PROGRAM QUALITY AND OVERSIGHT

Services offered through the Program of All-Inclusive Care for the Elderly (PACE) are monitored to assure compliance with Centers for Medicare and Medicaid Services (CMS) and the Louisiana Department of Health (LDH) as well as applicable State and Federal rules and regulations. Oversight is conducted through licensure compliance and program monitoring.

The PACE provider must designate one (1) staff member to coordinate and oversee implementation of quality assessment and performance improvement activities.

The PACE program agreement will outline the quality initiatives required. This includes the development of a Quality Assessment and Performance Improvement (QAPI) program, Level One External Reporting Requirements, and Level Two External Reporting Requirements. CMS and LDH/Office of Adult and Aging Services (OAAS) monitor outcomes through review of data submitted through CMS reporting systems and onsite visits.

Quality Assessment and Performance Improvement Program

The PACE provider must develop, implement, maintain, and evaluate an effective data-driven QAPI program. It is important that the QAPI program reflects the full range of services furnished by the PACE provider. In developing the QAPI program, the PACE provider must use organizational data to identify and improve areas of poor performance and take actions to make performance improvements in all types of care.

PACE providers have the flexibility to develop the QAPI program that best meets their needs in order that they may fully meet the obligations to care for their beneficiaries. PACE providers must operate a continuous QAPI program that does not limit activity to only selected kinds of services or types of beneficiaries. The PACE provider must use the QAPI requirements to drive and prioritize continuous improvements.

The QAPI program must include, but is not limited to, the use of objective measures to demonstrate improved performance with regard to the following:

- Utilization of PACE services, such as decreased inpatient hospitalizations and emergency room visits;
- Caregiver and beneficiary satisfaction;
- Measure and evaluate caregiver and beneficiary satisfaction with care and services;

- Outcome measures that are derived from data collected during assessments, including data on the following:
    - Physiological well-being;
    - Functional status;
    - Cognitive ability;
    - Social/behavioral functioning; and
    - Quality of life of beneficiaries.
- Effectiveness and safety of staff provided and contracted services, including the following:
    - Competency of clinical staff;
    - Promptness of service delivery;
    - Achievement of treatment goals and measurable outcomes;
    - Non-clinical areas such as, beneficiary and caregiver complaints and grievances, transportation services, meals, life safety and environmental issues; and
    - Mechanisms to receive and address beneficiary and care giver complaints and grievances.

The QAPI program must be written into a Quality Improvement Plan (QIP) and at a minimum, the QIP must contain the following:

- Identify areas in which to improve or maintain the delivery of services and beneficiary care;
- Develop and implement plans of action to improve or maintain quality of care; and
- Document and disseminate the results of the QAPI activities to the PACE staff and contractors.

The QIP must:

- Be submitted annually to CMS;
- Be submitted to OAAS annually for approval and inclusion into the PACE program agreement; and
- Reviewed by the PACE Governing Body annually and revised, if necessary.

Quality Improvement Activities

The PACE providers must ensure that their program is consistently working on internal quality improvement activities by conducting the following:

- Using a set of outcome measures to identify area of good or problematic performance;
- Taking actions targeted at maintaining or improving care based on outcome measures;
- Incorporating 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;
- Setting priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes;
- Immediately correcting any identified problem that directly or potentially threatens the health and safety of PACE beneficiaries; and
- Ensuring that all Interdisciplinary Team (IDT) members, PACE staff and contractors are involved in the development and implementation of quality improvement activities and aware of the results of these activities.

The QAPI Coordinator must encourage PACE beneficiaries and their caregivers to be involved in quality improvement activities, including information pertaining to the satisfaction of their PACE services.

Quality Committees

The PACE providers must establish one (1) or more committees with community input that perform the following:

- Evaluate the data collected that pertains 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."

Level One (I) External Reporting Requirements

PACE providers are required to submit data elements for monitoring that are regularly reported by PACE providers via the Health Plan Management System (HPMS) PACE monitoring module. These monitoring elements are detailed in the HPMS PACE User's Guide, Fall 2005 (https://www.cms.gov/PACE/Downloads/hpmsmanual.pdf).

Level one data elements include routine immunizations; grievances and appeals; enrollments; disenrollments; prospective enrollees; re-admissions; emergency (unscheduled) care; unusual incidents; and deaths. The HPMS database is regularly monitored by staff in the CMS Regional Office (RO) and LDH/OAAS.

Level Two (II) External Reporting Requirements

PACE providers are required to report events resulting in significant harm to beneficiaries, or negative national or regional notoriety related to their PACE program. The CMS Manual and the CMS PACE Level Two External Reporting Guidance (the "Level Two Guidance") clarify the Level Two reporting events that must be expeditiously reported to CMS. Examples of Level Two reportable incidents may include: deaths, falls, infectious disease outbreaks, pressure ulcers, traumatic injuries, etc.

PACE providers are required to report level two reporting incidents within 48 hours to CMS Central Office and Regional Offices and OAAS. Level two incidents require internal investigation and analysis of the occurrence by the PACE providers with the goal of identifying system(s) failures and improvement opportunities. PACE providers must begin the investigation within 24 hours of reporting it to CMS and OAAS and must be concluded within 30 calendar days of reporting the incident. It is expected that the PACE provider's investigation include a root cause analysis and/or consult with CMS if the PACE provider feels that a root cause analysis would not yield programmatic improvements.

The National PACE Association (NPA) uses a web based benchmarking data collection system, DataPACE 2, which is maintained and managed by NPA. The DataPACE 2 data is used to create the PACE profile. DataPACE 2 provides NPA members the ability to cross-site data analysis and benchmark the data, prepare reports on beneficiary characteristics and monitor the development of the PACE model of care. Data collected includes, but is not limited to, areas of

quality of care, beneficiaries served, and service utilization. This data is compiled quarterly. Louisiana PACE programs must participate in DataPACE 2. Data must be submitted by the PACE program according to the most current NPA Data Calendar schedule. The data must be submitted timely so that validation is accurate. The due date for complete data submittal is 30-90 days after the end of a quarterly reporting period ends. The PACE program must review the measurement results for the reporting period and validate their accuracy 120 calendar days after each quarter. LDH/OAAS monitors and reviews the compilation of data collected.

Reviews and Monitoring

The PACE provider must take action to correct deficiencies identified during the reviews. CMS and/or OAAS monitors the effectiveness of the corrective action through the following:

- Ongoing monitoring of the PACE provider;
- Reviews and audits of the PACE provider;
- Complaints from PACE beneficiaries or caregivers; and
- Any other instance CMS or the LDH/OAAS identifies programmatic deficiencies requiring correction.

Failure to correct deficiencies may result in sanctions or termination. Disclosure of the review results must be available as demonstrated by 42 CFR 460.196.

Results

The PACE providers must ensure that all Interdisciplinary Team (IDT) members, PACE staff, and contract providers are involved in the development and implementation of quality improvement activities.

The information on voluntary disenrollments must be used in the PACE providers' internal QIP as specified by 42 CFR 460.164 (c).

Corrective Actions

CMS and LDH/OAAS report the results of the reviews to the PACE provider, along with any recommendations for changes to the provider's program. The PACE provider must write a corrective action plan, a description of the action plan that will be taken to correct the identified deficiency.

Sanctions, Enforcement Actions, and Termination

CMS and LDH/OAAS work together to ensure the benefits and services provided are of high quality and meet the requirements set forth in the statute and regulations. When compliance actions fail to achieve the desired result or an instance of non-compliance is especially egregious, CMS and/or LDH/OAAS may take enforcement action.

Some enforcement actions may include the ability to apply sanctions as follows:

- Civil money penalties;
- Suspension of payments; and
- Termination of the contract (for a variety of offenses as they relate to the operation of the PACE program).

CMS may impose sanctions if the PACE provider commits any of the following violations:

- Fails substantially to provide a beneficiary medically necessary items and services that are covered by PACE, if the failure adversely affected (or has substantial likelihood of adversely affecting) the beneficiary;
- Involuntarily disenrolls a beneficiary in violation of 42 CFR 460.164;
- Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid beneficiaries, or both, who are eligible to enroll in a PACE program, on a basis of an individual's health status or need for health care services;
- Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by 42 CFR 460.150, by Medicare beneficiaries or Medicaid beneficiaries whose medical condition or history indicates a need for substantial future medical services;
- Imposes premium charges on beneficiaries enrolled under Medicare or Medicaid that is more than the allowable amount;
- Misrepresents or falsifies information that is furnished to CMS or the State or to an individual or any other entity under part 460;

- Prohibits or otherwise restricts a covered health care professional from advising a beneficiary, who is a patient of the professional, about the beneficiary's health status, medical care, or treatment for the beneficiary's condition or disease, regardless of whether the PACE program provided benefits for that care or treatment, if the professional is acting within his or her lawful scope of practice;

- Operates a physician incentive plan that does not meet the requirements of section 1876(i) (8) of the Act; and

- Employs or contracts with any individual who is excluded from the participation in Medicare and Medicaid under section 1128 or section 1128A of the Act (or with any entity that employs or contracts with that individual) for the provision of health care, utilization review, medical social work, or administrative services.