritional assessments, barrier treatments)</td>
</tr>
<tr>
<td></td>
<td>For existing wounds, appropriate interventions to prevent deterioration and to promote healing and treatment, appropriate reevaluation time frames, and use of community-based services as needed to manage outside the PACE center</td>
</tr>
<tr>
<td>Infection Control and Intervention/PACE Center Immunization Rates</td>
<td>Evaluation of identification of participant and/or staff infections, including infection criteria or definitions; trends of infection spread; trends of antibiotic use</td>
</tr>
<tr>
<td></td>
<td>Evaluation of staff and participant/caregiver education</td>
</tr>
<tr>
<td></td>
<td>Assessment of measures in place to prevent infections, including staff and caregiver training on infection control, hand washing, diagnostic testing for susceptibility to increased risk for infections</td>
</tr>
<tr>
<td></td>
<td>Evaluation of immunization compliance and adherence, with evaluation of staff and participant/caregiver education concerning immunizations</td>
</tr>
<tr>
<td>Care/Service/Event</td>
<td>Examples of Quality/Utilization Management Measures</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Care Encounters by PACE Personnel/Clinic Visits</td>
<td>Evaluation of assessments and care by RN and therapy staff Assessment of necessity for and appropriateness of staff encounters, e.g., whether a PT visit might negate the need for care outside the PACE center</td>
</tr>
<tr>
<td>Behaviors</td>
<td>Evaluation and trending of behaviors of concern for determination of organic vs. environmental etiology Potential for prevention of behaviors of concern, via earlier recognition of infectious processes, improved staff and caregiver education, etc.</td>
</tr>
<tr>
<td>PCA Hours in the Home, Provided by PACE</td>
<td>Evaluation and trending of PCA hours provided in participants’ homes, for over- and underutilization, necessity and appropriateness</td>
</tr>
<tr>
<td>Falls</td>
<td>Evaluation and trending of every fall, for site, contributing factors (e.g., medications, incontinence, infection) and prevention opportunities</td>
</tr>
<tr>
<td>PACE Admissions</td>
<td>Enrollments, for source of referral, problematic issues, day center attendance, and in-home PCA/home care needs</td>
</tr>
<tr>
<td>Disenrollments/Discharges</td>
<td>Identification of reason for or cause of disenrollments/discharges from PACE and opportunities for prevention</td>
</tr>
<tr>
<td>Deaths</td>
<td>Analysis/trending of deaths for location, cause, learning opportunities for PACE staff Determination of whether hospice was involved in care</td>
</tr>
<tr>
<td>Satisfaction Survey Results</td>
<td>Positive and negative issues reported in satisfaction surveys Corrective actions catalyzed by satisfaction survey results</td>
</tr>
<tr>
<td>Physician/Medical Encounters</td>
<td>Evaluation of physician or physician extender encounters, for frequency, appropriateness, under- or over-utilization</td>
</tr>
<tr>
<td>Specialist Encounters</td>
<td>Evaluation of specialty encounters, for frequency, appropriateness, under- or over-utilization</td>
</tr>
<tr>
<td>Institutionalizations</td>
<td>Evaluation of institutionalizations (hospital, LTAC, nursing home), for rationale, bed days, appropriateness, missed opportunities for prevention Hospital readmissions and ER revisits, for necessity and missed opportunities for prevention Respite days in a nursing facility, for PO interventions that could have prevented a nursing home respite placement</td>
</tr>
<tr>
<td>Use of Community-Based Resources</td>
<td>Evaluation and trending of use of home health and hospice services, including appropriateness and timeliness of care. (Certain states prohibit PACE personnel from making home visits. These PACE centers use home health and hospice for weekend and after-hours nursing care, wound care, IV infusions and other nursing tasks.)</td>
</tr>
<tr>
<td>Employee/Staff Monitoring</td>
<td>Evaluation of staffing ratios and safety of participant care Tracking of employee absences from work, with frequency of absences and reasons for call-ins, illness, turnover and Worker’s Compensation claims</td>
</tr>
<tr>
<td>Grievances</td>
<td>Monthly tracking and trending, by reason for grievance, correct documentation, timely resolution</td>
</tr>
<tr>
<td>Service Requests and Appeals</td>
<td>Evaluation and trending of service requests, for appropriateness, necessity, compliant documentation, timeliness of organizational response Evaluation and trending of appeals, for appropriateness, necessity, compliant documentation, timeliness of organizational response</td>
</tr>
</tbody>
</table>

Note: Further discussion of these aspects of care can be found in other chapters of this handbook.
General Principles of Utilization Management

There are seven general principles to consider in utilization management:

1. High-Quality Care Is the Least Expensive in the Long Run: Continuous improvements in design and delivery of care will pay off with fewer problems and waste. UM and QI examine and interpret data for better outcomes. While utilizing extra home care hours, respite care in a nursing home, higher cost medications, specialist referrals or community resources may have an initial cost, they may prevent more costly institutionalizations in the long run.

2. Don’t Pay Someone Else If You Can Do It As Well Yourself: Whether it is transportation, clinical services/procedures or other services, it is best to provide these services within the PACE organization. Larger POs, or those in integrated delivery systems, may be more likely to have the internal capacity to provide their own food and transportation services. Smaller POs or those in rural areas may not yet have the capability to provide those services internally, but they may be a consideration for the future when growth and staff size permit. On the clinical side, it may be appropriate to provide additional training to staff in order to develop and maintain skills such as wound care, IV therapy skills or pap smears.

3. An Institution Admission Is a Failure of Care: This is a cultural mainstay for your IDT and not intended to place blame or induce guilt. A hospital stay, though not a desirable outcome, may be necessary to restore health and prevent disease progression or death. The mission of PACE is to keep participants safely in their home as long as possible. A hospitalization may not be avoidable. UM and QI audits of every hospital admission will track and trend to identify if the IDT and medical team did all that was necessary to avoid the inpatient stay and if the stay was truly necessary.

4. Just Because We Can Do It Doesn’t Mean We Should: Personalizing care is paramount to the success of PACE. Some medical standards of care can create a difficult atmosphere and not maintain the principles on which the PACE model is based. Every intervention carries the risk of harm, particularly in the care of the frail elderly. The IDT model of care, with evaluations from UM and QI, ensures that the best interest of participants and their caregivers are considered when ordering extensive therapies services, surgeries, tests, etc.

5. If You Don’t Turn Over Any Rocks, You Won’t Find Any Snakes: This ties in with the previous principle. While the PACE program aims to limit unnecessary interventions, it is necessary to look for the “right” problems with the patient and produce clinically relevant results via diligent evidence-based screenings and preventive care. UM and QI look at model practices and outcomes from the PACE program and from the outcomes of other programs to determine if service utilization is correct or if other services should have been involved or consulted, keeping in mind the individualized care for each participant.

6. Do the Right Thing, Always: To balance the ideals laid out in the previous two principles, PACE strives to intervene with skills, benefits and medical knowledge that best benefit the participant. Care should never be limited when it will help achieve real participant benefit.

7. Begin with the End in Mind: Right care, Right Place, Right Time, in the Right Amount: Ongoing efforts to track, trend, and evaluate data in regard to care and outcome, with participant and caregiver goals in mind, will assist in the delivery of quality care. PACE organizations need to obtain clear directives concerning care, end of life, and advanced directives to deliver appropriate care.
General Practices in Utilization Management

There are six general practices to consider in utilization management:

1. Consistency of Care: Many participants have one or more chronic illnesses. Common practices are formalized in evidence-based protocols as directed by data obtained from UM and QI evaluations and trending.

2. Intensity of Care: By adjusting care patterns to follow protocols, the need for services outside of the PACE program may be reduced. Some examples of these protocols are providing IV hydration or pain management in the PACE center; STAT X-rays, joint injections, podiatry and nail care, cardiac telemetry monitoring, wound care, dermatology or pap smears; and the ability to respond to an acute change in condition, such as a sickle cell exacerbation. Post-event analysis of any hospital admission can assist with the prevention of future institutional events. Through frequent discussions in IDT and management team meetings, the general UM and QI process is reported widely and frequently and referenced and reinforced among staff and managers.

3. Interpersonal Care of the IDT: Strong interpersonal relationships are modeled and encouraged among the clinical staff and IDT. This improves the appropriate utilization of resources and interdisciplinary communication and fosters positive participant outcomes.

4. Specialty/Network Care: A network of specialists who have good working relationships with PACE can help PACE control all aspects of care to participants and improve communication among the IDT, PACE physician and specialist. UM and QI review and track specialist visits, referrals and medication/diagnostic orders, as well as the effectiveness of those visits for positive and negative outcomes.

5. End-of-Life Care: UM and QI track and audit for health care wishes, advance directives, living wills and DNR orders to be documented clearly and correctly and be readily accessible for staff to reference. Hospice service referrals and consultations benefit both participants and family/caregivers. Comfort care is evaluated by UM and QI for appropriateness of referral and positive outcome.

6. Caregiver Care: The PACE IDT and social worker provide close collaboration with caregivers and families in regard to caregiver strain/burnout and home safety. The team maintains close contact with the caregivers to discuss interventions and prevent complications, injuries and even death. The provision of home care can prevent ED visits and hospitalizations. UM and QI trend and evaluate the quality of care, the frequency of home care, and the benefit of home care overall.
Overview and Relevance of PACE Program Data

This chapter provides a solid introduction to the universal data collection and submission activities currently performed by POs across the country.

The activities fall into two general categories: required submissions and voluntary submissions.

Required submissions are mandated via existing federal and State Administering Agency (SAA) reporting regulations. (Since each SAA has its own regulations, consult your health department representative and regulations for the specific reporting requirements.) The federally mandated requirements consist of the following:

➢ Diagnostic Risk Adjustment: The ongoing submission of diagnostic data incurred in the course of provider visits, hospital inpatient stays and hospital outpatient encounters.

➢ Health Plan Management System (HPMS): Data collected and submitted for predefined areas of monitoring for plan performance and quality and required under regulation for PACE performance improvement activity.

Voluntary submissions are conducted in participation with activities sponsored by the National PACE Association (NPA) that are intended to depict the common and differing characteristics of the demographics, operations, utilization and clinical profiles of PACE programs:

➢ DataPACE3 (DP3): Data submitted by NPA member programs to better understand the common and differing characteristics of demographic, clinical and operational characteristics intended to reflect the array of service variation and similarity that underpins PACE experience across the country. Some states require POs to submit DP3 data.

➢ PACE Data Analysis Center (PDAC): This is a voluntary submission to PDAC at the University of Rochester of the same diagnostic data submitted to CMS for risk adjustment. The purpose is to provide ongoing, cross-site comparisons of PACE diagnostic trends and variations among programs.

These two types of data submissions allow the PO to fulfill its regulatory requirements, communicate to the regulatory agencies the quality of care being provided, provide data that influence payments, allow the PO to understand the acuity of its participants, and compare the outcomes and demographic composition of its population to other POs.

Quality directors should be familiar with all of these activities because they may need to work in conjunction with other PACE leaders in the PO to guide and assist the successful collection, submission and analysis of this information. Purposes include the following:

➢ avoid the submission of fraudulent or incomplete data (Risk Adjustment, HPMS);

➢ track important quality markers to identify areas of improvement (HPMS, PDAC); and

➢ determine areas of variance with other PACE programs to prompt a review for underlying explanations for that variance or to identify a unique local experience (PDAC, HPMS, PDAC, Risk Adjustment).

The quality director must be aware of these important data uses and work with others to assist in developing workflows and audit processes in order to collect information successfully, verify its accuracy, and ensure that submission is timely and valid.
Because risk adjustment and other topics are reviewed thoroughly in publicly accessible documents, this chapter will not provide an exhaustive review of the individual subjects but will aim for the following:

➢ provide the conceptual framework for data collection that should educate the reader sufficiently in the fundamentals of the subject;
➢ refer to the primary source documents that provide the best grounding in each subject and explore subtopics in detail; and
➢ refer to other resources and personnel across the PACE community who can be of assistance in a subject area.

NPA Superbill

Many POs utilize the NPA Model Superbill to assist clinicians with the collection of diagnoses and assignment of diagnostic codes. The superbill can be found on the **NPA website**. Created by PACE medical directors in 2001 and revised periodically, the superbill provides a handy, one-stop location for many of the diagnoses relevant to PACE practice and risk adjustment. For specific codes not listed in the superbill, there is room to enter them. The superbill was designed to help clinical staff, at point of care, assign ICD-10-CM codes to diagnoses identified in the course of a patient visit.

For some organizations, the superbill may be the reference for direct ICD-10 submission into the CMS risk-adjustment system. For others, it is sent to other staff, including professional coders, who review direct documentation for the specificity of the data and then submit data supported by the documentation. For those with electronic medical records (EMRs), it may be useful as a guide to formatting the diagnosis reference and selection area in the EMR.

While there have been several revisions as codes changed, the most recent updates focused on the improved formatting of those disease areas (e.g., diabetes, pressure ulcers and cancer) in which the proper selection of the single most specific ICD-10 code is important for both clinical specificity and risk adjustment.

From a quality improvement perspective, the quality director should include the evaluation of superbills against what is documented in the medical record to confirm compliance with medical record documentation requirements and identify areas of improvement utilizing outcomes data.

Health Plan Management System

To comply with the PACE regulation (§460.140 and §460.200), all POs must meet external quality assessment and reporting requirements as specified by CMS and the SAA.

The Health Plan Management System (HPMS) is a secure web portal for information and data exchange that must be used by all Medicare managed care organizations for a variety of processes, including bid submissions and quality reporting.

In this section, “HPMS” refers to the specific PACE Monitoring Module. New POs may have to request to have this module added to their set when using their HPMS account for the first time. POs submit per reporting, due dates specified in HPMS and by their CMS account managers, a defined set of data elements intended to provide a marker for performance across PACE programs.

(***Note: Guidance about how to use the PACE HPMS Monitoring Module can be downloaded from the PACE Quality Monitoring Guide (5/6/16), located on the first page of the PACE Quality Monitoring Section of HPMS. Previous user guides for HPMS PACE modules may be available online, but they may not reflect all HPMS updates.***)
Additional guidance on Level I quality reporting can be found on the first page of the PACE Quality Monitoring Section of HPMS in the downloadable PDF titled “PACE Level I Guidance.”

HPMS passwords expire every 60 days and must be changed. The CMS EUA System sends out reminders several days before the password is due to be changed. To reset a password, contact the CMS IT Service Desk (800-562-1963), which provides an immediate response.

These specific points are related to the collection and entry process:

➢ Each PO (designated by an H number) is granted access for as many users as are necessary to submit and review data.

➢ Users must be trained to submit manually as no mechanism for automated uploads of data is available. Sites may designate a specific person to enter all data, or the task can be divided among several staff members.

➢ The data must be submitted quarterly, no later than 30 days after the end of the quarter, except for influenza immunization data, which are collected over the six months of the flu season and reported annually at the end of the first quarter (January through March). Aggregate data are submitted for the period of Oct. 1 through March 31. All data are due by the end of April of that year.

The HPMS Help Desk is available at hpms@cms.hhs.gov or 800-220-2028 for technical assistance on the use of the web portal or general questions regarding the reporting of PACE data elements. The help desk may take a few days to respond, and users may not receive a response before a deadline.

The data elements required for submission are noted explicitly in the Feb. 1 Level I Guidance PDF on the HPMS website. The submission format for each data area is specified in the User Guide. The following are of particular importance to the quality director:

➢ The manner in which the data for the various elements are collected and aggregated for submission is left to the PO to develop. PO leadership should understand the importance of collecting accurate data and design workflows to include elements that allow for data capture for the reporting requirements.

➢ The leadership should ensure the validity of the submitted data and that the data submitted are reflected in organizational performance improvement data that can be referenced easily for comparison. CMS looks to see that an organization uses this information in its performance improvement plans.

➢ Each organization should document internally in its operational policies and procedures and be prepared to describe its methods for collecting, validating, and submitting the data from each area.

➢ Data are submitted for each individual site (or center) in a program. The digital portal provides entry areas for each site of care designated by the organization.

➢ Several staff members may be responsible for collecting and monitoring different data elements, but the organization should create a central mechanism to ensure that timely and valid collection of all data occurs.

➢ The PO should incorporate the HPMS activity into its quality improvement program, reviewing the data with all organizational and center staff for whom it is relevant, and use the information to enhance organizational workflows and processes. HPMS data are only a subset of a larger array of performance improvement initiatives that comprise the annual performance improvement plan.
Levels I and II
An essential component of an effective quality improvement program is risk assessment and management. Risk management entails identifying and systematically reducing potential risks to the safety of PACE participants and the health care environment. Ideally, risk assessment is conducted prospectively to prevent occurrences that result in adverse health outcomes to participants or staff or harm to physical plant/equipment or fiscal status of the organization. Risk assessment most often is conducted in response to an event that results in medical, psychosocial, cognitive or functional harm to a participant or staff member. Every person employed or contracted by the PACE organization is responsible for risk assessment and management.

External monitoring activities refer to both of the following:

➢ submission of the aggregated monitoring data elements via the PACE Monitoring Module of HPMS Level I reporting, and
➢ reporting of events resulting in significant harm to participants or negative national or regional notoriety related to the PACE program (Level II Reporting).

This handbook and the PACE Level II External Reporting Guidance clarify the Level II reporting events that must be reported expeditiously to CMS.

Auditing and CAP Submission
During the trial period or periodically thereafter, an onsite audit by CMS staff may result in findings that require corrective action plans (CAPs). CMS uses the HPMS PACE Audit Module to manage and communicate with the PO regarding these plans and other correspondence associated with the audit. The module can be accessed through the HPMS PACE Auditing Module. During the exit conference for the audit, CMS staff provide specific instructions on how to respond with CAP elements to the findings. (For more information on the revised PACE audit process and audit-related submissions, refer to the NPA PACE Audit Preparation Guide.)

Complaints Tracking Module
The HPMS Complaint Tracking Module can be accessed under the Monitoring column on the homepage of the HPMS website. A help manual details how to use the module. For more information, contact the HPMS Helpdesk at 800-220-2028 or hpms@cms.hhs.gov. The Complaints Tracking Module is where complaints reported to 1-800-Medicare will be displayed for the PO. View the My Open Complaints display daily to ensure that all complaints are addressed.

DataPACE3
DataPACE (DP3) is a data collection and reporting service by NPA that seeks to describe the PACE enrollee and demonstrate the effectiveness of the PACE model. Only members that actively submit data can access DataPACE3 benchmarks.

DataPACE3 has three components:

1. Data Sources: The needed data source files for DP3 often can be generated from the EMR system of a PO containing individual participant information and may incorporate information from other reports generated for regulatory reporting.
2. Data Elements: A data element is an individual/single field of relevant collectable data from participant/program records (i.e., enrollment date, date of birth, disenrollment reason).

3. Measurement Sets: Data are organized into the categories of participants served, quality and service utilization. Demographic and payor information is collected for participants served. The quality category includes data collected on immunizations for influenza and pneumonia, the number of falls per 100 member months, and the number of ER visits per annum, as well as voluntary disenrollments and percentage of participants living in the community. Service utilization measures encounters for primary care, specialists, therapists, social workers, skilled home care and personal care and counts hospital and nursing home days, PACE center attendance, transportation trips, and the average number of prescriptions and meals.

Health Outcomes Survey-Modified

The Health Outcomes Survey-Modified (HOS-M) is mailed to beneficiaries enrolled in a PO to measure their health status. CMS has implemented a Medicare payment approach for POs that takes the frailty of enrollees into account. The health status information collected via the survey supports this payment approach. CMS adds a separate frailty score to member risk scores when paying POs. The HOS-M collects activities of daily living (ADL) scores used to calculate frailty scores. All PACE organizations are required to contract with DataStat to conduct the brief survey. Proxy respondents are allowed and may be family members or other caregivers. POs provide a file with detailed information to help survey vendors reach enrollees by mail and telephone. POs are encouraged to publicize the HOS-M with staff and members and to provide their logo to the survey vendor for use in mailings.

POs with enrollments under 1,200 must create a detailed contact file for their community-residing enrollees. (Long-term nursing facility enrollees are not included in this process.) To comply with regulations regarding the protection of confidential data, CMS requires POs to encrypt and password-protect the contact information files that are sent to RTI, which sends an email to the PO contact requesting the files each year.

All PACE organizations with Medicare contracts in effect on or before Jan. 1, 2015, are required to participate in the HOS-M, as well as those with at least 30 beneficiaries as of Oct. 1, 2015. CMS determines which POs are eligible for the survey each year.

For More Information

➢ DataStat: Ellen Johnson, for survey implementation.
➢ RTI International: Rebekah Love, for survey implementation, or project director Edith Walsh.
CHAPTER 8

Using Data to Support Quality Improvement
Data collection is not a useful exercise if it is not used. Many PACE organizations (POs) have extensive data collections that, while exhaustive, detract from their ability to prioritize quality resources in the service of needed improvements. Collected data must be analyzed to create actionable information for change and ultimately improvement.

Performance improvement is facilitated and optimized by a formal quality structure supporting a balanced organization-wide quality program as described in chapters 2, 3, 6 and 7. This chapter builds on that information to address indicator development; data collection; tiers of quality measures; reporting results (dashboards, storyboards and committee reports); use of charts, graphs and management tools; and tying quality to performance.

Once the foundational base for quality is established, data collection becomes the main focus. The quality plan, approved by the governing body, provides the structure and processes for that foundational base, describing the mission, goals, scope, roles, authority, services provided, quality committee and subcommittee functions, reporting requirements, and method used to evaluate, review and revise areas of measurement. With the designated individual in place to coordinate and oversee the implementation of quality assessment and performance improvement activities, priorities for measurement selected and approved, and a quality committee structure established, the next major steps are indicator development for the identified priority measures and data collection for these indicators.

**Indicator Development**

Data collection is contingent on the development of quality indicators, which are objective measures of process or outcome performance. Optimally, indicators should be developed for performance measures supporting the strategic goals of the organization and be meaningful to stakeholders. They also should be controllable, i.e., the organization must have the ability to make meaningful interventions to support improvement and to act on information obtained through measurement. Finally, indicators should lend themselves to data collection for the selected measure. (Note: Data collection that proves more difficult than expected might require a discontinuation of the collection and revision of the measure.)

If resources are limited, the quality director, PO leadership and governing body must prioritize what gets measured and restrict the use of quality resources to measurement efforts that propel the organization and strategic plan forward.

Developing an effective indicator for the prioritized performance measure involves the following:

- identifying the problem/issue warranting the development and measurement of an indicator;
- clearly defining what is being measured;
- identifying the numerator/denominator;
- determining an appropriate sample size;
- developing a plan of how, when and where data will be collected; and
- assigning who will collect, collate, analyze, and report the collected data.
Table: Process for Overseeing a Selected Indicator

<table>
<thead>
<tr>
<th>Definition of What Is Being Measured</th>
<th>Participant complaints about meal choices offered in day center. (Note: The indicator does not include complaints/grievances about meals in the home or snacks at the day center and focuses on participant complaints/grievances only, not including those of staff members involved in meal service.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifying the Numerator/Denominator</td>
<td>The number of participant complaints/grievances about meal choices divided by the total number of meals served.</td>
</tr>
<tr>
<td>Determining Sample Size</td>
<td>The number of meals served per day, per week or other specific period.</td>
</tr>
<tr>
<td>Developing a Plan of How, When and Where Data Will Be Collected</td>
<td>A complaint/grievance is documented on the grievance log when it occurs per the PO policy and procedures. Staff involved in meal service, the PAC meeting leader, a family member, or a staff person in another department may be collectors of complaints/grievances about meal choices. The critical step is capturing the complaint/grievance.</td>
</tr>
<tr>
<td>Assigning Who Will Collect, Collate, Analyze, and Report Collected Data</td>
<td>The department leader, PAC leader or dietitian may be in the best position to collate all the complaints received about meal service into a single source for analyzing and reporting results.</td>
</tr>
</tbody>
</table>

Note: The role of the quality director is to support and guide the indicator development and data collection processes but not to do the actual work.

This approach facilitates staff involvement, increases staff learning about quality improvement (QI) processes, and supports a culture of shared ownership for quality.

Data Collection

Both quality control and QI indicators warrant data collection. Indicators should be vetted through departments involved in the design of the indicator and in data collection to determine the best definition of what is being measured. Clearly defined indicators support the integrity of the data being collected. For example, before creating indicators for medication errors, a PO can use specialty-approved definitions for medication errors or define whether to include near-misses, timeliness or at-home variances in its data collection. In addition to vetting indicators and recognizing not all POs have access to statisticians, working with a statistician or epidemiologist may be helpful in determining clearly defined indicators and data collection strategies.

Quality control indicators are simple yet important collections of data, analogous to the collection of surveillance data in infection control programs. This category of data includes the temperature of refrigerators and freezers, equipment calibration, expiration dates of medications and food, narcotic counts, fire extinguisher checks and van safety checks. These indicators are just a few of the daily or timed frequent checks that may indicate a potential or existing problem if not in an expected range, count or date. The quality control measures are warnings to investigate further, sometimes uncovering system or process issues. For example, monitoring temperature and calibration logs helps identify potential equipment malfunction. Similarly, expired medications may point to process breakdowns within the clinic or with the pharmacy provider.

Quality control data collection ideally is performed by the department responsible for the piece of equipment being monitored, such as van safety checks by transportation, or who performs the process...
related to a particular measure, such as narcotic counts and checks for expired medications by clinic nurses. Quality control indicator results, which are part of department-specific measures, are reported to the appropriate quality committee or subcommittee as specified in the quality plan.

QI indicators are more complex than quality control measures in that they can apply to one or more departments or to the structure, processes, systems or outcomes of an entire organization. QI indicators can assess how well care and services are delivered in the collaborative and integrated model of PACE or by a single department within the PO. A single department QI indicator may measure a specific process unique to the department, such as the process of assigning RNs for home health visits. A complex QI indicator measures beyond the internal indicator of a department for a specific area of measure and looks across departments. For example, the medication administration process involves at least pharmacy, nursing, physician staff, medical record documentation system and medication delivery process for participants. The provision of lunch services at the PACE center minimally involves the dietitian, physician, kitchen staff, center aides, food service vendor, and communication and documentation systems for dietary orders. Both areas involve high-volume processes, as well as components of quality such as appropriateness, safety, timeliness, accessibility, effectiveness, efficacy, efficiency, and participant satisfaction of care and services provided.

QI indicators are used to measure the desirable or undesirable performance of prioritized events, outcomes or processes. Thus, managing these indicators is an important aspect of QI activities. Organizing the indicators is key in assisting the quality director with oversight of the QI actions taken throughout the PACE site(s). As discussed in Chapter 3, the quality work plan (QWP) contains the priorities of the organization and the indicators used to measure these priorities. It also guides the quality director and organization in improvement activities. An effective tool to complement the QWP is a folder, file or binder for each indicator.

The folder for each indicator includes a description of the reason the indicator was chosen, definitions of terms contained in the indicator for further clarification for data collection, an explanation regarding the usefulness of the indicator, the process or outcome being measured, and the components of quality that are being assessed by the indicator. The next part of the folder is a description of the population included in the data collection, which directly translates into the numerator and denominator of the indicator description. A description of the various data sources to be used to collect the indicator data is included in the folder. Finally, most quality directors will choose to include an explanation of any factors that may cause variations in indicator data, such as participant factors beyond the control of the PO (e.g., comorbid conditions, severity of illness, or refusal to consent) and practitioner and organizational factors. The folder also should contain the data collection tool, data results, actions taken for improvement, and re-measurement results to demonstrate improvement and sustainment of improvement.

These indicator-specific folders contain information that can be used as supporting documentation for the QI tracer process during PACE audits. They also provide a look-back on improvements made and the corresponding actions taken and provide the foundation for the annual QI report to the governing body and other stakeholders. In addition, the folders provide the background for storyboard development. Storyboards can be used by individual departments to display steps taken that led to improvements or by QI teams to demonstrate how improvements to processes and outcomes were achieved by working across departments. Typically, storyboards are developed by the staff members who conducted the work leading to the improvement and own the “bragging rights” to their accomplishments.
Tiers of Quality Indicators

POs vary considerably in size and structure. Some are stand-alone, one-site centers; and others are one business line with multiple PACE sites within an integrated delivery system. Structure and size are factors that contribute to how a PACE quality program is implemented, how oversight of the quality program is done, and what the reporting structure is. Because POs vary in size, structure and resources, it is helpful to think of the quality indicators as levels or tiers of measure that can be displayed on a dashboard or scorecard as a single-page view clearly displaying the progress of a PO in quality improvements supporting its strategic objectives. A dashboard backed up by in-depth data is an effective tool for presenting to the governing body.

Following is the outline of a suggested approach.

Tier 1: Department-Specific Indicators

Each department in a PO should have one or two key department-specific indicators – measures addressing the key functions or services that the department provides as seen through the eyes of “customers” receiving their services. For example, customers of the physical therapy department might value effective therapy, communication from the PTs, and prompt treatment. Once the top two or three expectations are identified, the department staff develops an indicator for these expectations. Relevant staff collect the data and report results to the appropriate committees. The quality director includes the department-specific indicators in the QWP and assigns each department a date to report the status of each indicator, the results and any improvements. This will be a continuous process, rather than one that only emerges as errors or deficiencies are noted. Typically, departments provide quality updates on a rotating basis. To maintain the efficiency of these departmental processes and ensure the full workload does not fall on the shoulders of the quality department, the quality director may need to provide ongoing education on indicator development and data collection tool development and should approve the indicators, tools, and data collection processes and sources of each department before data collection begins. The quality director and individual department may opt to test the data collection tools, indicator definition and parameters for two to three weeks before going live with the data collection tool and data collection process.

Tier 2: Organization-Wide Indicators

The next tier consists of indicators that are organization-wide. The rules for developing these indicators are the same as for department-specific indicators except multiple departments are involved in defining the indicator and collecting the data. Emergency room use, Level II events and care plan indicators are examples of organization-wide indicators. These indicators are also part of the work plan. The quality director is usually the keeper of the data folders for these indicators since multiple departments are involved. The director need not be the leader for the indicator data collection efforts but should support the leader of this interdisciplinary group. Tier 2 indicators also are used across a PACE plan with multiple PACE centers. Each center can be viewed as a single organization or collectively as a department in very large systems.

Tier 3: System-Wide Indicators

This tier applies to POs that belong to larger systems and/or have multiple PACE sites. One or two key system indicators usually are mandated by the parent company. Examples include employee satisfaction,
patient/participant/customer satisfaction, budget targets per line of business, or center of excellence around a specific disease or body system. These indicators are top-down, and the PO may be involved in contributing data if the system-wide indicator includes the PACE population.

**Table: Guide to Reporting Format(s) for Different Customers**

<table>
<thead>
<tr>
<th>Customer</th>
<th>Tailored Report to Audience or Mandated Report</th>
<th>Dashboard</th>
<th>Storyboard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governing Body</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Staff</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>QI Committee</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vendor</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>CMS</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regional Office</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State Administering Agency</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPA</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**Use of Charts**

The use of charts to communicate the results of the collected and analyzed data is an effective means to visually convey main points to stakeholders. Most organizations include brief narrative explanations or summaries, as well as titles, labels and legends, to ensure viewers comprehend the context and correct conclusions from the data rather than being left to interpret the data on their own.

**Table: Common Applications for Charts, Graph Formats and Management Tools**

<table>
<thead>
<tr>
<th>When to Use</th>
<th>Type of Chart, Graph or Management Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Define the Problem</strong></td>
<td></td>
</tr>
<tr>
<td>Emphasize the best or worst result</td>
<td>Pareto diagram (80/20 Rule)</td>
</tr>
<tr>
<td>Display large amount of data over time</td>
<td>Pie diagram (break out a slice)</td>
</tr>
<tr>
<td>Display size of gaps between reality and goals</td>
<td>Bar chart</td>
</tr>
<tr>
<td></td>
<td>Radar charts, scatter diagrams</td>
</tr>
<tr>
<td><strong>Analyze the Problem</strong></td>
<td></td>
</tr>
<tr>
<td>Detect trends or patterns over time</td>
<td>Line charts (data over time, identifies trends, shifts, cycles)</td>
</tr>
<tr>
<td>Detect and examine variation and sources of process performance over time</td>
<td>Statistical process control charts</td>
</tr>
<tr>
<td><strong>Problem-Solving Tools</strong></td>
<td></td>
</tr>
<tr>
<td>Identifies and narrows possible causes</td>
<td>Fishbone (cause and effect)</td>
</tr>
<tr>
<td>Identifies all steps and decisions of a process</td>
<td>Flowcharting</td>
</tr>
<tr>
<td><strong>Team Management Tools</strong></td>
<td></td>
</tr>
<tr>
<td>Reduce or eliminate root causes</td>
<td>Force field analysis</td>
</tr>
</tbody>
</table>
Evaluation grid

<table>
<thead>
<tr>
<th>Action plans</th>
</tr>
</thead>
</table>

### Sustaining Improvement Tools

<table>
<thead>
<tr>
<th>Prevent the problem and its root causes</th>
<th>Root Cause Analysis (RCA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take care of participant, contain the event, preserve the information</td>
<td>Level II events</td>
</tr>
</tbody>
</table>

**Tying Quality to Performance**

In any organization, what gets measured gets done. Quality improvement initiatives are the most effective and successful when the following dynamics are present:

- leadership buy-in for a QI program,
- dedicated resources to support quality activities,
- staff educated about the tools and methods for QI activities, and
- culture that supports active participation from all levels of staff for ownership of QI activities.

All PO staff should be exposed to the quality principles, model and work plan of the PO during orientation. Education training and refreshers of QI committee members and QI teams are ongoing responsibilities of the quality director. A number of widely used strategies are available for incorporating quality education and facilitating a culture of quality throughout the year:

- inclusion of the role/task of active participation in quality initiatives to all job descriptions;
- maintaining quality participation as a metric or criterion on annual employee performance evaluations, validated by having employees describe their contributions to QI over the past year;
- inclusion of the status of department-specific indicators as a standing item at department meetings;
- use of a quality display table at annual skill/competency fairs to exhibit storyboards, FAQs or progress on PO prioritized measures; and
- structured report-outs by staff on the status of specific department quality indicators on a rotating calendar as part of the QWP.

Involving all staff in QI is important to establish support for a culture of quality improvement. Tying QI to staff performance evaluations underscores the importance an organization places on a successful and participatory QI program.
42 CFR § 460.210

The participant medical record presents a total picture of the care provided. The medical record is a useful tool in diagnosing, treating, and caring for the participant. The medical record facilitates communication among the various health care professionals providing services to the participant, provides a focal point for coordinating IDT actions, provides an accurate picture of the participant’s progress in achieving care goals, and provides team members with data for evaluating and documenting the quality and appropriateness of care delivered.

Quality improvement (QI) and medical records are linked by what is and is not documented, how interventions and outcomes are documented, and ensuring that participant rights are not compromised.

Content of the Medical Record

The medical record must be a single record containing all information about the participant. The record must be housed at the PACE center where the participant receives primary care. Some PACE organizations (POs) maintain a hybrid record: an electronic medical record (EMR) and a paper record. The paper record may be necessary for information related to the care received by the participant at outside facilities and contracted vendors that are not synchronized with the PACE electronic record. Some POs scan documents received from external sources into the EMR to create a complete single record.

The medical record should paint an accurate, detailed picture of the participant and the care and services provided. It should be organized so information is easily and readily available and accessible. The medical record is a legal business record and must be maintained according to professional and legal standards that govern the health care operation. It also is used as a communication tool among providers and to defend the organization in the case of a lawsuit.

PACE regulations stipulate that the medical record must contain the following:

- Appropriate identifying information: Name, address, date of birth, race, ethnicity, etc.
- Documentation of all furnished services, including interdisciplinary assessments, reassessments, plans of care, treatment and progress notes that include the participant’s response to treatment; lab, radiological and other test reports; medication records; services provided by PACE employees; services provided by contractors and their reports; summary of emergency care and other inpatient or long-term care services; hospital discharge summaries; reports of contact with informal support; physician orders; disenrollment notes; advance directives; signed authorizations permitting the disclosure of protected health information; and source of referral.
- Additional required documentation, including a copy of the signed enrollment agreement and financial information such as eligibility and participant financial responsibilities.

Documentation Practices and Policies

Entries into the EMR or paper medical record should be authenticated by the individual with first name or initial, last name and professional credentials. The record should contain only facts, not conjecture or opinion. Documentation should be accurate, clear, timely, legible, complete and concise.

POs should develop policies regarding documentation based on their use of a paper record or EMR. Amendments, deletions, late entries and corrections are allowed; but specific policies that adhere to legal guidelines should be written and implemented.
Access, Security and Storage

Both paper medical records and EMRs should be readily accessible and available to all staff.

Electronic Medical Record

Permissions to sections of an EMR may be limited by role and “need to know.” All users should have individual log-ons and signatures, even temporary employees and students. Access should be removed once an employee is terminated or temporary employees/students are no longer with the organization or no longer need access to the medical record.

Paper Medical Record

Hard copy or paper medical records must be stored securely in fire-proof cabinets. Access to records and removal from the storage area should be facilitated by a medical records staff person and/or a replacement file noting the person removing the record.

Security

All contents of the medical record are protected by the HIPAA Privacy Rule. Access to records is allowed without participant-specific permission for purposes of care and treatment, insurance/payment and health care operations. All other releases are allowed only with written permission by participants or their agent. Psychiatric records require specific releases.

Storage

Paper and electronic medical records are maintained by the organization for 10 years after the final entry. This is a requirement of Part D providers. Paper medical records in off-site, long-term storage must be kept in a secure, fire-proof and easily retrievable location or facility.

QI and Medical Records

Some entries are not appropriate for inclusion in the medical record and should be maintained separately as a part of the overall QI tracking. Grievances and incidents should not be documented in the medical record, but health-related issues or interventions related to them should be.

Conducting chart audits as part of a QI activity can ensure the PO is compliant with maintaining the contents of the medical record. Audits can and will be conducted by CMS, SAA, and any state or local licensing or accrediting bodies.

Periodic, random chart audits should be included as a measure in the QI work plan. These audits need not be the responsibility of the quality director. A user-friendly, well-defined chart audit tool should be developed to facilitate performance of these audits by individual disciplines or departments. The audit tool minimally should audit for the presence of signed, dated notes with the discipline noted, timely assessments, executed orders, completeness of the record, a signed and dated advance directive, completed face sheet, and accurate participant/caregiver contact information. The chart audit also should include a review for information that should not be included in the medical record, such as incident reports or paper records filed in the wrong section (e.g., a nurse’s notes filed in the therapy section of a record and paper records from another participant filed in the wrong record).

Audit results should be communicated to staff members and used to educate them about areas for improvement related to documentation. Qualitative and quantitative audits are useful for providing insight into required elements of the medical record, as well as clarity of the participant picture presented.
PACE Audit Process

A medical record review continues to be an integral part of the CMS PACE audit process. CMS auditors review paper and electronic components of the medical record for completeness, accuracy, care plan content, intervention effectiveness measures, and evidence of IDT management of participant care.

The PACE Audit Preparation Guide contains information on universes and sample selection by CMS for the medical record review. Refer to the guide for more information on submitting the participant medical record universe.
The use of customer satisfaction surveys (for participants, caregivers, etc.) is a compliant response to regulatory requirements and provides a PACE organization (PO) with the opportunity to learn how its customers experience the care and services that are provided. Although most processes are designed carefully by PO staff and leadership, the ways they are experienced by participants may be quite different.

A survey is a data collection tool used to quantify the opinions, attitudes, knowledge, beliefs and behaviors of a group of people. Survey responses are subjective in nature but quantified to understand and measure the level of the quality of care and services provided. The adage “quality is in the eye of the beholder” is an apt description of the subjective responses submitted in satisfaction surveys.

An example of a fluid, crowd-sourced satisfaction survey is Yelp, which gauges satisfaction with the services provided by a store, hotel or restaurant and the experiences of the customer interacting with the staff. Similarly, surveys used by POs can measure customer experiences and the level of satisfaction with services and care. The following are important differences:

➢ the potential respondents are a specific, targeted group;
➢ the scope of a PO satisfaction survey is limited; and
➢ the survey is thoughtfully designed and structured.

This chapter provides an overview on PACE surveys and includes a section on “Designing a Survey,” which addresses scope, population, data collection, format and testing.

Overview

Developing a satisfaction survey requires thoughtful planning to determine the scope, target population, methodology for data collection, and formatting of the questions. Since well-constructed surveys are designed carefully, working backwards from the desired information generally will inform the content, style and format of questions, as well as the methodology that data can best be collected, collated, and analyzed. Testing the survey ensures that data collection efforts yield information consistent with expectations when the survey initially was designed.

POs are required to provide many services and care to participants in various community settings. Organizations often use contractual arrangements with other providers and vendors to supplement internal resources for required services and care. These providers and vendors can have complex customer relationships with the PO:

➢ They may perceive themselves as customers of the PO, even though they are providing services to the organization or its participants, because they are reliant on receiving accurate, timely data or requests to deliver their own services in an accurate, timely fashion and to receive payment.
➢ Conversely, the PO is a customer of the external provider or vendor, contractually required to perform services acceptable to the PO.
➢ Since participants/caregivers often view the contractor or vendor as an extension of the PO, they are, independently, customers of the vendor as well.
➢ Even internal staff can be viewed as customers of other internal staff, exemplified by the social work staff delivering critical family support or other information to the IDT.

Thus, awareness of who the customers are in relation to the focus of the satisfaction survey affects the scope, population, data collection and format of the survey.
The satisfaction of customers who receive care and services from the PO is critical. In addition to reflecting compliance with regulatory requirements, customer satisfaction surveys point the organization to possible areas of improvement and provide information for its use in validating to CMS, external partners and stakeholders, internal customers and participants the value of the care and services delivered.

**Survey Design**

**Scope**

The first step in designing a survey is to determine the scope of what is being assessed by the target population. One way to frame the scope is to determine the questions that need to be answered by the results. Once the list of survey questions has been drafted, it is useful to review the questions with individuals who were not involved in creating them to determine if they are asking what was intended. The questions also should be reviewed to determine additional information that may be needed to stratify answers and interpret results. For example, in soliciting satisfaction levels from participants about activities offered in the day center, a PO might find value in determining gender-based differences in satisfaction levels. That level of stratification might necessitate adding a gender question to the survey.

Ask these key questions when determining the scope of a survey:

- What other information will be needed to interpret the results?
- What audience will see the survey results, and what additional questions or information are they likely to request after seeing the results?
- Does the PO want to make specific statements that are dependent on the results?

Finally, all draft questions should be reviewed to determine potential responses that may require solutions that are not feasible due to the level of available resources.

**Population**

The PO then needs to identify the population that will be surveyed and its size. When determining the sample, consider the following:

- A high response rate is better than a larger denominator in obtaining responses relevant to the surveyed population.
- The quality of the data collected is more important than the quantity.
- Careful selection of the survey population improves the validity of responses.
- The selected population sample should represent the universal population as much as possible.
- The size of the population sample depends somewhat on PO resources to do follow-up. The value of the data directly depends on the ability of the organization to analyze, interpret, and provide follow-up on the results.

**Data Collection**

The methodology of data collection relies on several factors, including the length and level of survey detail; the characteristics of the study population, such as access to and familiarity with electronic devices; the size and location of the sample population; and resources available to conduct the survey.
Data can be collected in a variety of ways. In-person interviews are labor-intensive, costly, and not the best way to collect sensitive information. However, they allow the interviewer to observe behavior, be interactive, and ask probing questions to find out more information. If multiple interviewers are involved, this method is open to potential biases and stylistic differences during questioning and result interpretation.

Conducting interviews by phone also is costly compared to using a questionnaire. Respondents must have access to a phone and the availability to answer it, and the respondent’s identity may not be validated easily. Complicated or lengthy questions are often difficult to convey over a phone, making shorter and simple yes/no questions preferable with this method. The advantages of phone surveys are a wide reach in the number of respondents and locations, rapidity of efforts to gather data, and the requirement of only one step from the respondent, compared to the multiple steps required when respondents complete and mail in a written survey. As with in-person interviews, phone interviewers can clarify responses. Language may be a barrier, but populations with a low literacy rate may fare better in phone and in-person interviews with interpreters, when needed.

Questionnaires can reach a wide population sample in many locations at a lower cost than other methods. Conducted anonymously, they protect the respondent’s identity and increase the chance of gathering sensitive information than phone or in-person interviews.

A focus group is another option for collecting satisfaction data. This method offers a high response rate and immediate feedback and is a good way to test questions that are being considered for larger surveys.

**Format**

Survey formatting requires determining the type(s) of questions that will be included, the wording of the questions, and the physical structure and appearance of the survey tool.

Questions can open-ended or close-ended. Close-ended questions, such as those in a multiple-choice format, are more easily analyzed because the answers are chosen from a provided selection of responses. Open-ended questions require more time and thought from the respondent, which increases the probability of incomplete surveys. An onerous level of effort may be required to create an inventory of open-ended responses for analysis. Interviewers and analysts also may have difficulty understanding the point the respondent is making in a narrative response.

Survey questions should be worded as simply as possible, without biasing the respondent toward a particular answer. If a scale such as 1-5 is used (with 1 meaning the worst and 5 the best), clear descriptions of the response numbers must be included on the survey to ensure the respondent interprets the scale the way it is intended.

The appearance of the survey tool should be user-friendly, uncluttered, and conducive to data entry and analysis. Instructions for completion should be easily understood and included on the survey form. Make sure the provided response options are distinguished easily from the question. A helpful format is to list response options vertically under each question to prevent the chance of mistaken answers.
**Testing**

As with any data collection tool, a draft survey using a small number of respondents representative of the larger population may help validate the usefulness and accuracy of the survey. This practice also assists in evaluating the ease of use of the tool, the value of the chosen methodology, and the clarity of questions and instructions.

Satisfaction surveys serve as a barometer to the governing body and PO leadership about the level of quality that participants and other customers experience when interacting with the organization. Survey results should be shared periodically with PO staff and leadership, communicated on scorecards or dashboards for the governing body and other interested stakeholders, and included in the annual quality report. Many organizations share high-level summaries with the survey respondents and include the planned actions or actions taken to improve the quality of services.
CHAPTER 11
Compliance/FWA

Authors: Cyndi Young and Cheryl Dexter
PACE organizations (POs) that offer a prescription drug benefit program must consider compliance program guidelines. These guidelines are delineated in Chapter 9 of the Part D Prescription Drug Manual and Chapter 21 of the Medicare Managed Care Manual.

Quality directors may have no role in fraud, waste and abuse (FWA) and compliance, may have a very low level of responsibility, or may have complete responsibility and oversight. Their role usually is determined by the size and maturity of the organization. New POs or those maintaining a census of less than 150 often combine the quality and compliance roles. Organizations affiliated with larger health systems that have a compliance department in place may choose to leave FWA/compliance to the corporate entity and create a role for a quality director at the PO.

Whether the roles are combined or there is a distinct and separate compliance officer, the areas of quality, FWA and compliance are linked and must work closely with finance, human resources, pharmacy and the medical director.

While quality ensures that we are doing the right thing the best way possible to achieve optimal results, compliance is about doing the right thing in accordance with applicable rules, regulations and policies. An effective compliance program protects an organization by detecting and preventing improper conduct and promoting adherence to the legal and ethical obligations of the PO.

According to applicable regulations, the foundation of an effective compliance program includes at least seven components:

1. Written Policies, Procedures and Standards of Conduct

   The PO must establish standards and procedures to prevent and detect criminal conduct and communicate them effectively. If the organization expects its employees to do the right thing, it needs to communicate what that is and how it can be accomplished through standards and procedures. The information must be communicated to employees in a manner that is easily understood.

2. Compliance Officer, Compliance Committee and Governing Body

   The PO must designate a compliance officer and a compliance committee that report directly and are accountable to the CEO or other senior management. Both oversee matters of compliance and report them to the CEO and governing body (e.g., board of directors or board of trustees), which must exercise reasonable oversight with respect to the implementation and effectiveness of the PO compliance program.

3. Effective Training and Education

   The PO must implement the program effectively through education and training. Training should not merely recite the law but explicitly explain organizational policies and ask employees to think through complex “gray areas” they may encounter in day-to-day tasks. The PO must ensure all employees are educated about FWA and compliance matters within 90 days of hire and annually thereafter.

4. Effective Lines of Communication

   The PO must establish and implement effective lines of communication, ensuring confidentiality among the compliance officer, compliance committee members, employees, managers and the governing body. This includes maintaining a hotline or other mechanism to receive complaints anonymously. The organization must have procedures to protect the anonymity of complainants and “whistleblowers” from retaliation.
5. Well-Publicized Disciplinary Guidelines for Non-Compliance

The PO should provide appropriate incentives to encourage employees to adhere to the compliance program and impose appropriate disciplinary measures when they fail to do so. The organization must enforce these rules consistently to maintain the credibility of the program and appropriately discipline those who violate any policies or regulations.

6. Effective Monitoring and Auditing

The PO must audit its compliance program to make sure the elements are implemented and to evaluate its effectiveness.

7. System of Prompt Response to Compliance Issues

The PO must address misconduct when it occurs, including self-reporting to the authorities at times, and must take reasonable steps to prevent future misconduct. It must develop and implement a corrective action plan (CAP) in response to identified misconduct. The status of the plan should be reported routinely to the PO leadership and governing body.

Once these seven elements are in place, the compliance program must be reassessed and modified periodically to ensure that it is kept current and effective.

Additional information on compliance program guidelines can be found in Chapter 9 of the Part D Prescription Drug Manual and Chapter 21 of the Medicare Managed Care Manual.
New quality directors in PACE quickly realize there are many facets to the position. Their scope of responsibility encompasses a wide range of services furnished by the PACE organization (PO). Most of what initially is learned about the scope of responsibilities is referenced in materials developed by CMS. In particular, CMS Publication 100-11 Programs of All-Inclusive Care for the Elderly (PACE), Chapter 10 — QAPI, and the six CMS regulations under Subpart H: Quality Assessment and Performance Improvement.

The “minimum requirements” for a program include such areas as utilization, satisfaction, outcome measures, effectiveness and safety of staff and contracted provided care, quality plan, data-driven outcomes and performance. While it can be overwhelming, a safe, functional and supportive environment within the organization is necessary to preserve both quality and safety for participants and staff members. This safe environment is not just the PACE center itself; it includes transportation to and from the center, outside appointments and the participant’s home. Therefore, quality directors must have a good understanding of how their role both supports and helps to assess compliance with applicable regulatory requirements.

Decoding the Regulations

Since the scope of Environment of Care (EOC), Safety and Emergency Preparedness touches every staff member within and beyond the walls of the PO, it is essential that everyone understands the intent of the requirements within the regulations to ensure compliance. Quality directors have an innate ability to decipher regulations and “translate” the content in such a way that they are better understood so the requirements can be met. It is necessary to read and understand the regulations.

The requirements for EOC, Safety and Emergency Preparedness are delineated throughout the federal PACE regulations. There are detailed requirements regarding physical environment, equipment maintenance, fire safety, life safety, emergency and disaster preparedness, and staff training specific to the emergency plan (§460.72 & §460.84). Additional requirements also are delineated for employee and contracted staff orientation and training relative to occupational health and safety (OSHA), medical equipment, participant safety and body mechanics area (§460.71).

Reporting Structure

To assist quality directors in developing their knowledge of EOC, Safety and Emergency Preparedness within their role, they need to understand the reporting structure within their organization. The person accountable for these areas probably will depend on the maturity of the organization.

Programs Open Less Than Three Years

Young programs - those open less than three years - focus on PACE basics and often do not have a full complement of staff to have a “designated lead” or a fully functioning EOC committee. This is a normal part of a fledgling PO. Quality directors at new programs should consider establishing a “safety team.” Organizations hire talented staff, so quality directors should find out if anyone has previous experience with EOC, Safety or Emergency Preparedness. Discuss the initiation of a safety team with the PO leadership.

When our PO opened, the safety team consisted of the quality director, transportation manager, and a member of the facilities management team. We shared the responsibilities to ensure all CMS requirements were met. At our three-year point, we outgrew the safety team and established a formal EOC, Safety & Emergency Preparedness Committee and designated our center director as the chair.
Programs Open Four to Seven Years

When programs are open four to seven years, they are no longer considered new. Based on enrollment and staff growth, a safety team with a few members may no longer be feasible to meet regulatory requirements. Quality directors should inquire if their PO has an established EOC/safety committee. If it does, they should become a member because their role is critical in ensuring compliance with EOC, Safety and Emergency Preparedness requirements.

The next step is to review the minutes of safety committee meetings and meet with the committee chair. This allows quality directors to understand program vulnerabilities and inquire about past audit deficiencies related to EOC, Safety and Emergency Preparedness. How was the deficiency corrected and sustained? Quality directors should inquire about any concerns the chair may have that they could assist with prior to the next audit. If the chair is not already on the quality committee, invite him or her to become a member.

Because an official EOC/safety committee is not a requirement of PACE, an organization may not have a committee. In that case, the role of the quality director is to work with leadership to see the benefit of establishing a designated committee as a best practice. Once the concept of a committee is approved, the next step is to assist leadership in determining who should be the chair. The ideal committee chair should have operational oversight. The quality director then will work closely with that individual to select appropriate committee members. The chair and committee members are key to the success of EOC, Safety and Emergency Preparedness.

The committee has the overall responsibility for ongoing assessment, implementation, monitoring and evaluation of environmental safety. This list is not all-inclusive, but consider the following representation:

- operations lead as chair,
- home care RN for in-home safety,
- quality director for regulatory oversight,
- prevention and monitoring as infection control lead,
- facilities for building operations,
- social worker as community liaison,
- dietary for food safety,
- PT or OT as falls prevention lead,
- Transportation for transport safety,
- participant safety as day center lead,
- clinic RN for in-center emergencies, and
- staff safety as occupational health and safety lead.

Once committee membership is established, it is the responsibility of the quality director to work with the chair to establish the format and content of the meetings. Each meeting requires an agenda and formal documented minutes.

Programs Open Eight Years or More

Mature PACE program – those open eight years or more – likely have an established EOC/safety committee. Quality directors who are not already a member should request to participate in it. They should
meet with the chair early on to learn about the committee and the roles and functions of its members. The role of the quality director is to ensure the committee functions within regulatory requirements. If there is not an established committee, the quality director should begin one by following the steps outlined in the sections above.

**Occupational Health and Safety**

Staff safety is a component of EOC, Safety and Emergency Preparedness. Occupational health and safety include environmental safety or work safety and workman’s compensation. PACE staff members are not immune to injury. Something as simple as a fall in the parking lot resulting in a sprained ankle can cost the facility tens of thousands of dollars. An occupational safety component is an essential part of EOC, Safety and Emergency Preparedness in PACE. POs should have an active occupational health component. If none exists, the quality director may want to consider starting one. Occupational health should be a part of the infection control committee, while occupational safety is part of the EOC committee agenda.

RNs with a background in occupational health, emergency medicine or urgent care typically lead occupational health and safety. Quality directors can advise the lead in the areas of assessment, program development and outcomes monitoring.

**EMERGENCY PREPAREDNESS**

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While EOC and safety requirements can be quite daunting on their own, new quality directors also need to address the third component of EOC, Safety and Emergency Preparedness.

Emergency preparedness requirements originally were housed within 42 CFR §460.72(c) Physical Environment. However, CMS found that the regulatory requirements were inconsistent, generic, and not comprehensive enough to address the complexities of emergency preparedness. The focus of 460.72 addressed the physical environment with minimal guidance on emergency preparedness. The original requirements did not address the need for communication to coordinate with other systems of care within cities or states, contingency planning, or training of personnel. CMS believed it fell short of what was needed to keep participants and staff safe.

On Sept. 16, 2016, CMS published a final rule on Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers. The rule established national emergency preparedness requirements for numerous providers and suppliers, including PACE organizations. The new emergency preparedness requirements for POs establish a new §460.84 of the PACE regulation that appears on pp. 64026-28 of the final rule. It is instructive to review sections of the preamble to the rule that provide further guidance regarding the new requirements, particularly the executive summary (pp. 63861-62); requirements for hospitals that are the basis for requirements for all other providers and suppliers, including POs (pp. 63873-94); and guidance specific to POs only (pp. 63904-06).

The new rule requires POs to comply with all applicable federal, state and local emergency preparedness requirements. Four core components are identified for emergency preparedness programs: risk assessment and emergency planning, policies and procedures based on the risk assessment and planning, communication plan, and training and testing.
Risk Assessment and Emergency Planning

POs must develop and maintain an emergency preparedness plan that is reviewed and updated at least annually. The plan must be developed on the basis of a facility-based and community-based risk assessment, utilizing an all-hazards approach. In describing this approach, CMS states, “Rather than managing planning initiatives for a multitude of threat scenarios, all-hazards planning focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters.” In defining emergencies or disasters, CMS includes both “internal” emergencies that can affect the PO itself and emergencies that affect the community at large, as well as references natural and man-made disasters.

Examples include “care-related emergencies; equipment and power failures; interruptions in communications, including cyberattacks; loss of a portion or all of a facility; and interruptions in the normal supply of essentials, such as water and food.”

In developing their plans, POs must consider the following:

➢ identification of essential business functions that should be continued in an emergency;
➢ identification of all risks or emergencies that the PO may reasonably expect to confront;
➢ identification of all contingencies for which the PO should plan;
➢ consideration of the locations where the PO delivers patient care or services or has business operations;
➢ assessment of the extent to which emergencies may cause the PO to cease or limit operations; and
➢ determination of whether arrangements with other POs, other health care providers or suppliers, or other entities might be needed to ensure the provision of essential services during an emergency.

The plan must do the following:

➢ include strategies for addressing emergency events identified by the risk assessment, e.g., alternate care placement sites if the PACE center needs to be evacuated and consideration of back-up plans if these alternate care placement sites are unable to accept participants;
➢ address the participant population, including the type of services the PO has the ability to provide in an emergency, and continuity of operations, including delegations of authority and succession plans; and
➢ include a process for cooperation and collaboration with local, tribal, regional, state and federal emergency preparedness officials in order to maintain an integrated response to a disaster or emergency situation; this involves documentation of PO efforts to contact officials and, when applicable, of its participation in collaborative and cooperative planning efforts.
Policies and Procedures Based on Risk Assessment and Planning

POs must develop and implement policies and procedures based on the emergency plan, risk assessment and communications plan that are reviewed and updated at least annually. At a minimum, these policies and procedures must address the following:

➢ Subsistence needs for staff and participants, whether they evacuate or shelter in place, including food, water and medical supplies; alternate sources of energy to maintain temperatures; emergency lighting; fire detection, extinguishing and alarm systems; and sewage and waste disposal.

➢ A system to track the location of on-duty staff and sheltered participants under the care of the PACE center(s) during and after an emergency. If staff and participants are relocated during the emergency, the PO must be able to document the name and location of the receiving facility or other location.

➢ Safe evacuation from the PACE center, including consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evaluation location(s); and primary and alternate means of communication with external sources of assistance.

➢ Procedures to inform state and local emergency preparedness officials about PACE participants in need of evacuation from their residences at any time due to an emergency situation based on the participants’ medical and psychiatric conditions and home environment.

➢ Means to shelter in place for participants, staff and volunteers who remain in the facility.

➢ System of medical documentation that preserves participant information, protects confidentiality of participant information, and secures and maintains availability of records.

➢ Use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency.

➢ Development of arrangements with other POs, PACE centers or other providers to receive participants in the event of limitations or cessation of operations to maintain the continuity of services to PACE participants.

➢ Role of the PO under a waiver declared by the secretary of the Department of Health and Human Services (HHS), in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials. (Note: Under section 1135 waiver authority, the HHS secretary temporarily may waive or modify certain Medicare and Medicaid requirements for providers in an emergency area.)

➢ Availability of emergency equipment, including easily portable oxygen, airways, suction and emergency drugs and staff who know how to use the equipment.
Communication Plan

The communication plan must comply with federal, state and local laws and be reviewed and updated at least annually. They must include the following:

➢ names and contact information for staff, entities providing services under arrangement, participants’ physicians, other POs and volunteers;
➢ contact information for federal, state, tribal, regional and local emergency preparedness staff and other sources of assistance;
➢ primary and alternate means for communicating with the following: PO staff and federal, state, tribal, regional and local emergency management agencies;
➢ method for sharing information and medical documentation for participants under the care of the PO, as necessary, with other health care providers to maintain the continuity of care;
➢ in the event of an evacuation, means to release participant information as permitted under 45 CFR 164.510(b)(1)(ii), which allows a covered entity to use or disclose protected health information (PHI) “to notify or assist in the notification of...a family member, personal representative of the individual, or another person responsible for the care of the individual of the individual’s location, general condition or death.” (See Appendix 1.)
➢ means of providing information about the general condition and location of participants under the care of the facility as permitted under 45 CFR 164.510(b)(4), which allows for a covered entity to use or disclose PHI to a public or private entity authorized by law or its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by 45 CFR 164.510(b)(1)(ii).
➢ means of providing information about the needs of the PO and its ability to provide assistance to the authority having jurisdiction, the Incident Command Center or designee.

Training and Testing

The PO must develop and maintain an emergency preparedness training and testing program based on its risk assessment, emergency plan, policies and procedures, and communications plan. The training and testing program must be reviewed and updated at least annually.

The PO must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing onsite services under arrangement, contractors, participants and volunteers consistent with their expected roles; provide emergency preparedness training at least annually; demonstrate staff knowledge of emergency procedures, including informing participants of what to do, where to go, and who to contact in case of an emergency; and maintain documentation of all training.

In addition, the PO must conduct exercises to test the emergency plan at least annually; participate in a full-scale exercise that is community-based (referred to as a “community mock disaster drill” in the proposed rule) or an individual facility-based exercise when a community-based exercise is not accessible; and conduct another exercise that may include a second full-scale exercise that is community-based, facility-based or tabletop that meets specific requirements. The PO must analyze its response and maintain documentation of all drills, tabletop exercises and emergency events and revise its plan as needed.

POs that are part of integrated health care systems can participate in the “unified and integrated” emergency preparedness program of the system if it meets the requirements outlined above and each separately certified facility is in compliance with the program and capable of actively using it.
Creating an Emergency Preparedness Program

The quality director’s role and responsibility is to ensure the PO leadership understands and supports the requirements set forth in the regulation during the transition phase and beyond. Quality directors provide regulatory oversight to facilitate understanding of the requisites to maintain compliance.

Quality directors also assist the individuals responsible for EOC, Safety and Emergency Preparedness within their organization in transforming the requirements into a sound emergency preparedness program. A PO may choose to have a distinct emergency preparedness committee separate from an EOC/safety committee.

To support an emergency preparedness program, quality directors must develop multiple facets within each of the four critical elements. The first step is to identify the person responsible for the program, taking into consideration the age of the PO and the status of its EOC committee. The person chosen to take the lead may be the safety team leader or EOC committee chair. This individual is responsible for ensuring that each critical element is developed, staff members are trained, and the plan is tested.

The quality director works in tandem with the lead throughout this process. While the lead can delegate components of the program to others within the PO to develop, the lead and quality director must review and approve all documents prior to implementation. CMS developed several tools to aid in the development of the emergency preparedness program. In this chapter, the State Operations Manual, titled “Appendix Z: Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance,” was used to provide consistent interpretive guidance of the requirements.
CHAPTER 13
Medication Management in PACE
While the use of medications and other therapeutics is one of the cornerstones of care provided by PACE organizations (POs) to their population of frail elders with multiple co-morbidities, the PACE regulations are silent on requirements for quality oversight of medication management in PACE. The Medicare Part D regulations largely speak to compliance with procedural and administrative requirements, but the PACE regulations generally leave medication management to the discretion of the PO, other than brief mentions of “medications” as required components of participant assessments and the medical record. Absent a specific regulatory requirement for quality oversight of medication processes and practices, the most valid justification for diligent medication oversight is to support the goals of ensuring effective, safe and optimal outcomes for participants and a continuous improvement process and ongoing education for PO providers and clinical staff.

PACE participants receive medications under any and all of three Medicare entities. Medicare Part A generally covers medications administered in a hospital setting, acute rehab setting or hospice. Medicare Part B covers medications defined as “incident to” a physician’s office visit, typically restricted to injectables such as vaccines, other one-time or intermittent injections, or medications administered as treatment for cancer or a Medicare-approved organ transplant.

Most medications that fall under the purview of POs are covered under the Medicare Part D prescription drug plan, a benefit to which participants explicitly are entitled as enrollees in PACE. Part D medications, including those administered at the day center or at a participant’s residence, are the primary medication-associated areas overseen by the quality program of a PO. While POs have wide variation in their processes of medication procurement, dispensing and administration — internal pharmacies, contracted pharmacies, integrated delivery system pharmacies, pharmacy benefit manager (PBM) vendors, mail-order pharmacies, formularies, etc. — all have an obligation to maintain strong quality oversight because medication management has significant inherent safety risks, as well as financial costs to the organization.

**Medication Management Challenges**

Quality oversight of medication processes has unique challenges in a PACE environment not seen in many other care venues.

**Formularies**

Managed care organizations (MCOs) use a drug formulary, i.e., a restricted list of prescription drugs from which providers and practitioners may choose, based on cost-benefit analysis, drug safety and other factors. The formulary affords MCOs an opportunity to monitor utilization patterns, costs, frequency of adverse drug events (ADEs), and medication errors in their provider networks. The sheer volume of MCO prescriptions warrants the use of information technology to monitor these indicators. In contrast, few POs have reason to utilize drug formularies, in part because there are relatively few medication prescribers and a relatively small number of beneficiaries who are well known to their physicians and clinical staff. The impact on the quality program is that the PO has to maintain a robust surveillance program, sometimes manually, to ensure that medication management is monitored carefully.

**Factors Complicating Medication Management in PACE**

The U.S. Food and Drug Administration (FDA) defines a medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.”

Error tracking, a critical function for the quality director, is complicated by the unique characteristics of many PACE participants:

➢ The high prevalence of participants with multiple co-morbidities implies a higher number of medications per individual, raising their vulnerability to medication errors, drug interactions and drug intolerances.

➢ The frequency of Alzheimer’s disease and other forms of dementia among PACE participants creates problematic issues in medication oversight, especially where at-home self-administration of medications is necessary.

➢ Medical conditions that are widespread in the frail elderly require so-called “Beers criteria” drugs. These drugs potentially create high risks for use in the elderly, due in part to kidney and liver changes in advanced age and undue sensitivity to certain medications.2

➢ The rate of cognitive decline, mental and behavioral health issues, and health illiteracy tend to complicate medication management and create in-home environments in which unusual behaviors (e.g., hoarding) and drug diversion opportunities are disproportionally higher than the general population.

In the face of these factors, one important challenge for the PACE quality director is to devise and maintain a robust medication management oversight capability that accommodates the characteristics commonly present in participants. At the same time, the program should recognize and manage the uncertainty that results from the administration of medication in several locations that are not always under the control of PACE clinical staff.

**High-Cost Medications**

The recent emergence of increasingly costly medications for the treatment of diseases common in the elderly has added the necessity for active medication monitoring by POs. Drugs for hepatitis C (e.g., Sovaldi® and Harvoni®), certain autoimmune diseases (Humira®, Remicade® and Cosentyx®, among others), refractory heart failure (Entresto®), “overactive bladder” (Myrbetriq®), and anticoagulants with comparable safety to coumadin (Eliquis® and Pradaxa®) have potential applications, but their expense and relatively limited experience in the frail elderly population pose safety and financial challenges to POs.

The quality director should review unique questions with the provider group, the PO pharmacist or contractor, and PBM, if relevant:

➢ What safeguards can be implemented to ensure that these expensive medications will be taken as prescribed for the full duration of treatment? Can the medication schedule be adapted so administration is conducted at the day center, or can safeguards be implemented in the home to ensure adherence and exclusion of diversion opportunities?

➢ Is the likelihood of a beneficial clinical outcome or functional improvement high enough to warrant the expense and risks of potential harm of some of these medications, or are the benefits primarily cosmetic or related to convenience?

➢ Could the use of prescribing guidelines for these medications be misconstrued justifiably as having a de facto formulary? If so, would this misperception require the PO to submit a formulary to CMS, increasing compliance requirements for formulary adherence and additional Part D regulations?

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Developing a collaborative strategy regarding this group of high-cost medications would enable the quality director to put measures or indicators in place to help monitor the outcomes of participants on these agents.

**Fraud, Waste and Abuse**

The interests of CMS in fraud, waste and abuse (FWA) are as applicable to PACE programs as they are to other Medicare Part C entities. Though POs have relatively few beneficiaries as compared to large MCOs, there are still potential vulnerabilities for POs, especially in “chain of custody” practices in medication delivery, prescription fills and renewals, opportunities for diversion of controlled substances, and the use of patient assistance programs and/or pharmaceutical samples by contracted specialists to offset the costs of expensive drugs and biologicals.

Though these tend to be rare events in POs, the quality director’s most effective compliance tool is a comprehensive policy describing measures to monitor FWA in these areas, as well as a process for staff to report incidents of suspected FWA. The quality director can partner with leadership and the compliance officer to devise the policy and to ensure that staff and contractors understand and adhere to its provisions.

**Medication Management Oversight for the Quality Director**

The “typical” PACE participant is 77 years old, has multiple medical conditions, takes 9 Part D prescription drugs, and has a 47 percent likelihood of having some degree of dementia. This information alone suggests some of the inherent challenges in medication management for this frail population. As frequently as most participants attend the adult day center, living in the community rather than a nursing home implies that they do not typically receive direct clinical supervision 24 hours a day.

As a result, medication management in PACE faces multiple challenges:

- adherence with prescribed medication regimens;
- surveillance for medication errors;
- monitoring of adverse drug events;
- accurate reconciliation of medications during/after transfers between care sites (e.g., inpatient rehabilitation to home or hospital to home); and
- management of mental and behavioral health issues and/or opioid dependence.

Acumen, LLC, and Westat published a monograph for CMS titled “Medication Therapy Management (MTM) in Chronically Ill Populations” (August, 2013). This study offered research support regarding the impact of aggressive medication management on adherence, prescription safety and related issues for populations with elderly and other chronically ill individuals. The publication, posing key questions and highlighting best practices in drug management, is applicable to much of the PACE population. However, the challenge for quality directors is to help their organizations in customizing medication oversight and management to meet the unique demographic and cultural needs of their participant populations.

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3 NPAonline.org, Infographic
Medication Adherence

The Acumen study noted the serious challenges in ensuring that chronically ill populations comply with medication regimens prescribed by their clinical providers. Many in this population see multiple providers for multiple co-morbidities and typically receive multiple medications with different dosage regimens. Nearly 50 percent of PACE participants have some degree of dementia and health literacy issues – the ability to fully comprehend the purpose, need for, and potential adverse effects of their medications – that further complicate their ability to adhere to their regimens. Additionally, PACE participants commonly receive medications in multiple venues (e.g., clinic and home setting) through a variety of caregivers (e.g., clinic staff, multiple family members, home care services, self-administration). Finally, the emergence of behavioral health issues (e.g., hoarding behaviors, paranoia) can overlay the entire medication process.

For these reasons, systematic reviews of medication adherence are difficult to undertake in the PACE environment. Thus, most incidents of adherence variances likely go unreported and undiscovered until an unexplained clinical concern arises, a pharmacy notes changes in prescription refill frequency of a medication, a home health nurse or aide discovers too few or too many doses of medication in the household, or other variances are discovered by serendipity.

The challenge for the quality director is coordinating an adherence program in the midst of these complex variables. Attempts to establish a data-driven process for medication adherence is likely to suffer from both inaccurate numerators and denominators. As a result, the optimal quality tool simply may be a review of each case having identified medication adherence variances as a method of determining if there are opportunities for improvement.

Polypharmacy

The Centers for Disease Control and Prevention (CDC) defines polypharmacy as “treatment with prescription drugs from six or more drug classes concurrently.” Other common time-tested definitions – such as “administration of more medications than clinically indicated, representing unnecessary drug use” – are more compatible with definitions currently in use in POs. The use of multiple medications is unsurprising in a PACE population in which conditions with multiple co-morbidities are common, as well as multiple specialty physicians managing particular diseases. As a result, participants not only are exposed to the intended effects and side effects of multiple medications, they are susceptible to drug-drug interactions, drug-disease interactions, exaggerated drug effects related to impaired metabolic processes in the elderly, and physicians’ difficulty in distinguishing apparent side effects from other common symptoms. Thus, causes of symptoms seen in the PACE population (e.g., falls, mental status changes, dizziness, nausea) may be difficult to differentiate from drug side effects, and they present challenges to maintaining participant safety.

Most PO clinical staff and IDT members are well aware of the challenges that polypharmacy creates, so a quality director’s role may be limited to ensuring that periodic but systematic reviews of participants’ medications remain a priority for the PO. With a goal of reducing a participant’s medication profile to the fewest number of drugs safely, medication reviews are performed successfully in POs via several mechanisms:

➢ by the PCP or medical director at the time of enrollment and during each participant reassessment;

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➢ by an internal or contracted pharmacist or by geriatric pharmacy residents/fellows if affiliated with an IDS or teaching hospital; or
➢ by a pharmacy benefits manager or other contracted consultant.

The quality director can oversee and ensure the review of polypharmacy by including this review as an indicator for the pharmacy or clinic departments in the quality work plan.

**Medication Errors**

While most health care organizations use a definition of medication error that is similar to that of the CDC, there is less widespread agreement on what constitutes an error in a given health care setting. In general, opportunities for error can arise at any point in the medication chain: prescribing and dosing, transcription, fulfillment, labeling, delivery, administration and documentation. Each of these milestones in the medication chain provides multiple opportunities for potential errors. A prescriber, for example, inadvertently can order an incorrect drug, specify a dosage regimen or route of administration that is incorrect for the patient, or overlook allergies or incompatible medications. A pharmacy can supply the wrong medication, mislabel a blister pack, omit a medication, transcribe an incorrect frequency, or overlook an order.

A quality director has four primary “customers” of the PO medication error surveillance program:

➢ participants and caregivers, who benefit from a safe, therapeutic medication regimen;
➢ clinical staff, who practice most effectively in an environment that prioritizes safety and identifies opportunities for improvement;
➢ the PO, which has regulatory compliance and quality reporting obligations to CMS; and
➢ other stakeholders, including the governing body, health care system, NPA and others, which have expectations of receiving QI data that is aggregated, analyzed, and stratified, if necessary.

Because there are multiple customers of medication error data, the quality program generally will have to determine in advance the various metrics these customers wish to review. For example, some customers might wish to exclude error data for self-administered medications, because those events are not under direct control of the PO. Others specifically might want to focus on self-administration errors because they could help signal opportunities for improvement for in-home medication practices. Similarly, data customers may vary in the expectations of how the data is expressed, such as error events per month, per thousand participant-days, and per participant. As with most data collection and analysis initiatives, the optimal result may be derived working backwards from the desired outcome.

**Adverse Drug Events**

The Institute of Medicine (IOM) defines an adverse drug event (ADE) as an injury resulting from medical intervention related to a drug. The IOM includes medication errors in its definition, which also encompasses adverse drug reactions, allergic reactions and overdoses. While the vast majority of ADEs are said to be preventable in general, the evidence specifically regarding the PACE population is less clear. The Beers criteria, for example, were designed to remind providers of medications that are inherently high risk in elder populations, resulting more frequently in such side effects as sleepiness and fatigue, confusion, dizziness, falls, gastrointestinal intolerance and neurologic issues.

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As in the case of medication adherence, an important strategy for the quality director is ensuring the review of cases in which ADEs are identified because they may have significant impacts on participant safety and each event is a potential educational opportunity for PO clinicians. In addition, the PO has reporting responsibilities for serious adverse events, such as Level II reporting requirements to CMS and the State Administering Agency (SAA).

The PO may have other data reporting responsibilities, such as aggregate data documenting the prevalence of adverse events within their participant population. Unfortunately, these incidents are heavily reliant on characteristics of the unique participant population of the PO, suggesting that data from one organization may not be comparable to data from another. The task for the quality director is to collaborate with the IDT and clinical staffs to determine, track, trend, and analyze metrics that are appropriate for the enrolled population.

**Medication Reconciliation**

Most health care organizations have processes in place to support safe patient transfers from one facility or venue to another. The Institute for Healthcare Improvement defines medication reconciliation as “the process of creating the most accurate list possible of all medications a patient is taking – including drug name, dosage, frequency and route – and comparing that list against the physician’s admission, transfer and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the (health care system).” Because recent research has demonstrated that many medication errors occur at the seams of care, i.e., from hospital to subacute rehabilitation, hospital to home, or clinic to home health care, CMS has supported the collaborative Hospital Improvement Innovation Networks, known more popularly as the Partnership for Patients. Focusing primarily on preventable hospital errors and care transitions, its efforts are applicable to the care of PACE participants, whose care transitions occur between the hospital, skilled nursing facility, short-term rehab facility and home.

Thus, the quality director has a role in ensuring that the PO clinical staff maintains a systematic process to reconcile medications, especially when participants transfer in and out of care at other sites. In addition, tracking and trending lapses in the reconciliation process should benefit the quality director by identifying opportunities for additional training and staff resources to minimize preventable medication errors that can occur at these seams of care.

**Mental and Behavioral Health and Opioid Dependence**

Per anecdotal reports, POs currently are noting that they are observing a higher prevalence of mental and behavioral health issues and opioid dependence in recent enrollees. This is a relatively new population for many POs, who are looking to enhance their expertise in managing participants with these conditions and considering the addition of new resources (e.g., mental health social worker, psychologist or psychiatrist, substance abuse counselor). The impact on organizational quality programs is still evolving, and quality directors will be in the position to help the PO in developing metrics that assist in evaluating and improving the provision of care to these participants.

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7 Institute for Healthcare Improvement. Medication Reconciliation to Prevent Adverse Drug Events.
CHAPTER 14
Service Delivery Requests, Appeals and Grievances (SDAG)

Author: Emmanuel Cheo
Editor: Sunny Keeton
This chapter assumes the existence of written procedures for grievances, appeals and service delivery requests, as well as feedback and quality modalities such as a Participant Advisory Committee, and is intended to serve PACE quality directors and personnel as a guide-by-review. Whenever feasible, regulatory text is quoted verbatim for accuracy, and page numbers are included for reference. Sample diagrammatic representations of processes are included for illustration, with the understanding that procedures, sequences and internal time frames vary across organizations. Sample diagrams, tables and forms illustrated in this chapter are used with permission from Mercy LIFE in West Springfield, MA.

Service Delivery Requests (SDR)/Service Request

Definition (42 CFR §460.104 (d)(2))

A service delivery request refers to any instance in which “a participant (or designated representative) believes that a particular service needs to be initiated, continued, or eliminated for the participant” (Federal Register, 2006, p. 71289). A service request serves as a trigger for (an in-person) participant reassessment.

Regulatory Requirements (42 CFR §460.104 (d)(2))

➢ The PO must have explicit procedures for timely resolution of each service request.
➢ The appropriate discipline(s) with expertise relevant to the request “must reassess the participant” (Federal Register, 2006, p. 71289). This “requires an in-person reassessment when the participant or representative believes a participant needs to initiate, eliminate, or continue a particular service” (Federal Register, 2006, p. 71302).
➢ The reassessment shall “evaluate whether it is necessary to increase, continue, reduce, or terminate particular services and whether a different course of treatment is needed” (Federal Register, 2006, p. 71289).
➢ The appropriate discipline(s) reassessing the participant may trigger a comprehensive reassessment if the participant’s health status so requires or if the team member(s) deem it a significant change or in the best interest of the participant’s health.
➢ “The IDT must notify the participant (or designated representative) of its decision to approve or deny the request as expeditiously as the participant’s condition requires but no later than 72 hours after the IDT receives the request” (Federal Register, 2006, p. 71290).
➢ The IDT may extend the 72-hour deadline to approve or deny the service request “by five additional days if the participant or designated representative requests the extension or if the team documents its need for additional information and how the delay is in the interest of the participant” (Federal Register, 2006, p. 71290).
➢ The IDT must notify the participant or designated representative of its decision to approve or deny a service request as expeditiously as the participant’s condition requires, but no later than within 72 hours of the service delivery request unless the time frame is extended. Decisions to deny a request must be explained both orally and in writing (Federal Register, 2006, p. 71290).

Service Requests Operationalized

Requests: Any participant or designated representative may initiate a service request verbally or in writing per the procedures of the PO. A service request serves three functions: to provide an opportunity to periodically reassess the participant to ensure that the care plan is consistent with the participant’s health needs (medical and non-medical); to allow the participant or designated representative a meaningful say in the direction and design of care; and to give the participant or designated representative an “opportunity
to express any dissatisfaction with the manner in which care or services are furnished” (Federal Register, 2006, p. 71289).

**Informed Consideration of Requests:** Regulatory requirements call for participant in-person reassessment (to evaluate a service request) by the appropriate team members as a result of the service request, in accordance with PO policies. The methods of assessment used by IDT members should be in alignment with the operational procedures of the PO.

**Decision and Response:** CMS does not specify whether the 72-hour time frame for a service request decision begins when the request is made of an IDT member or when the request is presented to the full IDT. The safest course for a PO is to define in policy which interpretation it adopts and ensure that its practice in managing service requests follows that policy. The response period may be extended by an additional five days. The regulations assume that each request is urgent in light of the general frailty of the health of PACE participants. It is prudent for an IDT member to notify the participant or a designated representative as soon as possible following the team’s decision. This responsiveness may foster rapport, trust and participant satisfaction. All notifications must be documented. Referring to 460.104(d)(2)(iv), participants or designated representative must be informed orally and in writing of denials. Further, a PO is responsible for conveying the following: specific reasons for denial, right to appeal, explanation of both standard and expedited appeals processes, and continuation of appealed services through the appeal period.

**Adverse Action:** An adverse action is any determination or action that wholly or partly runs counter to the participant’s desire, request, or current plan or level of services, e.g., if the IDT fails to notify the participant or designated representative of its decision within the regulatory time frame(s) or if the participant or designated representative disagrees with the decision of the IDT. Such a decision may involve denial, wholly or in part, of a service request or the decision by the IDT to reduce or terminate services, for example. These constitute grounds for appeal as detailed in 42 CFR sections 460.122 and 460.124.

**Compliance Considerations:** Much can transpire between the receipt of a service delivery request from a participant or designated representative and consideration of the SDR by the entire IDT. Monitoring of the 72-hour clock - whether it is deemed to begin when the request is made of an individual IDT member or when the request is presented to the full IDT - holds value for both quality assurance and compliance purposes.

The role of the quality director in the service delivery request process is vital. Variances on the process that may seem minor may turn out to be impactful in terms of regulatory compliance or non-compliance. Therefore, QI activities should include close monitoring of handoffs, such as the substance of and time frames between points of contact, e.g., when the original request was made to PO staff (IDT or non-IDT) and handoff of the request to the appropriate disciplines and its presentation to the entire IDT, in-person participant assessment, IDT decision, and initiation of services/changes. Data analysis and trending also may illustrate areas (intervals) in need of improvement and good performance, thereby informing QI priorities. Collaboration between the quality director and IDT may yield outcomes that reinforce (review of regulations), streamline (process improvement), and invigorate the process (best practices) to facilitate optimal care, participant rights and well-being, and quality of life. The value of a keen knowledge of applicable regulations and industry trends and collaborative oversight of the service request process by the quality director cannot be overstated.

**Documentation and External Reporting:** Service requests and corresponding assessments, including IDT decisions, should be documented clearly in the participant’s records, including consideration of the request, actions taken to arrive at decisions, and outcomes. NPA and the Quality Committee Audit
Taskforce developed a service delivery request audit data universe template that can be utilized by POs. The audit data universe may be used to track elements of the service delivery process, and the NPA template facilitates the collection of the universe data.

A service request log should incorporate data elements that can be analyzed for purposes of quality improvement and compliance with regulatory mandates (§460.200):

- **Data Collection**: For analysis and trending to inform QI activities and for reporting, including to CMS and SAA.
- **Record Keeping**: “Protect from loss, destruction, unauthorized use or inappropriate alteration” *(Federal Register, 2006, p. 71324)*.
- **Access to records by CMS and SAA**, upon request.
- **Confidentiality**: Safeguard the privacy of personal identifying information.

(Note: The following form is utilized by Mercy LIFE Massachusetts and was developed to align with its policy.)
APPENDIX A

Service Delivery Request (SDR) Form

[Part of Medical Record – Please Write Legibly]

Participant: ______________________________________________________

Team: □ East □ West

Request DATE: ____________________________

Request TIME: ____________________________

Last First Middle

Date presented to IDT: ____________________________

Deadline for IDT decision = 72 hours after DATE presented to entire IDT: ____________________________

□ The participant and/or authorized representative (requesting party) has been informed of his/her right to request assistance in completing a Service Request (SDR) form, and that service requests can be made verbally, in writing to/through any Mercy LIFE staff. The participant (ppt) has been informed that a decision will be made within 72 hours after the service request is presented to the entire IDT, and that if additional time is needed to gather information, the team may take an additional five (5) days to make a decision.

Name of person making request (requesting party): ____________________________

Requesting party’s relationship to participant: ____________________________

Staff person assisting to make this service request: ____________________________

(Name and title of staff member)

This service request is/was made: □ Verbally, by phone □ Verbally, in person □ In writing □ Other: ____________________________

Summary of Request: [Check here □ if additional written documentation is attached]

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

IDT Person(s) Responsible: ____________________________

Name/Title

□ Additional time needed (5 additional days MAX) □ Extended DEADLINE: ____________________________

□ Requesting party aware/informed of need for more time and how it is in participant’s interest

□ Reason: ____________________________
In-Person Assessment

❑ ** An in-person service delivery request assessment was conducted on: ________________________
  By [if done by different person(s)]:

In-Person Assessment Findings

**IDT Decision** (Enter Date):

❑ Approved: ___________________  ❑ Denied: ___________________  ❑ Partially Denied: ___________________
❑ Rescinded: ___________________  → Reason: __________________________

IDT Decision Details:

________________________________________________________________________________________________
________________________________________________________________________________________________
________________________________________________________________________________________________

**Timeliness** [Approved, Denied or Deadline Extension]:

Requesting party **verbally notified within 72 hours** after SDR presentation to IDT

**Approved Request:**

Approved services or change(s) were [or will be] initiated on [date]: ____________________________

**Denied Request:**

❑ Oral denial notification provided to the requesting party on [date]: ____________________________
❑ Oral denial notification included the **specific reason** in clear and understandable manner
❑ Oral denial notification included the **right to appeal**

**Outcome of Oral Notification** – The Requesting Party:

❑ Wants more information on appeals process  ❑ Verbalizes understanding
❑ Other: ________________________________  ❑ Wants to appeal (Attach Appeal Request)

Full Name/Title of IDT Person Responsible _______________________________________________________
Signature __________________________________________ Date Completed ____________________________

**DO NOT WRITE BELOW THIS LINE – FOR QUALITY IMPROVEMENT (QI) AUDIT**

<table>
<thead>
<tr>
<th>Date received by QI:</th>
<th>SDR Log → IDT</th>
<th>In-person ASSESSMENT</th>
<th>Timely DECISION</th>
<th>Participant NOTIFICATION</th>
<th>Services INITIATED</th>
</tr>
</thead>
</table>

Appendix A courtesy of Mercy LIFE, Massachusetts
**Appeals**

**Definition (42 CFR §460.122)**

An appeal is “a participant’s (or designated representative’s) action taken with respect to noncoverage of or nonpayment for a service,” including “denial, reduction or termination of services” (CMS, 2006, p. 71301-3).

**Regulatory Requirements (42 CFR §460.122, §460.124, §460.104)**

The PO must do the following:

1. “Have a formal written appeals process, with specified timeframes for response.”
2. Inform all participants of the process in writing “upon enrollment into the PACE program, at least annually thereafter, and whenever the IDT denies a request for services or payment” (CMS, 2006, p. 71301).
3. Have an appeals process that ensures and includes procedures for the following:
   a. timely preparation and processing of written denials of coverage or payment;
   b. filing of appeal;
   c. documentation of appeal proceedings;
   d. appointment of “an appropriately credentialed and impartial third party who was not involved in the original decision” and will not have a stake in the outcome to review the participant’s appeal (p. 71301);
   e. appeal determinations to be “based solely on the participant’s medical need and not on other reasons, such as the cost of the disputed care, who is paying the third-party reviewer’s salary or fee, an individual’s reputation or other factors” (p. 71302);
   f. responding to and resolving “appeals as expeditiously as the participant’s health condition requires, but no later than 30 calendar days after the PO receives an appeal”;
   g. maintaining confidentiality of appeals;
   h. a shorter timeframe for expedited appeals; and
   i. protecting the participant’s or designated representative’s right to present supporting evidence in the appeal in person and/or in writing.
4. Continue providing non-disputed services based on the participant’s care plan that maintain the participant’s “functional status” during the appeal process since the participant “must receive care solely through the PO” (Federal Register, 2006, p. 71301-302; see also §460.98).
5. Report all adverse appeal determinations to CMS and the SAA in a timely manner. To safeguard participant rights, conduct an external review during the CMS/SAA audit of the PO and trend and report via HPMS quarterly.
6. Assist the participant or designated representative to understand additional appeals options, noting that either process is valid but cannot be utilized concurrently:
   a. Dually eligible participants: May elect to appeal via the contracted Independent Review Entity (Medicare) or the State Fair Hearing (Medicaid) process. (See Figure 5.)
   b. Medicaid participants only: Via State Fair Hearing (SFH) process.
   c. Medicare participants only: Via Independent Review Entity (IRE).
7. Comply with state laws regarding timeframes for external appeals through the State Fair Hearing process by incorporating timeframes in PO procedures and notices.

8. Facilitate participants’ access to the state external appeals process (State Fair Hearing) for those who challenge adverse disenrollment actions. (See also §460.164.)

**Appeals Operationalized (42 CFR §460.122, §460.124, §460.104)**

**Grounds for Appeal:** Appeals can be triggered by, and when, a participant or designated representative notifies PO staff verbally or in writing of intent or desire to challenge an IDT decision (denial, reduction, termination, nonpayment or noncoverage of services), or disenrollment determination. The appeal is an exercise of participants’ rights and promotes participant involvement in care decisions.

**Notification:** The PO must provide the participant or designated representative a written notice regarding participant rights and the appeal process in instances outlined in the above “Grounds for Appeal.” The PO also must advise participants of “additional appeal rights under Medicaid or Medicare, assist participants in choosing which appeals process to pursue if both are applicable, and then forward the appeal to the appropriate external entity” (*Federal Register*, 2006, p. 71303). A determination on the appeal must be rendered no later than 30 days from the date of receipt of the appeal (except in the event of an expedited process), and the PO must notify the participant or designated representative of the outcome.

**Considerations for Expedited Appeals:** In cases where the participant or designated representative believes “life, health or ability to regain maximum function would be jeopardized” if the disputed service is not provided, the PO must have an expedited process. While 72 hours is the regulatory maximum timeframe within which to review and render a determination, the deadline can be extended by no more than 14 calendar days under the following conditions:

- the participant so requests;
- the PO justifiably demonstrates “need for additional information and how the delay is in the interest of the participant” (DHHS, 1999, p. 66258).

**Medicaid Participants:** During the appeals process, the participant may elect to continue receiving disputed services with the understanding that an unfavorable determination may result in the participant or designated representative being responsible for the cost of the disputed services received during the appeals process. This must be clearly communicated to those involved.

**Documentation and External Reporting**

- **Data Collection:** For analysis and trending to inform QI activities, and reporting including to CMS and SAA.
- **Record Keeping:** “Protect from loss, destruction, unauthorized use or inappropriate alteration” (*Federal Register*, 2006, p. 71324).
- **Access to records by CMS and SAA, upon request.**
- **Confidentiality:** Safeguard of the privacy of personal identifying information.
- In addition, “determinations that are wholly or partially adverse to the participant must be forwarded to CMS and the SAA” (*Federal Register*, 2006, p. 71302).
Figure 1: Sample Appeals Process

A Notice of Action (denial letter) is provided to the participant or designated representative following an adverse IDT decision involving non-coverage of, or non-payment for services; or denial, reduction, or termination of services

Participant appeal rights, process and timeframes explained in writing

Participant or designated representative expresses disagreement with decision(s) outlined in Notice of Action

Participant or designated representative files an appeal verbally or in writing (assisted if so desired) with PO

Quality Director acknowledges receipt of formal appeal (in writing) within 5 days

Participant or designated representative believes life, health, or ability to regain maximum function would be jeopardized if the disputed service is not provided?

YES → Expeditied Appeals Process (determination within 72 hours)

NO → Standard Appeals Process (determination within 30 days)

Expeditied Appeals Process (determination within 72 hours)

Credentialed Impartial 3rd Party appointed to review appeal

Participant or designated representative notified of proceedings in writing and may present evidence in writing or in person (interpreter services provided if needed)

The 72 hour timeframe may be extended by up to 14 days if participant or designated representative so requests, or PO justifies the need to the SAA

Standard Appeals Process (determination within 30 days)

Credentialed Impartial 3rd Party appointed to review appeal

Participant or designated representative notified of proceedings in writing and may present evidence in writing or in person (interpreter services provided if needed)

Determination partially or wholly adverse to the participant?

NO → PO notifies participant of appeal outcome and initiates/resumes services as expeditiously as the health condition of the participant requires

YES → PO notifies CMS and SAA. PO notifies and assists participant or designated representative with additional appeal options

Figure 1 courtesy of Mercy LIFE, Massachusetts
**Figure 2: Additional Appeals Options**

**EXTERNAL APPEALS**

- **Medicare ONLY Participants**
  - Appeal to/through Medicare's Independent Review Entity

- **Dually Eligible Participants**
  - **EITHER Process (NOT BOTH)**

- **Medicaid ONLY Participants**
  - Appeal to/through the State's Fair Hearing Process within 20 days of Notice of Action

**Participant or designated representative believes life, health, or ability to regain maximum function would be jeopardized if the disputed service is not provided?**

- **YES**
  - Expedited appeal process (determination within 72 hours)
    - Participant or designated representative notified of proceedings in writing and may present evidence in writing or in person (interpreter services provided if needed)
    - The 72 hour timeframe may be extended by up to 14 days if participant or designated representative so requests, or PO justifies the need to the SAA
    - PO notifies participant of appeal outcome and initiates/resumes services as expeditiously as the health condition of the participant requires

- **NO**
  - Standard appeal process (determination within 30 days)
    - Participant or designated representative notified of proceedings in writing and may present evidence in writing or in person (interpreter services provided if needed)
    - Determination partially or wholly adverse to the participant?
      - **NO**
      - **YES**
        - PO notifies and assists participant or designated representative with additional appeal options

*Figure 2 courtesy of Mercy LIFE, Massachusetts*
References


Grievances

Definition (42 CFR §460.120)

A grievance is “a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished [by a PO or its agents, including contracted service providers]...whether medical or non-medical” (Federal Register, 1999, p. 66256).

Regulatory Requirements

1. Each PO, in accordance with the requirement to “establish procedures for grievances,” must have a “formal written process to evaluate and resolve grievances, whether medical or non-medical in nature, by PACE participants, their family members or representatives” [Department of Health and Human Services (DHHS), 1999, p. 66256-257]. This provision ensures that each PACE employee is knowledgeable about the process and thus able to assist participants or their designated representatives.

2. The grievance process must be explained verbally and in writing upon enrollment, at least annually thereafter (in plain understandable language), and whenever the participant or participant’s representative expresses dissatisfaction with service delivery or quality of care over which the PO has jurisdiction, responsibility or oversight. This information also should be furnished as a reminder to the participant or participant’s representative whenever a grievance is filed.

3. The minimum requirements for a PO grievance process include (written) procedures for:
   a. Filing a grievance.
   b. Documenting the grievance: Using a grievance form. (See sample below.)
   c. Timely resolution of the grievance, and communication of the resolution plan to the participant or participant’s representative
   d. Safeguarding confidentiality of the participant’s grievance (from filing of grievance through investigation, resolution, documentation, quality assurance analyses, external regulatory reporting and record keeping). This provision is “intended to prevent reprisal against the participant” (Federal Register, 2006, p. 71300).

4. Fair, uniform consideration of grievances and coordination of resolution.

5. Optimal “communication between different individuals who are responsible for reviewing and resolving grievances” (DHHS, 1999, p. 66257).

6. “The PO must maintain, aggregate, and analyze information on grievance proceedings” to inform continuous performance improvement activities (Federal Register, 2006, p. 71300).

Grievances Operationalized

The grievance process is broken down into segments for illustration, each of which has a specific focus, though not separate from the preceding or subsequent one. These steps should be viewed as parts of a continuum rather than separate or independent procedures.

Grievance Filing: Any participant or designated representative may file a grievance, verbally or in writing, with any PO staff member. Interpreter services should be made available to those who need it to facilitate communication.
Grievance Documentation: A sample grievance filing form (Appendix B), and grievance resolution form (Appendix C) are included here for illustration. Maintenance of grievance documentation must comply with regulations that mandate the following:

➢ Data Collection: For analysis and trending to inform quality improvement activities and for reporting, including to CMS and SAA.
➢ Record Keeping: “Protect from loss, destruction, unauthorized use or inappropriate alteration” (Federal Register, 2006, p. 71324).
➢ Access to records by CMS and SAA, upon request.
➢ Confidentiality: Safeguard the privacy of personal identifying information.
➢ Communication: Between persons involved in grievance resolution efforts.

Timely Resolution: It is both a regulatory requirement and prudent practice to resolve all grievances in a timely manner. However, the regulations do not stipulate specific timeframes for grievance resolution. “As expeditiously as the participant’s health requires” may serve as a de facto guideline for setting appropriate timeframe(s) for grievance resolution and internal PO procedures regarding time. For example, while a goal of resolving each grievance within 30 calendar days (20 business days) may be generally reasonable, it is not optimal for every grievance. Some grievances may be resolved fairly immediately, such as dissatisfaction regarding a food selection/item during a mealtime. More complex grievances requiring collaboration and coordination between departments, including contracted services, may take several days or weeks to resolve. The sooner a grievance is resolved, the less likely it is to persist, resulting in similar negative experiences by other participants and caregivers. Trending the turnaround time (from filing through resolution and participant notification) may be useful to a quality director for evaluating process efficiency.

Grievance Dilemma: There may be situations where PACE participants or designated representatives express dissatisfaction with a service, an outcome or a process and yet decline to file a formal complaint (grievance) on the premise that they do not want to “get anyone in trouble.”

It is important to view and treat each grievance as actionable feedback. Each grievance serves a triple purpose of providing input that drives quality and performance improvement, informing customer satisfaction activities, and ensuring participant rights are protected and actualized. On the one hand, participant rights include the right to self-determination within the context of receiving care services through the PO. On the other hand, the PO is duty-bound to continually improve for the benefit of each participant in a manner consistent with CMS regulations and internal procedures. Hence, PO processes should be geared toward addressing each complaint (grievance) for resolution through timely improvements.

Faced with the above dilemma, consider the two approaches commonly applied by POs. The first is to treat and track each complaint as a grievance, addressing each until resolved to the satisfaction of the participant or participant’s representative, and include each in HPMS Level I reports. The second is to treat and track formal grievances for resolution and HPMS Level I reporting, while complaints that the participant or participant’s representative do not wish treated as formal grievances are addressed using the grievance resolution process but not tracked for HPMS Level I reporting. As a practical matter, for purposes of continual process improvement and participant satisfaction, the first option would be optimal for a number of reasons. Each grievance and resolution plan becomes part of the fabric of PO operations. Consequently, the second option may not reflect the breadth of the PO process improvement activities relative to
grievance resolution, particularly in terms of external reporting. When in doubt, seek guidance from the regional CMS account manager and State Administering Agency (SAA).

Another tested approach to decreasing the stress participants experience with the notion of filing a formal grievance is to incorporate alternate terms such as “feedback” and “concerns” into the PO grievance policies and procedures to be used interchangeably with the word “grievance” (complaint). This should be done in consultation with the regional CMS account manager and the SAA.

Anecdotal reports from one PO indicate relative success at decreasing the level of anxiety some participants experience as a result of the grievance dilemma. This PO proposed to the CMS account manager and SAA the words “feedback” and “concerns” for use interchangeably with the word “grievance” for the purposes of communicating grievance resolution action plans with participants who were reluctant to file a grievance to begin with. Because each grievance is feedback that the PO uses to identify improvement needs, the participant population of the PO responded positively (less negatively) to the idea of providing feedback using the PO grievance process. This required staff education and participant awareness campaigns that included reinforcement of the organization’s openness to feedback, discussions with participants and caregivers at participant council and PAC meetings, and with each participant who verbalized apprehension with filing a formal grievance (complaint).

**Grievance Investigation:** CMS regulations allow POs flexibility to investigate and resolve grievances proactively. Thus, our duty to beneficence, non-maleficence, as well as justice requires that each grievance be investigated and resolved fairly and timely. A quality director is in a unique position to ensure that investigations are conducted by the appropriate person(s) to resolve the issue(s) effectively or comprehensively that are the subject of the grievance.

**Grievance Resolution:** Each grievance must be resolved. Regulations require that the PO “acknowledges the participant’s concern, tries to address the problem, and makes any necessary adjustments in service delivery” (*Federal Register*, 2006, p. 71300). Each grievance resolution should demonstrate process improvement(s) as a result of the corrective actions implemented by the PO and met with an expression of satisfaction by the participant or designated representative. The ultimate test for satisfactory resolution of a grievance is participant satisfaction.

**Notification:** The PO is required to notify the participant or designated representative upon receipt of his or her grievance. It is also prudent to notify the participant or participant’s representative of the outcome of a grievance – in addition to the regulatory requirement for written annual and periodic notification regarding the grievance process – to ensure that corrective action plans and improvements appropriately address the grievance.

**Process Improvement:** “By analyzing the number and types of grievances, a PO will be able to develop activities to monitor and improve the grievance resolution process, as well as identify and make improvements or modification in care” (*Federal Register*, 2006, p. 71300). Consequently, periodic internal systems review and update of procedures, in collaboration with the executive team, are necessary. Figure 1 outlines a process for testing and improving the internal grievance apparatus for regulatory compliance and efficacy. It illustrates an internal systems review cycle that can be applied to other internal processes and procedures such as the service request cycle. Analysis findings are reported per PO procedures and CMS and SAA regulations.
Figure 3: Grievance and Resolution Internal Systems Review Cycle

- **Periodic evaluation of processes**
  - Collect, analyze, trend & report data

- **If NO**
  - Are grievances timely resolved?

- **If NO**
  - Are grievances appropriately investigated?
    - **If YES**
      - Staff training
    - **If NO**
      - Staff training

- **If NO**
  - Are grievances timely resolved?

- **If YES**
  - PACE Organization’s grievance procedures consistent with CMS/PACE regulations?
    - **If YES**
      - Review and update written procedures for regulatory compliance
    - **If NO**
      - Staff training

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Figure 4: Sample Grievance Process

GRIEVANCE PROCESS

1. Participant or designated representative expresses dissatisfaction with service delivery or quality of care.

2. Participant or designated representative is informed of the grievance process, and assisted with filing a grievance.

3. Complaint documented on grievance form by staff member, participant, or designated representative.

4. Grievance form submitted to Quality Director & documented for tracking.

5. More than one department named in the grievance?
   - NO
   - YES

   - NO: Grievance form submitted to Center Director.
   - YES: Quality Director assigns staff with expertise on the grievance issue(s) to investigate and resolve.

6. Findings and grievance resolution action plan Documented on grievance resolution form, and submitted to Quality Director.

7. Quality Director notifies participant or designated representative of findings and corrective action plan.

8. Participant expresses satisfaction with outcomes?
   - NO: Participant or designated representative expresses satisfaction with outcomes.
   - YES: Quality Director coordinates meeting with relevant staff to review outstanding issues and collaborate with participant or designated representative and seek alternate solution(s).

9. Quality Director reviews and files documentation for analysis, aggregation, trending, and reporting.

   *** sustain improvements

Courtesy of Mercy LIFE, Massachusetts
Participant and Caregiver Feedback

“One of the best sources of information about the strengths and weaknesses of a program are the users of the program,” states the Department of Health and Human Services (DHHS, 1999, p. 66260).

Involving participants and caregivers in the quality improvement activities of a PO, “including providing information about their satisfaction with services,” is a minimum regulatory expectation that stems from the core concept and mission of PACE (DHHS, 1999, p. 66260). Feedback from participants and caregivers is paramount in the effective design and delivery of care services for the benefit and satisfaction of participants and their overall quality of life.

It is worth reiterating that grievances serve as feedback that spurs improvement-oriented actions, perhaps even more so considering that each grievance stems from dissatisfaction with the quality of services or the way services are delivered. Inherent in the grievance resolution process is a need for active listening and collective problem-solving until each grievance (complaint) is resolved satisfactorily. Furthermore, each grievance drives concrete actions for improvement and resolution (participant satisfaction).

In addition to grievances as a critical source of PACE community feedback, the following sections discuss other sources and methods of feedback within the PACE model of care, including participant councils and survey mechanisms.

Regulatory Requirements (42 CFR §460.136(a)(5))

Committees with Community Input: Each PO is required to develop and sustain at least one committee with community input, the purpose of which includes providing guidance, evaluating QI activities and providing feedback on the following:

➢ quality outcomes data;
➢ QI plan implementation and outcomes; and
➢ ethical issues and decision-making related to topics such as end-of-life issues and implementation of the Patient Self-Determination Act.

Operational Considerations

Open Feedback Loop: An open feedback loop ensures that participant rights are protected through oversight of and engagement in QI activities. Figure 5 illustrates the feedback loops of two committees with community input: the Participant Advisory Committee (PAC) and the Participant Council (PC). Note that the PAC serves an oversight function, retains representation on the QI committee, and provides direct feedback to the board of trustees.

Data Collection and Trending: Participant satisfaction can be assessed in many ways, including direct interaction, self-report satisfaction surveys (internally or externally via a contracted vendor), committees with community input, and grievances. Data collection, aggregation and analysis are essential for trending to inform QI priorities and activities. Prompt redress of problem areas and strategies that sustain good performance cannot be overemphasized. Based on anecdotal feedback from a number of PO quality directors, a strategic and measured frequency of data collection via questionnaires may be necessary to prevent a paradoxical decline in participation rates due to “survey fatigue” among PACE participants and caregivers. In other words, the more surveys participants and their families are exposed to, the less motivated they are to engage in future surveys. QI personnel must strike a balance to achieve meaningful data collection for quality improvement.
Scale and Scope of Community Input: There are more opportunities for internal data collection (input) from participants and caregivers. External inquiries such as the annual Health Outcomes Survey (HOS/HOS-M) often are done through surveys. The outcomes may impact program appraisal and funding.

Figure 5: Committees with Community Input

Courtesy of Mercy LIFE, Massachusetts
References


APPENDIX B

Mercy LIFE Grievance Form

(Do not include in participant’s medical record)

Date Reported: _______________  Participant: Last _______________ First _______________ Middle __________

Team:  ❑ East  ❑ West

Formal grievance process initiated on (date): ____________________________________________________________

❑ Participant has been informed of their right to request assistance in completing the Grievance Form and has received written information on the grievance process.

Name of person filing grievance / complaint: ___________________________________________________________

(If a participant is not filing the complaint please identify below who is filing the complaint)

Person assisting participant to file this grievance: _______________________________________________________

(Staff member, participant, participant representative)

Reason for grievance/complaint/feedback/concern:

❑ Dissatisfaction regarding the quality of medical care services
❑ Dissatisfaction regarding the quality of long-term care services
❑ Dissatisfaction regarding the delivery of services
❑ Other: __________________________________________________________________________________________

❑ Dissatisfaction which involves an imminent and serious threat to the health of the participant or violation of Participant Rights (expedited review process)

Provide a summary of the grievance/complaint/feedback/concern:  

(Include date of the event and a brief description. You may attach additional written documentation)

_________________________________________________________________________________________________
_________________________________________________________________________________________________
_________________________________________________________________________________________________
_________________________________________________________________________________________________

Signature of Participant or Authorized Representative: ______________________________________________________

Name of Person Documenting Grievance: ________________________________________________________________

Title of Staff Position: ______________________________________________________________________________

Signature of Person Documenting Grievance: ______________________________________________________________

Date submitted to QI Director: ___________________  Date reviewed by QI Director: ___________________
APPENDIX C: SAMPLE GRIEVANCE RESOLUTION FORM

Resolution of Grievance

Participant: ________________________________

Last Name    First Name

Deadline for Grievance Resolution: ____________________

Staff Involved in Grievance Resolution

Grievance Documentation Process
1. Complete grievance form (as much as possible)
2. Submit grievance form to quality director
3. Grievance reviewed and logged by Quality Team
4. Grievance Resolution team (RP) identified on form
5. Grievance presented to IDT by Quality Team
6. IDT Responsible Person(s) investigate, institute resolution (Res.) actions, and submit resolution to QI Director
7. Quality Team: Participant or participant representative notification of grievance resolution
8. IDT is notified of mailing, and IDT updates IDT log
9. External reporting to CMS by Quality Team

DATE:

Actions Taken to Resolve Grievance (Enter information below)

Staff Coordinating Grievance Resolution: ________________________________

(Name/Title)

Date submitted to Quality Improvement Director: ________________________________

Date reviewed by Quality Improvement Director: ________________________________

Outcome of Grievance (Enter information below):

Notification

Date participant informed of outcome (see Grievance Log): ________________________________

CMS notification date (if before Level I call): ____________________ HPMS Reference #: ____________________

State Administering Agency notification date (if before Level I call): ____________________

Date Closed: ____________________

Appendix C courtesy of Mercy LIFE, Massachusetts
CHAPTER 15
State Readiness Review and Audits

Author: Clare Thomas
This chapter is a culmination of the previous chapters, which focused on specific areas within PACE and the quality director’s role. The quality director is typically the dedicated lead for audit preparation.

Depending on the age of a PACE program, new without any participants or well established, the process of preparing for any audit is essentially the same. The first step for a quality director is to ask the executive leadership what external audits, in addition to the CMS audit, the PACE organization (PO) is subject to. Consider the following:

➢ If state statutes dictate that a PO is licensed as an adult day care center, periodic audits are required to maintain licensure.
➢ The State Administering Agency (SAA) may do random periodic audits or hold a full audit separate from the scheduled CMS audits.
➢ The state regulatory agency will routinely audit the kitchen of a day center, and the results must be available for the CMS/SAA audit.
➢ If a program is starting up or expanding, the facility will be required to pass the States Readiness Review (SRR) a one-time audit conducted at prospective POs as part of the initial application process and on existing POs seeking to open new PACE centers.

While referencing CMS audits, this chapter focuses on audits undertaken by the SAAs of PACE organizations. For detailed information on the current CMS audit process, refer to the guidance on the CMS website, particularly the document titled “PACE Audit Process and Data Request.” NPA has developed a PACE Audit Preparation Guide (September 2017), located on the Compliance page of the NPA website, as well as additional materials to assist POs with compliance efforts and preparation for future audits.

**State Readiness Review of New and Expanding POs**

The purpose of a State Readiness Review is to determine the readiness of a PO to administer the PACE program and enroll participants. The review assures the PO has developed policies and procedures (P&Ps), obtained commitments from key staff, created a solvency plan, and established a facility that meets state and federal requirements at the time of the application. The state conducts the review at the site of the new PO. An SRR also is undertaken when an existing PO opens a new PACE center. Results of the review are shared with CMS as part of its application process.

At the time of the review, the PACE center is not operational, and no participants are enrolled. In addition to P&Ps, the review focuses on the design and construction of the building, emergency preparedness, adherence to life safety codes, and compliance of the site with the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), and state and local laws. Although CMS does not conduct the readiness review, the agency has the option to accompany the state during the review to provide technical assistance in assuring compliance with federal standards.

CMS establishes the criteria for the SRR in conjunction with the states. Please note that the state can add any additional criteria to the review it deems necessary to help determine that the PO meets the requirements stipulated in the PACE regulations, has developed P&Ps consistent with PACE regulations, and has established the contracts necessary to provide all-inclusive quality care to participants.

Below is an excerpt of the document used by the state for the readiness review. The complete readiness review document can be accessed on the CMS website.
Sample Format for the Readiness Review

<table>
<thead>
<tr>
<th>PACE Regulation Requirement</th>
<th>Readiness Criteria</th>
<th>Criteria Met</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Environment (§460.72)</td>
<td>Evidence of Compliance with All State and Local Building, Fire Safety and Health Codes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.A. The PACE center must be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel and visitors</td>
<td>Evidence of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Fire exit system</td>
<td>☐ Met</td>
<td>☐ Not Met</td>
</tr>
<tr>
<td></td>
<td>☐ Doorways that provide adequate width to allow easy access and movement of participants by wheelchair or stretcher</td>
<td>☐ Met</td>
<td>☐ Not Met</td>
</tr>
<tr>
<td></td>
<td>☐ Doorways and stairways that provide access free from obstructions at all times</td>
<td>☐ Met</td>
<td>☐ Not Met</td>
</tr>
<tr>
<td></td>
<td>☐ A written plan that outlines scheduled maintenance for the PACE center to include building maintenance</td>
<td>☐ Met</td>
<td>☐ Not Met</td>
</tr>
</tbody>
</table>

Preparing for the Readiness Review: P&P Development

When hired by a start-up organization, a quality director likely will begin the new role before the PO undergoes an SRR. Initially, the new quality director will assist the leadership in preparing for the review, including P&P development.

While this step may appear to be a daunting task, it can be quite manageable. Always begin with the end in mind - the end being the readiness review. The criteria for the SRR are based on CMS PACE regulations. The criteria outline the types of P&Ps a PO needs to have in place for the SRR, as well as future CMS audits.

The areas of focus are as follows:

1. Physical Environment (§460.72)
2. Infection Control (§460.74)
3. Transportation Services (§460.76)
4. Dietary Services (§460.78)
5. Emergency Preparedness (§460.84)
6. Bill of Rights (§460.110)
7. Personnel Qualifications (§460.64)
8. Training and Competency (§460.66 and §460.71)
9. General Provisions:
   a. Evidence of all current licensure required by the state
   b. Safeguarding of participant data; confidentiality and HIPAA compliance (§460.200 & §460.210)
   c. Participant reassessments, reassessment at the participant’s/caregiver’s request (§460.104)
   d. Verification of actual service area (§460.22)
   e. Participant access to care 24 hours a day, seven days a week (§460.98)
   f. Required services (§460.92 & §460.94)
   g. Health information system to collect, analyze, and report participant data (§460.202)

10. General Safety Requirements:
   a. Evidence of state pharmacy licensure
   b. Narcotic inventory control and disposal
   c. Medication and food storage
   d. Oxygen storage in accordance with fire safety and FDA laws
   e. CLIA certification, if applicable

When creating the P&Ps for their PO, quality directors must reference the regulations. They can quote the actual verbiage from the regulation in their P&P, but they also must show how their PO operationalizes the regulation. They are encouraged to reach out to other PACE quality directors for a copy of their P&Ps as a guide in developing their own. This can be helpful for those without prior experience in P&P development.

Quality directors should consider the following when developing P&Ps:

➢ References: The primary reference for all P&Ps is the PACE regulation. The readiness criteria in the SRR document provide more details regarding CMS expectations for compliance with regulatory requirements, as does the CMS PACE Audit Process and Data Request document.

➢ Contact Quality Directors in the CMS Region: They are familiar with the emphasis that CMS auditors in the region place on such areas as infection control, service requests, or grievances and appeals.

➢ Create New P&Ps: Although quality directors may receive sample P&Ps from a PACE sister site, they should not adopt them verbatim. It is not sufficient to just change the name of the PO on the document. A P&P must reflect what a particular organization will do.

➢ Affiliated Hospital P&Ps: Quality directors may reference a P&P from their affiliated hospital/health care system as appropriate in their P&P, but they should not give any auditor their hospital P&Ps in lieu of their own.

➢ P&P Attachments: Include appropriate monitoring logs, forms, sample correspondence and other documents as attachments to P&Ps. This “one-stop shop” will provide the reader and user with a complete picture of the process.

➢ P&P Nomenclature: A sample of how to systematically identify each P&P is shown below.
1. Organization Name

2. Type of P&P: Classify P&Ps by type (e.g., Clinical, Operational, Part D). In the sample P&P, regulation §460.78 governs Dietary Services. When an organization is developing Dietary P&Ps, it is supporting this regulation. Therefore, identify it as a Clinical Policy.

3. Title: The P&P Title should be as clear as possible. Align it as closely as possible to the applicable regulation. In the sample, “Safe Handling of Garbage and Waste” clearly aligns with regulation §460.78(b) (3): Sanitary Conditions: Dispose of Garbage and Refuse Properly and SRR Criteria IV(C): Safe Garbage Storage and Disposal.

4. Policy Number: The policy number was derived by the order of the approved Dietary Policy and is matched to the regulation, which is extremely helpful when organizing documents for CMS audits. The first three letters are the acronym for the program, and -01 corresponds to the policy number related to the regulation.

5. Original Date: The date the P&P was written with the approving body.

6. Review Date: It is recommended that each P&P author/owner review their P&Ps at least annually and document the review date even if no changes are made. The date shows that the P&P was reviewed and is current as is or as revised.

7. Effective Date: This is the date that the most current P&P was reviewed and approved.

8. Approving Body: Identify the body that the PO has determined will review and approve all P&Ps. There is no requirement to have a set group approve P&Ps; the PO determines that group. This can be the board of directors, executive staff or a committee. It shows that someone other than the author reviewed the document to ensure it aligns with the regulation.

**Document Organization for Onsite SRR**

When the application is ready, the new PO is equipped with all required items to receive and care for the first participant, essential staff are hired, the PO has the date for the SRR, and the conference room for the auditors has been identified, the next step is to organize and assemble all required documents in a systematic fashion.

Identify binders for the SRR with the name of the PACE regulation and component. For example, Regulation §460.72, Physical Environment contains eight requirements. Each binder should be marked...
clearly to identify it with the component and criteria. More than one binder may be needed to house all of the required documents supporting the criteria.

Below is an example of how to set up and label binders. It is recommended to use dividers in the binders, as well as a table of contents to identify the items within each section.

1. Physical Environment, 1.A: Center Design, Equipment and Safety
   a. Evidence of State and Local Building, Fire Safety and Health Codes
   b. Scheduled maintenance P&Ps for facility and equipment.
2. Physical Environment, 1.B: Center Design, Delivery of Participant Services
   a. Evidence of Certification or Licensure for Adult Day Centers
   b. P&Ps:
      1. Address the PO procedure to ensure participant privacy and dignity.
      2. Effective insect and rodent pest control.
      3. Tobacco use: If smoking is permitted, is the area clearly marked and limited to participants and/or staff? Signage to prohibit smoking while oxygen is in use.
      4. Proper storage, handling and disposal of all chemicals, compounds and biohazardous waste. Include all Safety Data Sheets (SDS) for all chemical, cleaning and medical supplies.
      5. Safe Equipment storage.
3. Physical Environment, 1.C: Adequate Space for Participant Services
   a. Evidence of Adequate Space for team meetings, medical treatment and other care, therapeutic recreation, restorative therapies, socialization, personal care, dining.
   b. Evidence of sufficient and maintained equipment to transfer a disabled participant safely onto an exam table, tub, bed, etc.
4. Physical Environment 1.D: Center and Home Equipment Maintenance
   a. Written maintenance plan that identifies the PO point of contact, logs/records and maintenance schedule as recommended by the manufacturer.
      b. Procedure to report device-related injuries or death to MedWatch, the FDA safety information and adverse event reporting program. This procedure falls under tje External QI Activity Reporting P&P.
      c. User’s guide: Create a separate binder to hold the hard copy of every manufacturer/user guide for each piece of equipment in the facility.

**Final SRR Pre-Audit Preparations**

Quality directors ensure all documents are in place in the designated conference room for the auditors to review during the SRR. Actual practices within PO operations must mirror what is written in the P&Ps. Random audits should be conducted in at least three areas prior to the SRR for document validation. These areas may include Temperature Monitoring, Safety Data Sheets (SDS), Equipment User’s Guide and Oxygen Storage Signage.
Temperature Monitoring

➢ Refrigeration: The P&Ps of a PO must include a procedure to check, record, and monitor the temperatures of all refrigerators within the facility. For example, the clinic will have a P&P specific to maintaining safe temperature ranges for medication and vaccine storage, and the dietary department will have a P&P for maintaining safe temperature ranges for food, beverage and nutritional supplements. Each P&P should have a corresponding log to record the daily temperature readings. Conduct a periodic random audit of the refrigerators. Check the log to ensure it is documented and that the recordings are within the identified safe temperature range. If at any time the readings are not within the acceptable range, inquire about it with the department supervisor as to what occurred and what was done to ensure the temperature is now within the accepted safe range.

➢ Restroom and Shower Water: Because the elderly are at high risk for burns, monitoring hot water temperature is looked at during the SRR and may be checked in future audits. Ensure that several reliable thermometers are available to use to test the water. A digital thermometer provides the exact temperature compared to a traditional thermometer, which can be misread. In addition to reviewing the water temperatures documented on the logs, the quality director should conduct several periodic random tests of participant sink and shower water temperatures. When planning to conduct water temperature testing, choose a different time of the day, as water temperatures can vary with usage. Also, use two separate thermometers to validate the temperature. If at any time the water temperature in the participant areas exceeds 110 degrees, the quality director must notify the point of contact at the facility to adjust it accordingly.

Safety Data Sheets (SDS): Just prior to the SRR, quality directors should take the SDS binder and conduct their own audit with each department supervisor. It is highly recommended to open each cabinet, closet and drawer to ensure there are no surprises, e.g., cleaning supplies, wipes, nail polish remover swabs, etc., for which there is not an SDS. The SDS must be obtained if procured through the facility, or the items need to be removed.

Equipment User’s Guide: The quality director should conduct rounds with each department supervisor to validate that the binder for the SRR contains the user’s guide for each piece of equipment in that department, as well as the cleaning log.

Oxygen Storage Signage: Areas where oxygen is stored must be clearly label to easily locate full tanks, partially filled tanks and empty tanks. Staff responsible for participants using oxygen must be trained. The quality director should ensure that the training is reflected in their personnel files.

During the SRR

When the work preparing for the audit is done, quality directors should ensure they are available to answer any questions or provide any additional information or documents that are needed. While most of the survey is focused on document review and interviewing staff members, the auditors will want to tour of the facility, ride on the participant transportation van, check water temperatures with their own thermometers, take the quality director or other staff member on a tour of the facility with the SDS binder to validate there is a corresponding SDS for each chemical, and validate a manufacturer’s/user’s guide is available for each piece of equipment in the center.
**Post-SRR**

Upon completion of the State Readiness Review, the state will prepare and submit a report of its findings to CMS. This report explains the state review process and any additional review criteria utilized. If the PO meets all the criteria in the readiness review, the state will submit a brief report to CMS on its findings. If the PO does not meet all the established criteria, the state, in conjunction with the PO, will request additional information and/or develop an initial compliance plan to bring the PO into compliance. This plan will outline both the unmet criteria and the plan of correction. Once the initial compliance plan has been completed to the satisfaction of the state, the review team will submit a complete report to CMS that includes an explanation of the state review process, any additional review criteria, the list of unmet criteria, the reason the PO failed to meet the criteria, the initial compliance plan, and an explanation of the changes that were made to bring the PO into compliance with the requirements. If additional information is needed by the state, the quality director will assist in the document preparation.

Upon receipt of all the responses to the request for additional information and the completed SRR, CMS has an additional 90 days to either approve or disapprove the application and notify the entity in writing of the basis for a denial and the process for requesting reconsideration. An application is deemed approved if CMS fails to act on the application within 90 days after the date the application is submitted by the organization or the date CMS receives all requested additional information. For purposes of the 90-day time limit, the date that an application is submitted to CMS is the date the application is delivered to the address designated by CMS. Once CMS reviews the SRR report and approves the application of a facility, it is now an official PACE organization. The PO should enroll participants within the month following receipt of the CMS letter. During this period, it is highly recommended that the PO be well aware of the most current version of the [CMS PACE Audit Guide](#), as it will be audited annually during the initial trial period. Given that the audit process requires POs to submit data universes related to service delivery requests, appeals, grievances, personnel, participant’s medical records, quality assessment initiatives and after-hours calls, it is imperative that they have processes in place to collect and analyze the data on an ongoing basis.

If a PO is undergoing an expansion project to open a new PACE center, CMS will have 45 days to request additional information or to approve or disapprove the application. This period will last a minimum of three months and possibly longer. Once CMS reviews the SRR report and approves the facility application, the new PACE center can open.

Quality directors should meet with department supervisors and review the regulatory requirements that include those within the scope of CMS audits. This gives them the opportunity to create new processes, ensure current processes and documents are compliant with CMS regulations, or make changes as appropriate. Quality directors should offer their assistance as needed.

Once a PO begins to enroll participants, quality directors should reach out to the department supervisors again to inquire about the appropriateness of their current P&Ps, documents and monitoring tools. The following questions should be considered during the meeting.

- Are the P&Ps written for the SRR still applicable “as is” now that there are participants? Are they truly operational?
- Are the P&Ps and/or documents capturing the intent as originally written?
- Do the P&Ps and/or documents need modifications?
- Does the supervisor need a separate P&P to meet the intent of a particular regulation, or can two or more be combined to prevent redundancy?
Does the supervisor have P&Ps and/or documents that need to be rewritten from scratch to capture the actual process?

Have staff members read the department P&Ps? Do they understand them, and are they followed?

Interim Period Between the SRR and First-Year Audit

Many quality directors in a start-up program have roles or duties assigned to them in addition to the responsibilities for which they were hired. These roles could include compliance/Part D FWA, infection control officer, training, grievance, and service request denials and appeals. During this time, quality directors are developing their own programs, plans and P&Ps. They are cautioned not to wait until the PO receives CMS notification of the impending audit to begin preparations. When a PO enrolls the first participant, it is time to begin audit preparation.

2017 CMS PACE Audit Process

Historically, CMS has conducted comprehensive onsite audits of POs to evaluate their compliance with PACE regulations. These audits occur annually for POs operating in their initial three-year trial period and at least once every two years thereafter. Over the years, CMS has made updates to the audit process. Most recently, CMS implemented a new audit process for PACE beginning in 2017.

Changes to the audit process include the following:

- reduction in the number of elements;
- participant-centered audit approach;
- new HPMS Module/Electronic Data Submission;
- citation at condition level;
- classification of conditions as Observation, Corrective Action Required (CAR), or Immediate Corrective Action Required (ICAR); and
- PACE Audit Consistency Team Review.

Focused Audits

A focused audit can happen at any time. This audit is conducted when CMS and/or the SAA become aware of a new or ongoing/unresolved issue, requiring an in-depth review to bring the PO into compliance.

CMS and the SAA discuss the issue and determine if the PO has failed to provide its participants with necessary care or services having the potential to affect participants adversely. They may conduct one or more technical assistance conference calls with the PO to gain additional information.

The PO will need to develop and implement a corrective action plan (CAP) to resolve the issue. If CMS and the SAA are satisfied with the CAP, the PO will implement the plan and monitor the results to gain compliance. CMS and/or the SAA can investigate the issue further at any time. They each have the option to conduct an offsite desktop/document review or an announced or unannounced site visit.

Quality directors should be involved whenever an issue or potential issue surfaces in the PO. They need to investigate and thoroughly document the issue and meet with executive leadership regarding their findings. The PO may contact the SAA and/or CMS regarding the issue. Compile all documents in one location for easy retrieval.
The following example can initiate a focused audit: “It has been determined that your PO is inaccurately assessing, staging, and documenting participant pressure ulcers. As a result, one participant required a below-the-knee amputation and several hospitalizations with debridement, in-depth wound care and intravenous antibiotics. Several Level II events were not reported to CMS.”

CMS and/or SAA auditors will look at all documents and processes specific to pressure ulcers. If they decide to conduct an unannounced onsite audit, the PO will not have time to gather all related documentation and “prepare the staff.”

The quality director will be involved closely with the audit, and the PO will need to be prepared to answer the auditor’s questions and produce required documentation. The questions are comparable to those outlined in a root cause analysis.

The questions below related to policy and procedure are typical of the ones that may be presented. They may require supplemental documentation as evidence of compliance. The documents should be ready to give to the auditor, but the PO should not forward the documents until specifically requested to do so. Provide only the documents requested by the auditor. If the documents are not satisfactory or do not tell the whole story, quality directors should use their own judgment in choosing further documentation to support compliance by the PO.

1. What are your P&Ps related to assessing and identifying pressure ulcers? (Be prepared to provide the auditor with a copy of all related P&Ps if the auditor requests copies. Have the P&Ps related to pressure ulcers in a separate binder for auditor review.)
   a. scheduled and unscheduled reassessments
   b. plan of care
   c. wound care
   d. quality/risk management (Level II events)

2. What are your interdepartmental communication processes when a possible or actual pressure ulcer is discovered?
   a. in-center personal care or clinic visit
   b. during home care
   c. verbalized by a caregiver
   d. verbalized by a contract provider

3. Do the comprehensive reassessments by the RN and PCP include complete skin checks? (Have ready a list of all participants who currently have or have had pressure ulcers.)

4. How are pressure ulcers tracked? (Have ready documentation of the tracking tool and describe the process.)

5. Has your PO received any participant/caregiver complaints or grievances related to lack of follow-up to a health-related concern such as sore or reddened pressure points? (Have ready a copy of all related grievances.)

6. Is pressure ulcer identification included in the orientation for participant care staff? (Have ready a copy of the orientation checklists.)

7. Is the competency of participant care staff verified/re-verified in pressure ulcer assessment? How often is the staff re-verified? How do you conduct remedial training? (Have a copy of the competency document/proficiency checklists.)
8. Did your staff receive formal training on pressure ulcer assessment as soon as it was determined there was a need? When was the training completed? Is ongoing training planned for staff who are new to the department? (Have ready a copy of the lesson plan and training documents, trainer qualifications, attendance rosters, orientation and competency documents, post-training tests and proficiency checklists, and the PO training calendar.)

9. Does your PO have a medical records review team or committee?

10. Did your chart audit identify any actual or potential pressure ulcers? Did documentation include a description of the wound (location, appearance, measurement, odor, drainage/slough, necrosis, edema, erythema, induration, pain upon palpation, etc.); evidence of communication to the clinic RN and/or PCP; treatment plan (in-center wound care, visit to wound clinic, in-home wound care); and procurement of an assistive device to prevent friction? Were they reflected in the care plan? (Have ready a copy of the completed audit tool used for each pressure ulcer medical record audit.)

11. What is your process when documentation is lacking in the medication record? Is the cause identified and corrected? What is the overall reason for poor documentation efforts: staffing, training or behavioral?

When an onsite focused audit is conducted, the auditors may observe clinic and/or in-home wound care and interview one or more participants/caregivers. They also may conduct interviews with contracted staff and providers.

Once the focused audit is over, the auditors will write a report that includes PO compliance and/or non-compliance. The PO will need to develop a CAP if not in compliance. Please note that a PO can be cited when repeated focused audits and frequent technical assistive visits result in failure to comply with regulatory requirements. These citations include “Notice of Imposition of Civil Money Penalty,” “Notice of Imposition of Sanctions to Suspend Enrollment,” and/or other enforcement actions as described in 42 CFR 460, Subpart D. CMS has the right to consider taking action to terminate the PACE contract immediately when identified or uncorrected issues pose a serious threat to the health and safety of PACE participants.
CHAPTER 16
Education in the PACE Environment

Authors: Mary Austin and Cheryl Dexter
Education, training and competency ensure that quality care is provided by all staff at all levels.

**Onboarding, Training and Education**

PACE organizations are committed to empowering employees through traditional educational tactics in addition to hands-on mentoring that leads to professional growth. It should be the intent of the program to offer employees access to information and education that will allow them to provide high-quality, compassionate and thoughtful care. This is critical as it is the foundation upon which all other experiences are built.

QI must play a role in the on-boarding of new employees. They should meet with the quality director or designee sometime during orientation and training to learn how QI is woven throughout the organization and how they fit into the QI plan. During CMS surveys, employees often are asked about their role in QI. If they are not going to be part of the QI team, it is helpful to have them attend at least one QI meeting.

The orientation and training process should include other areas of education:

➢ Grievances: How to complete grievance forms, grievance analysis and use, reporting requirements for grievances.
➢ Service Requests, Appeals and Denials: Timelines, documentation requirements and the appeals process.
➢ HPMS and Level II Reporting: Overviews of the indicators submitted quarterly and of the Level II reporting thresholds.
➢ Quality Plan: How quality initiatives are determined, who is involved in the quality teams.
➢ Surveys: Types of surveys conducted at the organization, expectations during the surveys.
➢ Fraud, Waste and Abuse: This may be the responsibility of the quality director. It is required within 90 days of hire and annually thereafter.
➢ HIPAA: Particular regard to new technologies used beyond the PACE site.

**QI Role in Ongoing Education**

The ongoing educational needs of employees may be identified from the following quality reports:

➢ Grievance Analysis: May identify gaps in skills or knowledge.
➢ Satisfaction Survey: Identifies areas for improvement that can be shared with managers and staff and may focus on learning opportunities.
➢ Current and Ongoing Quality Initiatives: Educational needs often are identified through quality initiatives, studies and improvement processes.
CHAPTER 17
Committees with QI Input (Internal/External)

Authors: Mary Austin and Donna White
Quality improvement (QI) typically has input into most committees and systems in the PACE organization (PO) because of its integral nature and association with all program outcomes. All POs develop and implement a QI program to meet their individual needs, and most include a structure of subcommittees within the QI program itself. Successful POs have strong relationships between QI and other systems that address regulations, participant needs and clinical outcomes.

Following is a general description of committees typically found in PACE. Some are required by regulation, some are considered best practices, and some are purely optional based on the needs of the organization. Included are a description of the committee and a discussion of the role of QI related to its work. (Note: This is not an all-inclusive list of potential committees that POs may establish. Organizations may institute committees with similar scopes of responsibilities and member composition but with different names.)

### Governing Body

The role of the governing body in QI is delineated in the following sections of the PACE regulations: §460.62(a), §460.62(a)(6), §460.62(a)(7), §460.132(a), and §460.132(b). Ultimately, the governing body has full legal authority and responsibility for the quality program of the PO.

Directly or through delegation, the governing body must do the following:

- lead the organization toward continuous quality improvement (CQI) of participant care and services through oversight of the mission and operation of the organization;
- incorporate findings from QI activities in strategic, program and resource planning;
- provide guidance toward continuing education concerning the approach, methods, tools and applications of CQI; and
- establish broad guidelines for QI activities in conjunction with the medical director.

These required aspects of the governing body are related to the QI program and plan of the PO:

- The governing body is accountable for the development and management of the QI plan, any modifications and its effectiveness, including an annual evaluation of the QI program.
- The governing body reporting structure should be outlined in the annual QI plan, both in summary form and organizational chart format.
- The QI plan should outline a clear path to the board, stating its responsibility for allocating resources to carry out the QI plan and clear approval (or disapproval) of QI program goals on at least an annual basis.
- If the PO is part of a larger health system, the responsibility of its governing body should be outlined up to the larger health system, if applicable. This line of responsibility should be clear and unambiguous.
- A QI program update should be on the agenda of every board meeting. The QI reports provided to the governing body should include quality indicator outcomes, specific goals and compliance, among other components, and usually are presented by the quality director, executive director, medical director or other designee.
- The governing body is provided with an annual quality report, which is a detailed summary of the quality and safety outcomes of all care and services. Quality reports should be detailed and comprehensive. Typically, quality directors will prepare a dashboard or scorecard summary addressing key indicators that best reflect the clinical and operational performance of the PO supplemented by brief narratives to highlight challenges and successes.
➢ The board minutes should include specific information regarding the issues discussed, comments, recommendations from the governing body, and follow-up needed. The minutes also must include documentation of the review and approval of the QI plan.

**QI Committee**

The QI Committee usually is comprised of the medical director, executive director, program director, quality director, and other designated key personnel who have responsibility for key aspects of the PO services. Other key stakeholders, such as contracted providers and participant representatives, may participate on the committee as well. The medical director chairs the committee, and the quality director coordinates the meetings. The QI committee typically meets on a quarterly basis.

The responsibilities of the QI committee include the following:

➢ oversee the development of outcome measures and performance indicators;
➢ provide the QI director with data on service utilization and data from studies conducted by all other committees in order to facilitate analysis of the data;
➢ review data and analysis conducted by the quality department and related subcommittees and task forces;
➢ support the development and review the recommendations and corrective plans of action to improve quality using the analysis presented by the quality director and recommendations made by the various committee chairs and members;
➢ assist in identifying solutions using performance improvement processes as indicated to address these conditions and monitor effectiveness of the implemented solutions;
➢ suggest priorities for performance improvement based on prevalence and severity of identified problems;
➢ facilitate communication to staff regarding clinical quality issues, changes in service delivery, policies and procedures, and approved plans for quality improvement;
➢ ensure that ethical issues are referred to the ethics committee as indicated;
➢ ensure the implementation and effectiveness of the QI program on an ongoing basis;
➢ ensure that the annual evaluation of the QI program is conducted and propose changes that effectively address and improve quality of care, member satisfaction, cost-effectiveness, and appropriateness of services rendered to members (depending on the organizational structure of the PACE program and its QI plan, this annual evaluation is conducted in different ways that include the committee, quality director, medical director and ultimately the governing body);
➢ ensure that performance indicators are appropriate and reflect the scope of services;
➢ collaborate with the medical director, who will review and evaluate the analysis of information and data presented and offer guidance and scientific-based evidence/direction as indicated;
➢ approve or disapprove recommendations and plans to address the issues presented, which may include approving changes to the QI policies and procedures and/or methods for service delivery via the medical director, quality director or their designees;
➢ set priorities for performance improvement based on the prevalence and severity of the issues presented, giving priority to improving interventions that affect clinical, functional, quality-of-life and member satisfaction outcomes;
➢ set time frames for implementation of plans for improvement;
➢ ensure that all recommendations and plans of correction are implemented within established timeframes and are effective and maintained;
➢ designate ad hoc committees or workgroups to study specific quality issues as planned during the yearly evaluation of the QI and as they arise; integrate the findings of these teams into the overall quality assessment; and
➢ ensure and monitor that all required performance data are reported to the board of directors, the state health department and CMS, as requested.

Corporate or System-Wide QI and Clinical Committees

For some POs, QI can be part of the quality and compliance program of the larger organization. In this case, the activities of the PACE program may be approved or disapproved at a higher committee level, with input available on trends needing study and intervention. The review and final approval would be done by the governing body of the PO and recorded in the minutes.

Staff Meetings and Committees

Staff at all levels are to be involved in identifying quality problems and issues on an ongoing basis. Staff also should be involved in the resolution of issues and in the development of ongoing plans to improve quality. This is done through regular staff meetings and day-to-day communication among all levels of staff, including support, clinical and management. POs can do this in a variety of ways, including QI updates in morning meetings, postings in the center with project progress information, and discussions in other IDT committees.

Participant Council

The Participant Council is similar to a residents council in the traditional nursing home setting. The council meets on a regular basis (usually monthly) to allow an open forum for participants to ask questions, make requests, voice grievances, and offer suggestions in the day-to-day operations of the PACE program. The meeting also can be a wonderful venue to review participants’ rights in a language and level that they understand. Participant Council membership should comprise all participants, a board liaison, recreation therapy, and the directors (or designee) of Site Operations. The council should maintain minutes of the meetings and communicate them to the QI committee and the board of directors.

The QI committee should review the minutes to ensure issues, comments and concerns are reflected appropriately in QI activities. Minutes also should be disseminated to the Participant Advisory Committee. For example, if participants are commenting about the quality and variety of food offered in the PACE center, the QI committee should address the issue by evaluating the food service and ensuring the analysis is incorporated into the QI plan. Similarly, the QI committee should inform the Participant Council of QI activities and request its feedback. For instance, if there is a QI project underway to improve transportation timeliness, the comments and suggestions made by participants could be important in developing the plan and measuring progress.

Sample to Operationalize a Participant Council

A Participant Council meeting is held to present information to the PACE participants and hear their concerns and opinions. The meetings focus on topics in the Participants’ Bill of Rights, grievances, treatment decision appeals, incident reporting, disenrollment procedures, special events, and key issues affecting residents.
The PACE marketing staff works with the center administrator, social worker and recreation activities representative to coordinate and host the meeting on a regular basis at the PACE center. Meeting flyers are posted throughout the PACE center with the date, time and discussion topics.

Letters about the Participant Council meeting that provide the date, time and discussion topics are mailed in the respective language to participants with identified cognitive impairment to inform their family or caregiver of the scheduled meeting.

On the day of the meeting, the marketing staff and social worker or designee review and discuss the Participants’ Bill of Rights, grievances, treatment decision appeals, incident reporting and disenrollment procedures. A question-and-answer session is included in the meeting to assure understanding by participants and clarification of the topics discussed.

The PACE marketing staff maintains all attendance logs and materials. Informational packets containing the items discussed at the meeting are mailed to participants who were unable to attend.

**Participant Advisory Committee (PAC)**

PACE organizations must establish a Participant Advisory Committee (PAC) to provide advice to the governing body on matters of concern to participants. PAC meetings should be held quarterly and provide participants and family/caregivers a forum for expressing concerns to the PACE staff. The PACE regulation requires that the majority of PAC members be participants and representatives of participants. The PAC serves as a liaison to the governing body, with a representative selected to report on meeting proceedings. PAC is referenced in these sections of the PACE regulation: §460.62(b)(1), §460.62(b)(2), §460.62(c)(1), §460.62(c)(2), and §460.62(c)(3).

**Program Advisory Committee**

The Program Advisory Committee (or Plan Advisory Committee or Professional Advisory Committee) is comprised of members outside the PO, as well as staff and management. The structure and membership of the committee should be spelled out in the QI plan. The committee is run by members who set the agenda and vote on actions, if necessary. External members include caregivers, participants and others with a vested interest in the ongoing mission of the PO who are unpaid. PACE staff report on clinical, operational and QI activities and outcomes but do not vote on any resolutions. In some POs, this committee acts as a resource to review appeals.

**Safety Committee**

Some PACE programs have a Safety Committee. While not a specific requirement, the committee serves a purpose in some cases. The objective of the committee is to support and enhance the safety program, with a primary focus on preventing occupationally-induced injuries and illnesses. To the highest degree possible, this committee provides employees a forum to ensure all mechanical and physical facilities required for personal safety and health are controlled and maintained.

Unless the PO is very large, safety issues can be discussed at monthly quality assurance or management meetings as part of a standing agenda. The Safety Committee also can be carved out as an ad hoc committee and closed depending on the issues at hand.
Falls Committee
The rehab director or quality director usually chairs the Falls Committee, which provides an interdisciplinary approach to fall prevention. The committee meets regularly to review incidents of falls, analyze trends, and implement improvement plans as indicated. It provides to the QI Committee regular reports on data, trends, improvement activities that have been implemented, and measurable results. Falls also are reported to the IDT on a regular basis for team discussion, problem-solving and care planning. In newer or smaller programs, falls can be discussed as part of the regular QI Committee agenda.

FWA/Compliance Committee
The FWA/Compliance Committee meets regularly to review results of ongoing and focused auditing practices related to Medicare and Medicaid compliance, as well as Fraud, Waste and Abuse (FWA) auditing related to Medicare Part D to ensure compliance with state and federal regulations.

Finance staff are active members of this committee, and clinical and dispensing pharmacists should participate as well. The committee reviews data related to drug costs, prescriber patterns, reasons that medications were wasted or refilled early, and issues of non-compliance. Pharmacists should help keep the PO on track with state rules on dispensing, wasting drugs, etc. Committee reports are reviewed by the QI Committee, including minutes, data analysis, audits, and improvement plans being implemented.

Clinical Committees
Depending on the size of the PACE program and the structure of the parent organization, clinical committees may be incorporated into the work of the QI Committee or function separately. Either way, each committees should report plans, interventions and outcomes to the QI Committee on a regular basis.

Pharmacy and Therapeutics Committee
The Pharmacy and Therapeutics Committee, which is chaired by the medical director, meets regularly to review medication use within the program and to provide advice, direction, information and education on pharmaceuticals to reduce polypharmacy. The committee recommends safe, quality and cost-effective methods for treating the PACE population. Pharmacy consultants are active members of this committee.

Skin Care and Nutrition/Wound Committee
A committee on skin care and nutrition or wound committee tracks, trends, and reviews all wounds to ensure appropriate interventions are in place. The committee reviews participants with potential and actual skin breakdown to assess, prevent, analyze, and plan interventions. It also oversees program-wide trends related to skin and nutrition and plans system changes and other interventions as needed. Chaired by the clinical director or designee, the committee is comprised of nursing, dietary, rehab and others as deemed appropriate.

Infection Control
The Infection Control Committee develops, implements, and maintains an Infection Prevention, Surveillance and Control Program that includes procedures to identify, investigate, control, and prevent infections in all settings. The committee has the authority, through the medical director, to institute any appropriate surveillance, prevention and control measures or studies when there is reasonably considered to be a danger to any participant or personnel. The data collected, plans developed, and outcomes are reported to and monitored by the QI Committee.
Ethics Committee

The Ethics Committee advises PACE staff on individual participant matters involving ethical dilemmas and ethical decision-making encountered by the staff in the course of providing care to participants and their caregivers. The committee also may serve as a consultative resource in grievance issues raised by participants and their families. It advises the program on policy development related to ethical decision-making, including policies related to the determination of health care wishes, resuscitation and other end-of-life issues. The committee can be a hybrid of internal and external members that is written as part of the QI plan. It may meet on a regular basis or as needed depending on program needs. Membership may include leadership staff, community members, physicians and providers outside of the program, and clergy. Larger organizations often have a network-wide Ethics Committee available to the PACE program. In this case, the structure should be included in the QI plan, and an official report from the committee should be submitted to QI.

Appeals Committee

The Appeals Committee meets as needed to review and respond to appeals from participants according to the policy of the PACE program. This is an optional committee based on the needs of the program. The number, types and outcomes of appeals should be tracked and reported to QI for review. This information can be useful to the QI Committee in identifying potential quality issues. If issues or trends are identified, a plan should be incorporated into QI to address them.

Utilization Committee

A Utilization Committee reviews inpatient, consultant and other service utilization to ensure effectiveness and efficiency of team decision-making. Since the purpose of PACE is to maintain participants in the community as much as possible, utilization is one measure of the quality of services. Therefore, it is important for the QI Committee to review data, trends and interventions of the Utilization Committee and incorporate this into the QI plan. The Utilization Committee also may monitor data on the severity of illness through accurate diagnostic coding and proper use of resources by utilizing participating providers and authorizing appropriate services.

Contract Oversight Committee

In most PACE programs, one staff member is designated as the liaison with contracted providers and for dealing with contracts. The QAPI program should include plans to monitor the care given on a routine basis and to conduct audits for compliance and quality assurance. This responsibility of the QI Committee may be performed by the Contract Oversight Committee.

Members of this committee vary but typically include the director of health information systems, the compliance officer, program director, executive director, medical director and quality director, as well as other staff members and service providers deemed appropriate.

This committee usually is responsible for monitoring and maintaining the provider network, verifying and reviewing credentials, identifying areas related to quality of care with contractors, developing recommendations and plans for improvement in these areas, and approving the credentialing policies and procedures.
Ongoing monitoring of the provider network is conducted through analysis of the issues identified from complaints and grievances, voluntary disenrollments related to contractors, member and family/caregiver satisfaction surveys, ongoing concerns with a provider, tracking appointment wait times, access to care, and applications for participation in the provider network.
Key Points

➢ Consider whether your PACE organization (PO) benefits by including community-based primary care physicians (CBPCPs) in the practice.
➢ Be knowledgeable of the CMS waiver requirements for inclusion of CBPCPs on the IDT.
➢ Program models of care to consider for CBPCPs.
➢ Be knowledgeable of the medical director’s oversight role for CBPCPs.
➢ Key performance metrics to be considered to ensure successful outcomes.
➢ Writing the waiver request.

Should a PO Consider CBPCP Arrangements?

As PACE has grown, the model has adapted to different situations, such as rural settings and staff shortages. One situation that can arise is the desire of a PO to occasionally work with contracted CBPCPs. This approach may come about for various reasons:

➢ the PO may open a site in a rural area or in a competitive market where there are not enough resources to hire a full-time or part-time physician;
➢ PACE-employed physicians may not have admitting privileges with the local medical system where a new PACE site has opened; or
➢ partnering with physician groups and expanding the geographic service area for individuals who wish to maintain a relationship with their current physician supports membership growth, in the context of CMS requirements for service area expansions.

These circumstances may lead a PO to ask CMS to grant a waiver from PACE regulations, allowing it to use community physicians. When developing a model that includes the use of community physicians, it is important to be aware of the PACE regulations and develop a program that will meet them. The PO also must make sure that the use of community physicians will lead to the same quality and financial outcomes that the traditional PACE staff model has demonstrated.

The use of community-based providers is not limited to physicians. PACE organizations also may contract with community-based nurse practitioners (NPs) and physician assistants.

CMS Waiver Requirements

Although waiver requirements for the use of CBPCPs and NPs are currently under review by CMS, regulations issued in 1999 and 2006 still apply until further guidance is issued. The 1999 PACE regulations required the PACE multidisciplinary team to serve primarily PACE participants (§460.102(d)(3)) and include employed primary care physicians (§460.102(f)(1)). However, §460.102(g)(1)(i-ii) allowed waivers to these regulations. In the 2006 final PACE regulations, these sections were replaced with §460.26 and §460.28, which detail the waiver submission process and requirements related to the CMS review of waiver requests.

CMS was explicit in describing waivers for the use of contract CBPCPs on the PACE team: “Although we have permitted the use of community-based PCPs, we require that effective and consistent communication be maintained. Whenever we have received a request for waiver pertaining to use of community-based PCPs, the PO has had to provide in-depth justification and meet our conditions for waiver. Among other conditions for waiver approval, the community-based PCP must perform all the requirements of the staff PCP including but not limited to participation in IDT meetings related to their participants’ participation in Quality Assurance and Performance Improvement (QAPI) activities and agree to PO oversight by the medical director.”

The PO that contemplates the use of a CBPCP must obtain the necessary waivers. The requirements include justification of the need, policies and procedures on the selection and orienting of the CBPCP to the PO, practice protocols that include attendance at IDT meetings, and participation in QI activities. The guidelines in this chapter provide a roadmap for requesting waivers and implementing the inclusion of CBPCPs in PACE once the waivers are approved.

Program Models of Care

There are many ways that a PO can integrate CBPCPs in practice. Currently, more than 20 POs utilize these waivers, many of whom can be resources for other organizations applying for waivers. Each organization has taken a different approach. For example, the NP or advance practice nurses and provider relations staff may play an important bridging role. Alternatively, a staff geriatrician and NP may play coordinating and consultation roles.

The outcomes of incorporating CBPCPs in PACE practice are encouraging thus far. With the medical director providing close oversight, the quality of care appears to be high. As expected, the utilization of acute care and other medical services may be high initially but ultimately can be controlled. IDTs and CBPCPs have generally favorable impressions of this practice arrangement (Reardon et al., 2008).

Most PACE programs agree that having an employed staff physician is still the “gold standard” for quality and utilization. For that reason, it is very important that a PACE program first develop a staff model with an employed physician before requesting waivers and developing a community physician model. In this way, the PO is able to establish benchmarks for quality, clinical and financial outcomes to which the CBPCP approach can be compared.

The role of the medical director is very important. Because a community physician serves as the PCP, additional oversight and communication are needed. The organization should set up policies and procedures that carefully outline how the community PCP will work with the organization. These policies should outline how the CBPCPs will work in their role as PCPs, how they will relate and interact with the IDT, and how they will collaborate with NPs, if the organization uses them. The policies should designate an employed physician to be part of the IDT on all teams with CBPCPs. For example, the PO might opt to use the NP in a bridge role representing the CBPCP at IDT meetings.

Medical Director Oversight and Incorporation of CBPCPs

The PACE medical director must be aware of the practice style of the group or organization from which the contracted physician comes. Each physician practice is different as to how they work together and how they cover for each other and take calls. In addition, their clinics may operate differently. It is important to understand all of the differences, as not all practices or physicians are comfortable with the team approach.

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to care. It is vital that there be a shared vision of the physician’s role on the team. The CBPCP must be willing to work in a team approach and to communicate with the NP and IDT as needed.

Following are examples of policies and protocols that the organization may want to develop.

**Selection of the Physician (or Group of Physicians)**

The criteria for choosing CBPCPs to contract with are similar to those for hiring employed staff physicians:

- excellent clinical skills that cross all aspects of medicine;
- comfortable with outpatient care and inpatient medicine;
- outstanding skills in assessing information from specialists and deciding how to integrate the information into the participant’s plan of care;
- adept at communicating with colleagues, team members and administration; and
- able to relate to others on the team as peers, combining confidence with humility.

Prior to contracting with a CBPCP, there are a number of items to discuss:

- shared mission and vision of the physician role, holistic and team approaches;
- PACE as a provider of care and the payor; successful outcomes within economic model;
- negotiation of fees for participant visits, team meetings, and other potential team and NP interactions;
- 24-hour access to the CBPCP from the team and participant; and
- assessment requirements, coding requirements, quality controls and data set preparation for submission to CMS.

**Orientation Plan for CBPCPs and Coverage Group**

The orientation plan for CBPCPs and the coverage group involves orienting the physicians to the PACE model of care, the organization and their responsibilities. There is a need for regular ongoing interaction among the CBPCP, medical director and IDT. The plan also involves orienting the physician’s office staff to the PACE model and team, developing effective means of communication, and establishing performance metrics and auditing measures to ensure successful outcomes.

Protocols must be established for how the CBPCP and IDT will work together. Develop a protocol for sharing clinical information and maintaining a complete PACE record, as well as a process for communicating critical information to the physician for their medical record. The PO maintains a comprehensive medical record and shares all pertinent medical information with the CBPCP, and the CBPCP maintains their own medical record and provides the PO with copies of all progress notes for physician visits and test results.

Other protocols are as follows:

- The CBPCP needs to be part of the initial and periodic reassessments.
- Evaluation and treatment of episodic illnesses in participants as needed.
- Maintain 24-hour on-call responsibility.
- Collaborative practice with the PO NP to provide all medical care for their participants.
- Referral to medical specialists as needed and per PO guidelines.
➢ Follow all PO screening and treatment guidelines.
➢ The CBPCP or delegated individual will attend team meetings in person or telephonically as needed to provide continuity of care.
➢ Team meeting attendance in person or telephonically when their participant has a significant change in condition or treatment change is discussed by the IDT.
➢ Provide acute care and nursing home coverage for participants within their practice.
➢ Consultation may be done with the physician in attendance or via telephone as needed to provide primary medical care.
➢ All treatment plans, whether recorded in the progress notes or in periodic reevaluations, are discussed with the CBPCP at periodic intervals based on the acuity of the participant’s condition.
➢ The PO NP and CBPCP will assure that all PO protocols, guidelines, standards and primary care policies are followed.
➢ The medical director or site physician designee is available for case consultation as needed.
➢ NP supervisors review cases with PO NPs as needed and oversee quality care guidelines, adherence to PO policies for care, competencies, and standards of practice for the NPs who work with CBPCPs.

The employed PACE team physician/medical director is responsible for the oversight of the CBPCP practice:
➢ The employed PACE physician attends team meetings regularly and is available to review difficult cases as needed.
➢ Discipline-specific QA review of the CBPCP charts are done in conjunction with an annual review and as needed to maintain quality and clinical outcomes.
➢ Liaison with CBPCP and team/NP as needed regarding difficult cases or treatment plans.

Key Performance Metrics Review and Quality Monitoring

Because CBPCP care falls outside the conventional model of clinical care directed by a PO-based PCP, medical records of participants with CBPCPs may be more likely to be reviewed during a CMS audit. This potential creates an opportunity for the quality director, in concert with the medical director, to develop and maintain performance metrics and monitoring capabilities that encompass the issues addressed above.

On at least an annual basis, the PACE medical director must review the performance of the CBPCPs per their policy and procedure and according to the contract agreements. The workflows for assessing the CBPCP’s performance, along with the tools to assess it, need to be defined so the process can be managed on an ongoing basis. This supports standards of practice and program integration and prevents workflow processes from becoming a major project at the end of each year with a minimal amount of information to complete it.

The tools used to assess the performance, cooperation and competency of the CBPCP should be built into the daily workflows dealing with the CBPCP and their office so information constantly is being collected and can be reviewed periodically during the year and summarized at the end of the year to determine if standards have been met or a corrective action plan is warranted.
Consider the following areas for quality monitoring:

➢ timeliness of assessments, coding, documentation;
➢ morning report participation;
➢ IDT meeting participation and care plan development;
➢ access and availability related to interim member issues;
➢ utilization metrics such as hospital and 30-day readmission rates, ER visits, specialty services and home care services;
➢ adherence to grievance, disenrollment, satisfaction rates; and
➢ adherence to formulary; percent brand versus generic.

Writing the Waiver Request

A waiver request should incorporate the rationale for why the PO is requesting the waiver along with the protocols and procedures that demonstrate how the PO will select and orient the physicians and define the practice protocols for team IDT attendance and participation in QI activities. The PO also should specify the number of physicians and sites they are requesting to be included in the waiver. CMS then will evaluate the request and possibly ask for additional information to make the determination.

Conclusion

Including community physicians in PACE primary care practice has rewards and challenges. The geographic location of a PO or its need for further growth may be compelling reasons to seek CMS waivers to develop the practice. Once developed, the quality director and medical director are pivotal in monitoring quality of care and service utilization patterns.

Contracted Services

§460.70(b), §460.70(b)(1)(iii), §460.70(b)(3), §460.70(d)(1)-(4), §460.70(d)(5)(vii)-(ix), §460.71(a), §460.71(a)(1), §460.71(a)(2), §460.71(a)(4)

The PACE regulations view contractors – for clinical services and rehab, transportation, food service and others – as extensions of PACE staff. Thus, the expectation is that a PO provides the same degree of oversight of services as would be required if the services were performed by employed staff. PACE staff receive orientation and training, health and licensure/certification assessments, and annual competency checks and participate in IDT meetings, perform participant assessments, and receive two-way communications from the quality program. The same standards apply for most contractors. The aspects of contractor oversight related to training, qualifications and competencies typically are overseen by the human resources staff and by individual department heads. A compliant process for oversight of the performance of contracted staff with a policy, documentation and inclusion in the quality plan becomes the responsibility of the quality director.
Alternatively, the PO has the option to delegate to the contracted entity the actual training, orientation, competency evaluations and quality oversight. In such cases, the contractor can provide either an attestation of compliance or more detailed documentation demonstrating the content and manner of oversight. In either case, the quality director has the responsibility to ensure that the training, competencies and quality oversight are comparable to that required of employed staff and can accomplish this goal by conducting an internal audit of contracted staff or actually reviewing each contractor’s files. In addition, contractors are expected to participate in the QI program of the PO.

**Conclusion**

In essence, any activity delegated to an outside entity mandates oversight by the quality director. As is the case with the options noted above, this can be accomplished by the following:

- requiring the vendor to collect data for measures defined by the PO and validating the submissions with spot checks by the PO;
- having the contractor liaison of the PO conduct data collection at the vendor site; or
- including the contractor as a member of the QI committee or subcommittees, depending on the relationship of the PO and vendor, and documenting and disseminating the results of the QI activities to the PACE staff and contractors (460.132).

**References**


CHAPTER 19
Ethical Issues in the PACE Model of Care
Two PACE regulations in the Code of Federal Regulations, Title 42, Chapter IV, Sub-Chapter E, address ethics: §460.71 Oversight of Direct Participant Care and §460.138 Committees with Community Input.

§460.71 Oversight of Direct Participant Care
(a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position.

(1) The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization’s mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff. This regulation speaks to the inclusion of ethics as part of all direct participant care employees’ and contractors’ orientations. The regulations do not go into detail about what should be included in an orientation about ethics, giving much flexibility and leeway to the PO to decide what the content should be. A good rule of thumb to demonstrate compliance with this regulation is to include the topic of ethics as part of the orientation agenda and the content about ethics included with the other orientation documents. Orientation material should include a description of the ethics committee and its purpose, and the processes used by the PO to identify and resolve an ethical issue.

§460.138 Committees with Community Input
A PACE organization must establish one or more committees, with community input, to do the following:

a. Evaluate data collected pertaining to quality outcome measures.

b. Address the implementation of, and results from, the quality assessment and performance improvement plan.

c. Provide input related to ethical decision-making, including end-of-life issues and implementation of the Patient Self-Determination Act.

The role of the quality director will vary depending on the resources available to the PO. Minimally, the quality director should support the establishment of an ethics committee and include a summary of the ethics committee’s work in the annual QI report to the governing body while protecting the identities of those involved with the ethical dilemma. Supporting the committee may simply be collecting information to include in the annual QI report. However, the quality director may be tasked with more responsibilities such as taking minutes, developing agendas, participating on the committee, supporting the committee chair, providing data and information, or assisting with the recruitment of community members. The quality director should be aware of the potential for ethical issues because they could be early warning signs of conflicts of interest affecting the level of PO quality.

Ethical areas can fall into either clinical or non-clinical areas of the PO. Examples include fraud, waste and abuse; intellectual capital protections; HIPAA violations; end-of-life issues; participant rights; involuntary disenrollment; and patient self-determination. The quality director may be included in the investigations of these areas or may work with a compliance officer, HR director or CFO to help determine the circumstances and identify relevant data and information to determine if an ethical dilemma exists and to aid the ethics committee in its resolution.

Additional demonstration of compliance with this regulation is an approved and established policy about the ethical decision-making process of the PO with a description of the ethics committee. The policy should be reviewed and updated periodically as needed. A summary of committee activities should be included in the quality report to the board at least annually.
Impact of Ethics on PO Quality Program

While the work of the ethics committee and an ethics oversight process contribute to the compliance of the organization with PACE regulations, there are circumstances under which ethics issues directly may impinge on the quality program of the PO. The three examples below illustrate potential conflicts of interest that could have direct impacts on the ability of the quality program to conduct its work with reliability and integrity.

**Example 1**
Participants in a PACE program receive home care and home health services from an entity owned and operated by the same integrated delivery system (IDS) to which the PO belongs. Multiple and repeated grievances are brought to the attention of the clinic nursing staff and the quality director from participants, noting missed appointments, perfunctory personal care, unprepared meals and missed medication doses. Root cause analysis demonstrates ongoing scheduling irregularities and staffing concerns, but organizational political and budgetary factors undermine efforts to bring about improvements. As a result, the irregularities persist, and the PO considers dissolving the current contract and switching to a community home care provider.

This is an issue seen in various permutations in the PACE community, where ethical considerations regarding quality oversight may be influenced by organizational politics, incentives, culture and financial implications of the IDS. The potential risks to the PO are multiple, obviously imperiling the outcome of CMS audits but also extending to participant and caregiver satisfaction, quality of care and services, staff satisfaction, and the need for ongoing collaboration with the IDS and other services it provides to the PO.

This type of issue, raising potential ethical issues relating to conflicts of interest by both the PO and its IDS, may nonetheless warrant a political, rather than ethical, solution. The quality director may have multiple paths available; but all of them begin with data collection (e.g., errors, grievances and appeals; observed impacts on the participant population), documenting the scope of the problem and a good faith root cause analysis. Through collaboration with PO leadership, contract review, confidential presentation and discussions with the PACE governing body, and a projected impact on organizational financials and reputation, the PACE team can put itself in the best position to improve the level of collaboration with the IDS and its multiple entities and services (e.g., dietary, transportation, biomedical engineering).

**Example 2**
A new physician with extensive expertise and experience in Utilization Management (UM) at a managed care organization joins the IDT of a PO. He gradually inserts aggressive UM criteria into the team’s consideration of service requests. The IDT, accustomed to approving, for example, maintenance physical therapy services on a continual basis, is now confronted with approving services only for a defined period of time. Members of the IDT receive data demonstrating a marked increase in service request denials and grievances from participants and their caregivers, noting they are dissatisfied with the apparent change in the process and outcomes of service requests.

Participants in a PACE program typically have multiple chronic health conditions and co-morbidities that render them nursing home-eligible. A foundational piece of the PACE model, the IDT is charged with optimizing the functional status of participants, averting preventable complications and incidents, and maintaining for participants the capabilities to live safely in the community. Explicitly acknowledged in the PACE model is the latitude of the IDT to provide customized interventions for each participant, potentially including the provision of even Medicare non-covered services (e.g., a pet, wheelchair ramp, pest control...
service). The plan of care, i.e., the customized road map of care for each participant, is conceived as a dynamic document, using desired outcomes and progress toward goals to determine the effectiveness of proven interventions and sometimes trial-and-error approaches that, in the judgment of the IDT, may be of benefit to a given participant. Additionally, the PACE regulations provide for consideration of participant preferences in IDT decisions. In summary, the IDT is granted the autonomy to provide care and services that might not be deemed “medically necessary” in a traditional managed care UM environment.

In contrast, the traditional Medicare managed care UM function is tasked with approving coverage only for Medicare-covered benefits that are deemed medically necessary according to general coverage determinations or peer-reviewed journals. A beneficiary intent on receiving uncovered or unapproved services typically will have to pay out of pocket, depending on the provisions in his or her enrollment agreement. Because of the unique nature of the PACE model of care, traditional UM functions typically are not applicable, leaving cost concerns to the discretion of the IDT function.

The care of and services to PACE participants are delivered in a capitated environment, and the IDT is faced with ensuring the successful delivery of services without imperiling organizational solvency. The ethical dilemma in this example arises from a disturbance in that balance that favors either service provision or financial solvency at the expense of the other.

For the quality director, surveillance of service request denials and participant/caregiver grievances and appeals are critical for ensuring the balance is being maintained. A grievance filed by a participant – for example, noting that she cannot get approval for replacement eyeglasses damaged in a fall because “only one pair of eyeglasses can be approved each year” – may be the first indicator that the services versus solvency balance has changed. Alternatively, a surge in grievances above baseline for service denials may be an early warning of decreasing participant satisfaction.

Ultimately, the quality director can maintain oversight of this conflict and its ethical component by continual scrutiny of organizational indicators, including participant outcomes and participant/caregiver grievances and appeals.

**Example 3**

A PO leadership team notes that the accommodative approach of the IDT recently resulted in approval of wheelchairs, stair lifts, and other assistive devices associated with significant expense. With a justifiable concern over organizational finances, the leadership team implements a process involving the medical director, executive director, program manager and CFO to review all IDT-authorized services in excess of $1,000. While this sub-group reinforces many of the IDT approvals, it retains veto power to overturn decisions it deems to be administratively excessive or medically unnecessary.

This case is similar to the second example, as it portrays an analogous strategy aimed at preserving a manageable service delivery/organizational solvency balance. While all POs have the explicit obligation to monitor costs of approved services, the PACE regulations have no provision for delegating financial oversight of IDT determinations to another entity independent of the IDT. As in both prior cases, ethical concerns – such as subordinating participant needs to considerations affecting organizational finances – may overlay concerns of other organizational functions or stakeholders, e.g., organizational politics, organizational culture or financial considerations.

The most obvious threat for the quality director is that the existence of this “super-committee” is likely to imperil the outcome of a CMS audit because it undermines the role of the IDT in rendering responsible participant-centered service decisions. The director has a full arsenal of data – participant outcomes, logs of grievances and appeals, financial indicators on the PO dashboard, etc. – to assist in after-the-
fact investigations of breaches in PO processes, functions and outcomes where necessary. However, the quality director may benefit from attending IDT meetings episodically to determine proactively whether organizational functions are operating in accordance with PACE regulations long before problems warranting full investigations can develop.

In summary, while the resolution of ethical conflicts in POs does not explicitly fall under the purview of the quality director, any number of steps can be incorporated into the quality program to ensure that impacts on participants, caregivers, staff and organizational finances are detected early and remediated.
For a new PACE quality director, the task at hand may appear daunting. The expectations of PACE quality directors differ from those of quality directors in other settings. A typical PACE quality director acts as a clinical resource, a PACE “expert,” as well as an administrator responsible for the implementation and oversight of QI. The role of the quality director is to learn the essential elements of PACE and the universal principles of QI and to blend them together to implement a comprehensive PACE QI program.

From a regulatory standpoint, the medical director of the PACE organization has overall responsibility for the QI program and usually is designated the chair of the QI committee. However, the operations of the program usually are the responsibility of the quality director. This includes the facilitation of committee meetings, communication with management and the IDT, record keeping and data tracking. Another very important function is the critical analysis of information about services and outcomes in the PACE program in order to maintain an effective improvement program. A collaborative relationship between the medical director and quality director also is essential to the success of the program.

The following steps are recommended for orienting to this position:

1. **Obtain and Read the Quality Director’s Handbook**

   The Quality Director’s Handbook is a valuable source of information that is directed specifically to quality directors of PACE programs. The chapters, written by PACE experts, capture all the essential dimensions of quality directorship. The handbook defines standards of practice expected of every PACE quality director and explains concepts that are unique and essential to PACE.

2. **Go Online**

   The CMS and NPA websites are very helpful.

3. **Attend NPA Meetings and Conferences**

   NPA holds a number of substantial meetings throughout the year. The NPA Summer Conference and the NPA Annual Conference in the fall are held in cities across the country where PACE programs are located. New quality directors especially benefit from the quality content of these conference. The NPA Spring Policy Forum is held in Washington, DC. The meetings provide educational and networking opportunities for all levels of PACE staff. An extensive array of topics is tailored to serve the unique needs of PACE programs at various stages of development.

   Each PO should be represented on the NPA Quality Improvement Committee to stay up to date on current standards and to network with other PACE quality directors. Additionally, the Primary Care and Nursing consortiums provide opportunities to learn about PACE and network with experienced PACE providers.

4. **Establish Relationships, Network with Other Quality Directors**

   The annual and summer conferences provide opportunities to meet other quality directors with various levels of experience. The interaction and discussions are quite unique since there is no other place where a majority of PACE quality directors are gathered in one venue.

   NPA also hosts e-communities that are organized for different disciplines in the PO, such as QI, primary care, nursing and recreation therapy. These e-communities allow the user to post a question and receive answers from POs all over the country.
5. Visit Other PACE Sites

New quality directors should visit other PACE sites whenever possible. These visits are a good source of education and provide direct exposure to different norms and practices. Keep in mind that, while the PACE regulations and standards of effective QI are universal, what works in one site may not apply at another. The development and ongoing success of a program depends on the organization in which the quality director operates, the characteristics of the program, and the needs of participants.

6. Participate in the NPA Quality Mentorship Program

The NPA Quality Mentorship Program partners experienced and new PACE quality directors for a six- to 12-month period to promote learning and networking. For more information, contact NPA.

7. Review the Established QI Program or Establish a Program

The information contained in this handbook will be very useful to quality directors who are in the process of establishing or revising a QI program. It is vital that its development be a collaborative effort with senior management, particularly the medical director. The most effective QI programs are woven into the fabric of the PACE program through staff development and IDT processes.

8. Develop Systems to Maintain QI Information and Reports

All minutes and summary reports need to be maintained in an organized fashion. This system should be secure so documents cannot be lost or altered. It also should be available to administration and retrievable for regulatory surveys. All documentation should be HIPAA-compliant and not include any identifying participant information. Finally, program information, including current projects and outcomes of completed projects, should be available to staff at all levels.
ADDITIONAL RESOURCES

PACE Regulation (in effect until CMS releases a new final rule)
➢ CMS Proposed Rule for PACE
➢ NPA Comment on the Proposed Rule for PACE (10/12/16)

NPA Federal Regulatory Policy
➢ NPA Comments and Summaries for Emergency Preparedness, New Provider and Supplier Enrollment Requirement, and more.

Compliance Section of NPA Website
➢ PACE Audit Process and Related Materials
➢ CMS Care Planning Guidance
➢ Level I and Level II Reporting Requirements
➢ Deficit Reduction Act Compliance Materials

Emergency Preparedness Section of NPA Website

Quality Improvement Section of NPA Website
➢ NPA Quality Improvement Committee: Each PACE organization is to have a representative on the committee.

Reporting Requirements for PACE:
➢ Risk Adjustment Processing System (RAPS): Data reporting for purposes of submitting diagnoses for risk adjustment.
➢ Encounter Data Reporting
➢ Prescription Drug Event (PDE) Data Reporting
➢ Level I and Level II Reporting
➢ Health Outcomes Survey-Modified (HOS-M): A contracted vendor administers the annual survey to PACE participants.
➢ Payment Section of the NPA Website: Topics include 1/3 Part D financial audits, encounter data reporting, Medicare risk adjustment.

PACE Audit Information
➢ Compliance Section of the NPA Website

PACE Audit Page on the CMS Website