

Programs of All-Inclusive Care for the Elderly (PACE)

Chapter 10 – Quality Assessment and Performance Improvement

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(Rev. 2, Issued: 06-09-11)

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10 - Introduction

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Title 42 CFR § 460, Subpart H – Quality Assessment and Performance Improvement (QAPI), establishes the quality improvement program requirements that the Programs of All-Inclusive Care for the Elderly (PACE) organizations must meet under the Social Security Act. Furthermore, Sections 1894(e)(3)(B) and 1934(e)(3)(B) of the Act require that, under a PACE Program Agreement, the PACE organization, CMS, and the State Administering Agency shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE participants.

20 - QAPI Program

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The PACE organization 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 organization. In developing the QAPI program, the PACE organization should use organizational data to identify and improve areas of poor performance. The PACE organization must take actions that result in improvements in its performance in all types of care.

Currently, 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 included in the program agreement. PACE organizations have the flexibility to develop the QAPI program that best meets their needs in order that they may fully meet the obligations of care for its participants. It is CMS's expectation that PACE organizations will operate a continuous QAPI program that does not limit activity to only selected kinds of services or types of patients. The desired outcome of the QAPI requirement is that data-driven quality assessment serves as the engine that drives and prioritizes continuous improvements for all the PACE organization's services.

[42 CFR §§ 460 Preamble Discussion, 460.130; 71 FR 71305 (Dec. 8, 2006)]

20.1 - QAPI Plan

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The PO must have a written QAPI plan. 42 CFR § 460.132(b) requires POs to have their QAPI plan reviewed annually by the PACE governing body and, if necessary, revised.

At a minimum, the PACE organization's QAPI plan must 1) identify areas in which to improve or maintain the delivery of services and patient care; 2) develop and implement plans of action to improve or maintain quality of care; and 3) document and disseminate the results of the QAPI activities to the PACE staff and contractors.

As per 42 CFR § 460.132(a)(b), the PACE organization leadership presents their QAPI plan and any revisions to their governing body for annual approval to assure effective

organizational oversight. CMS and the State Administering Agency approve the QAPI plan prior to its inclusion in the program agreement and also review the plan during subsequent monitoring visits.

[42 CFR § 460.132]

20.2 - QAPI Requirements

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Through the QAPI program, PACE organizations should evaluate the effectiveness of the wide range of services furnished by PACE organizations and use data to identify, improve and maintain program performance. CMS believes that each PACE organization should have the flexibility to design an internal QAPI that would best meet the needs of its enrolled participants and their caregivers; therefore, CMS neither specified a standardized quality assessment tool nor dictated the data-driven outcome measures that PACE organizations should internally collect, analyze, and act on to improve performance. However, CMS did provide in 42 CFR § 460.132 (and discussed in section [20.1](#)) the minimum requirements that must be addressed in the PACE organization's written plan for the internal QAPI program, including the requirement that the plan be reviewed annually and revised by the respective PACE governing body to assure organizational oversight and commitment.

A PACE organization's QAPI program must include, but not be limited to, the use of objective measures to demonstrate improved performance with regard to five areas: 1) utilization of services (e.g., decreased inpatient hospitalizations and emergency room visits), 2) participant and caregiver satisfaction, 3) outcome measures that are derived from data collected during participant assessments, 4) effectiveness and safety of staff-provided and contracted services, and 5) non-clinical areas including grievances and appeals.

- **Utilization of Services.** Collected utilization data such as hospitalizations and emergency room visits can be used to evaluate fiscal well-being, as well as evaluate quality of care. It can also be used to target reviews of PACE centers whose utilization data suggest, for example, that participants may be receiving fewer services than necessary to achieve expected outcomes. The purpose for including utilization data in the PACE organization's QAPI program is to help the PACE organization ensure that participants receive the appropriate level of care through their PACE center. Additionally, by collecting and analyzing information regarding utilization of and reasons for emergency care and hospital and nursing home admissions, the PACE organization can identify areas for improvement;
- **Participant and Caregiver Satisfaction.** Participant and caregiver satisfaction with services is an important element of a QAPI program. A PACE organization must survey, on an ongoing basis, participants and their caregivers to determine satisfaction with the services furnished and the

outcomes achieved. Given the large number of PACE participants who are cognitively impaired and the critical role caregivers play in keeping PACE participants in the community, it is important to survey caregivers about their satisfaction with the program. CMS expects the PACE organization to use this information to identify opportunities to improve services and caregiver and participant satisfaction. Although CMS does not require the use of a specific survey tool in measuring participant and family satisfaction, the PACE organization is expected to demonstrate a scientifically sound satisfaction measurement system and how it is used as part of the overall internal QAPI system;

- **Data Collected During Participant Assessments.** Outcome measures are derived from participant assessment data to determine if individual and organization-level measurable outcomes are achieved within a specified time period. The compiled data must include, at a minimum, the physiological well-being, functional, mental health, social and behavioral status, cognitive ability, and quality of life of the participant assessment information;

For example, PACE organizations are expected to focus their quality improvement activities on outcomes such as stabilization in ability to bathe, from a baseline period to each follow-up period; improvement in dyspnea from admission into PACE to a follow-up period; improvement in transportation services over a specific period of time; and improvement in caregiver stress from participant admission into PACE to a follow-up period (42 CFR § 460 Preamble Discussion/Federal Register December 2006);

- **Effectiveness and Safety of Direct and Contracted Services Delivered to Participants.** The effectiveness and safety of the PACE services provided by the PACE organization's staff or contracted services must be evaluated, to include competency of clinical staff, promptness of service delivery, and achievement of treatment goals and measurable outcomes.

For participants to experience the outcomes that the PACE benefit is intended to achieve, staff must demonstrate skills and competencies necessary to facilitate those desired outcomes. The PACE organization is expected to include data-based, criterion-referenced performance measures of staff skills, to utilize these data to ensure that staff maintains skills and to provide training as new techniques and technologies are introduced and as new staff are hired. Each PACE organization will be expected to demonstrate that it has a system of appropriate complexity for keeping track of the skills and competencies of the staff and for effectively identifying and addressing staff training needs. These data should be an integral part of the PACE organization's internal QAPI program that provides continuous feedback on staff performance;

- **Non-Clinical Areas.** The types of outcomes in this area include outcomes related to grievances and appeals, transportation services, meals, life safety, and environmental issues.

For example, if a PACE organization finds a high rate of grievances not resolved, the PACE organization might target its activities to improve the grievance process.

Furthermore, CMS requires that the PACE organizations ensure the accuracy, integrity, and completeness of all data used for outcome monitoring. A data-driven QAPI program must be based on accurate data. The regulations require that PACE organizations set up mechanisms to check for the accuracy, timely collection, and completeness of all data. As such, CMS would expect to see a formal data integrity training program and competency evaluation for all staff responsible for collecting or analyzing data.

[42 CFR §§ 460.130; 460.132(c)(2); 460.134(a) and (d); 71 FR 71304 through 71306 (Dec. 8, 2006)]

20.3 - Internal QAPI Activities

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

PACE organizations 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 these outcome measures. CMS expects PACE organizations to use the most current clinical practice guidelines and professional standards in the development of outcome measures applicable to the care of PACE participants. Continuous improvement is only possible through identification and use of current information, techniques, and practices. CMS also expects the PACE organization will utilize the current clinical and professional standards as a routine part of its daily operations. A PACE organization must ensure that all IDT members, PACE staff, and contract providers are involved in the development and implementation of QAPI activities and are aware of the results of these activities. As such, the PACE organization must:

- Establish and maintain a health information system that collects, analyzes, integrates, and reports data to measure the organization's performance, including outcomes of care furnished to participants. Staff involved in each stage of data collection and analysis must be sufficiently trained in data integrity concepts and practices to assure the soundness and applicability of the data the PACE organization will act upon;
- Use a set of outcome measures to identify areas of good or problematic performance;
- Prioritize performance improvement activities based on prevalence and severity of identified problems, and give priority to activities that improve clinical outcomes;

- Immediately correct an identified problem that directly or potentially threatens the health or safety of participants;
- Document and disseminate QAPI results to staff and contractors; and
- Incorporate improvements into standard practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time.

Furthermore, the PACE organization must meet minimum levels of performance on standardized quality measures which are specified in the PACE Program Agreement. Currently, CMS requires all PACE organizations to achieve at least an 80 percent flu immunization rate for their PACE participants. If a PO fails substantially to meet these specified requirements, the continuation of the PACE program agreement may be conditional on the execution of a CAP, or alternatively, some or all further payments for PACE program services may be withheld until the deficiencies have been corrected.

By virtue of being a full-service program targeting the vulnerable frail elderly, PACE leaders face unique challenges. An effective QAPI program requires continuous surveillance by all stakeholders (employed and contracted staff, caregivers, and participants) of the range of PACE services. CMS believes the designation of a dedicated QAPI coordinator is imperative to conduct continuous performance improvement activities that inform the PACE organization leadership ultimately responsible for care delivery including, but not limited to: ambulatory, home health, adult daycare, 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, transportation, as well as specialized services in the community.

CMS requires the PACE organization to identify the Medical Director as the person and position responsible for the oversight of the QAPI program. Furthermore, the medical director has oversight responsibility for patient outcomes, assures data completeness, plan development, performance of activities, and outcome evaluations for plan effectiveness.

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

[42 CFR §§ 460.134, 460.136, 460.202(a); Level Two Guidance, October 2010]

20.4 - QAPI Committee

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A PACE organization is required to develop a committee(s) with community input to 1) evaluate data collected pertaining to quality outcome measures, 2) address the implementation of and results from the QAPI plan, and 3) provide input related to ethical decision-making including end-of-life issues and implementation of the Patient Self-Determination Act. Through this committee(s), the PACE organization will be able to receive guidance regarding its QAPI program and the ethical issues faced by PACE organizations.

[42 CFR § 460.138]

30 - Additional Quality Assessment Activities

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

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 healthcare environment. Risk assessment ideally is conducted prospectively to prevent occurrences that result in adverse health outcomes to participants or staff, or harm to the organization's physical plant/equipment or fiscal status. In reality, risk assessment is most often conducted in response to an event that results in medical, psychosocial, cognitive, or functional harm to a participant or staff. Every person employed or contracted by the PACE organization has responsibility for risk assessment and management.

External monitoring activities refer to both:

- The submission of the aggregated monitoring data elements via the PACE monitoring module of the Health Plan Management System (HPMS) Level One Reporting; and
- The reporting of events resulting in significant harm to participants, or negative national or regional notoriety related to the PACE program (Level Two Reporting).

This manual and the PACE Level Two External Reporting Guidance (the "Level Two Guidance") clarify the Level Two reporting events that must be expeditiously reported to CMS.

[42 CFR § 460.140; Level Two Guidance, October 2010]

30.1 - External Reporting Requirements

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

This manual and the Level Two Guidance provide an overview of requirements for PACE organizations to report both aggregate and individual-level data to CMS and State Administering Agencies for their use in monitoring PACE organizations' performance.

PACE requirements include Level One and Level Two Reporting, Health Outcomes Survey-Modified (HOS-M) participation and additional reporting to other Federal and State health authorities as required.

The Level Two Guidance replaces the Sentinel Events Reporting Policy issued by CMS in 2004. In so doing, CMS is discontinuing use of the term "sentinel event" and adopting an external reporting paradigm that distinguishes between Level One and Level Two Reporting Requirements as described below.

[42 CFR §§ 460.140; 460.202(b); Level Two Guidance, October 2010]

30.2 - Level One Reporting Requirements

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Level One Reporting Requirements refers to those data elements for monitoring that are regularly reported by PACE organizations 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>) and include:

- Routine Immunizations;
- Grievances and Appeals;
- Enrollments;
- Disenrollments;
- Prospective Enrollees;
- Readmissions;
- Emergency (Unscheduled) Care;
- Unusual Incidents; and,
- Deaths.

The HPMS database is regularly monitored by staff in the CMS Regional Office (RO) and State Administering Agency (SAA).

Data reported in response to the Level One Reporting Requirement are used by PACE organizations to identify opportunities for quality improvement. For example, based on their review of Level One data reported in HPMS, PACE organization's may:

- Conduct a QAPI activity using a standardized methodology (e.g., Plan, Do, Check, Act known as PDCA) if a policy or system problem is identified;
- Institute QAPI-driven change in policies, procedures, systems, or training as appropriate;
- Evaluate the effectiveness of the intervention;
- Track and trend for sustainable improvement;
- Reevaluate until improvement is sustained;
- Document for review during CMS/State Administering Agency audit as evidence of a performance improvement activity;
- Report findings at least annually to oversight committees including the PACE organization's governing board.

[HPMS PACE User's Guide, Fall 2005; Level Two Guidance, October 2010]

30.3 - Level Two Reporting and Reporting Thresholds

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

When unusual incidents meet specified reporting thresholds, PACE organizations are required to report them on a timely basis as Level Two Reporting Incidents to CMS Central Office and Regional Offices and the State Administering Agency. Level Two incidents require internal investigation and analysis of the occurrence by the PACE organization with the goal of identifying system(s) failures and improvement opportunities.

For example, Level Two reportable incidents may include:

- **Deaths** related to suicide or homicide (known or suspected), unexpected and with active coroner investigation;
- **Falls** resulting in death or in injury requiring hospitalization of five days or more, or resulting in injury for which the determination is made within 48 hours of the fall that permanent loss of function is expected;
- **Infectious Disease Outbreak** that meet the threshold of three or more cases (or the respective State standard if more stringent) linked to the same infectious agent within the same time frame;

- **Pressure Ulcer** acquired while enrolled in the PACE program;
- **Traumatic Injuries** which result in death or hospitalization of five days or more, or result in injury for which the determination is made within 48 hours of the injury that permanent loss of function is expected.

For a specific listing of reportable incidents and thresholds, refer to the Level Two External Reporting Guidance, October 2010.

30.4 - Reporting Requirements of Level Two Incidents

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

When an incident meets a Level Two reporting threshold, the PACE organization must complete the following steps:

Within 48 hours of determining the threshold for Level Two reporting has been met, notify CMS via e-mail at the dedicated PACE mailbox PACE@cms.hhs.gov and copy the State Administering Agency and the Regional Office.

Examples:

- If an incident results in a participant's death, the incident must be reported within 48 hours of the participant's death;
- If an incident results in a hospitalization of five days or more, the incident must be reported within 48 hours of the 5th day of the hospital admission;
- In cases where a determination is made within 48 hours that permanent loss of function is expected, reporting must take place within 48 hours of such determination.

Email notification must provide:

- Subject Line: "PACE Level Two Report";
- The age and gender of participant involved;
- Identify the date and type of unusual incident, and the threshold for reporting, e.g., 87-year-old female participant experienced a fall on DATE which resulted in a hospitalization of five days or more;
- PACE organization name and reporting staff contact information.

If the PACE organization is unsure if a Level Two reporting threshold has been met, the PACE organization will consult with its CMS Regional Office Account Manager by

telephone. The PACE organization's contact with the CMS Regional Office Account Manager must be made within 24 hours (or next business day) of determination that Level Two reporting may be required.

The PACE organization must undertake an internal investigation of the incident. The investigation must be initiated within 24 hours of reporting the incident to CMS and the State Administering Agency, and must be concluded within 30 days of reporting the incident. If the internal investigation cannot be completed within 30 days, then prior to the 30-day deadline, the organization must notify CMS by sending an email to PACE@cms.hhs.gov with a copy to the State Administering Agency and the CMS Regional Office. The notification must describe the circumstances preventing completion of the investigation within the 30-day time period and provide information on when the investigation will be completed.

In general, it is expected that the PACE organization's investigation will include a root cause analysis as described below. There are instances, however, when PACE organization staff may feel that a root cause analysis will not yield programmatic improvement information. If this is the case, the PACE organization is to consult promptly, by telephone, with its CMS Regional Office Account Manager.

It is important to document all participant-specific events in the PACE medical record, particularly if they result in injury or require a treatment or a change in the care plan. Documentation should include a statement of the event, an assessment, a diagnosis (if appropriate), any follow up plans and participant progress. However, any specific details that relate to the investigation of the event (e.g., what were the contributing factors, was care inconsistent with policy, any concerns of quality of care, etc.) do not need to be included in the medical record. All such documentation should be kept separately in a Quality Assurance file.

Notify CMS via PACE@cms.hhs.gov with a copy to the State Administering Agency and CMS Regional Office when the internal investigation is completed. CMS will schedule a conference call within 30 days of this notification to discuss the organization's internal investigation, subject to the availability of key individuals from all entities. Any additional follow-up required subsequent to the call will be coordinated by the PACE organization, CMS RO and the SAA.

[Level Two Guidance, October 2010; <http://www.cms.gov/pace/>]

30.5 - Process for Conducting Root Cause Analysis

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A root cause analysis must be completed for events for which the PACE organization's staff, or PACE organization staff in consultation with the CMS Regional Office, determines the identified event is sufficiently serious that an in-depth understanding of how it could occur is essential, and/or multiple fail-safe measures are required as part of the organization's improvement plan. As described above, PACE organizations are to

consult with their CMS Regional Office Account Manager in cases where the PACE organization believes a root cause analysis is not necessary.

There are many print and web-based resources to guide PACE personnel in conducting a root cause analysis. Several essential elements are outlined below:

- **Describe the details of what happened.** The description will help define the underlying problem. Who was involved? What were the circumstances of the event? When did it occur? Where did it happen?
- **Identify the immediate factors that contributed to the event.** This step enables the team to gather evidence. CMS recommends that the team ask why the event occurred and what relationships were associated with the defined problem. Specify factors that, if removed or changed, could prevent a recurrence;
 - **What were the human factors?** (Staffing levels, knowledge, training, competency, fatigue, distractions, etc.);
 - **Was the risk identified, adequately assessed, and a reduction strategy put in place prior to the incident?** (Timely, comprehensive, documented, communicated to pertinent persons, etc.);
 - **What were the equipment-related factors?** (Maintenance, mechanical failure, age, operational history, etc.);
 - **What were the environmental factors?** (Lighting, noise, clutter, cleanliness, temperature, inspections, security, etc.);
 - **What were the communication factors?** (Adequate tools in place, in-service training, documented policies and procedures, reciprocal flow from/to management, information readily available, technical support, etc.);
- **Develop a risk reduction strategy for each identified problem that differentiates effective solutions that meet team goals:**
 - Discuss the rationale if the team determines that no action should be taken;
 - Develop and implement a corrective action if the team determines that a policy, procedure, system, training, or process should be improved;
 - Design a performance measure to assess if the team's corrective action is effective and sustained over time;

- o Define the period during which progress will be monitored for improvement;
- **Evaluate the effectiveness of corrective action:**
 - o Assess the improvement in performance;
 - o Revise the action plan accordingly.

30.6 - Format for Level Two PACE Organization Conference Call Case Presentation

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

When the PACE organization has completed its internal investigation of the incident meeting the threshold for Level Two Reporting, the PACE organization must notify CMS via PACE@cms.hhs.gov with a copy to the State Administering Agency and CMS Regional Office. The PACE organization must prepare a case presentation for discussion on the call. When preparing the case presentation, the PACE organization will include the following information in its discussion:

- Summary of the care history;
- Age and gender of participant;
- Date of enrollment into the program;
- Significant diagnoses;
- Participant's degree of involvement in PACE program;
- IDT team's main concerns related to participant prior to event;
- Summary of the event;
- Precipitating/contributing factors;
- Participant's involvement/actions surrounding the event;
- Immediate actions taken;
- Participant's status;
- Working relationship with contracted facility, contracted services (if applicable);

- Compliance with organization's established policies and procedures;
- Identification of risk points and their potential contribution to the event;
- As appropriate, proposed improvements in policies, training, procedures, systems, processes, physical plant, staffing levels, etc., to reduce future risks.

For a specific listing of reportable incidents and case scenarios, refer to CMS, PACE Level Two External Reporting Guidance, October, 2010 (effective 01/04/2011).

30.7 - Health Outcomes Survey – Modified (HOS-M)

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The Medicare Health Outcomes Survey-Modified (HOS-M) was fielded for the first time in the spring of 2005. Originally entitled the Programs of All-Inclusive Care for the Elderly (PACE) Health Survey, the HOS-M is administered to vulnerable Medicare beneficiaries at greatest risk for poor health outcomes. All PACE organizations that are operational on or before January 1 of the preceding year are required by CMS to administer the HOS-M during the current reporting year (e.g., January 1, 2009 for the 2010 HOS-M administration).

The HOS-M is a modified version of the Medicare HOS that is administered by CMS. Similar to the HOS, the HOS-M design is based on a randomly selected sample of individuals from each participating PACE organization. The HOS-M is a cross-sectional survey, measuring the physical and mental health functioning of beneficiaries at a single point in time. This differs from the HOS, which has a follow-up component.

One of the main goals of the HOS-M is to assess annually the frailty of the population in these PACE organizations in order to adjust plan payment rates. Initial eligibility for payment purposes is based on community-residing participants who do not have end-stage renal disease (ESRD) and are 55 or over.

30.8 - Medicare HOS-M Sampling

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A random sample of Medicare beneficiaries is drawn annually from each participating PACE organization and surveyed in the spring. Participants are defined as eligible for the HOS-M if they are enrolled in a participating PACE organization, reside in the community, do not have End Stage Renal Disease (ESRD), and are age 55 and over. Participants are randomly selected for HOS-M if the organization has a population of at least 1,400 participants. All eligible participants are included in the sample for PACE organizations with populations of less than 1,400.

30.9 - HOS-M Instrument

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The Medicare HOS-M contains the following core components:

- The Veterans RAND 12 Item Health Survey (VR-12);
- Activity of Daily Living (ADL) items.

The HOS-M instrument is a shorter, modified version of the Medicare Health Outcomes Survey and contains 6 ADL items as the core items used to calculate the frailty adjustment factor for payment purposes. The survey also includes 12 physical and mental health status questions from the VR-12. In addition, the HOS-M includes questions about the following: lifting or carrying objects as heavy as 10 pounds; walking a quarter mile; health or physical problems interfering with daily activities, receiving help with ADLs; physical and emotional health compared to one year ago; memory loss; urinary incontinence; and a question on whether the survey was self-completed or completed by a proxy. If the participant received assistance completing the survey, the respondent was asked information about the proxy respondent.

30.10 - Dissemination of HOS-M Results to Plans

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

After each yearly administration of the Medicare HOS-M, a PACE organization-specific report is produced and is available for each PACE organization participating in the survey. The HOS-M report presents physical and mental component summary scores, ADL items, and selected health status measures for the frail, elderly Medicare beneficiaries for each organization compared to the entire HOS-M sample.

The corresponding beneficiary level data for a report are disseminated to participating PACE organizations. In addition to the data files, each PACE organization is provided with a Data User's Guide that describes the Medicare HOS-M file specifications and the appropriate use of Medicare HOS-M data.

All distribution of HOS-M reports occurs electronically to participating PACE organizations through CMS' Health Plan Management System (HPMS) in the fall of each year. Plans are alerted to report and data availability through HPMS and may request data from HOS Technical Support (hos@aqzio.sdps.org or toll free 888-880-0077).

30.11 - HOS-M Program or Policy Questions

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Any program or policy questions concerning the HOS-M may be directed to hos@cms.hhs.gov. Additional information on both the HOS and HOS-M programs is available at <http://www.hosonline.org/>.

30.12 - Additional Required Reporting

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

In addition to required CMS and State Administering Agency reporting, certain unusual incidents are regulated and must also be reported to other Federal and State agencies consistent with these agencies' requirements.

For example:

- If a PACE organization suspects an incident of elder abuse, it must notify the appropriate State agency with oversight for elder affairs;
- PACE organizations experiencing an incident related to equipment failure or administration of medication to a participant that results in a serious adverse participant outcome are strongly encouraged to report the incident to the Federal Food and Drug Administration (through MedWatch on the FDA website);
- PACE organizations experiencing an infectious disease outbreak (three or more participants affected by the same agent in the same time period) caused by an agent, such as Hepatitis A, must report the outbreak to the State public health agency with responsibility. In some situations, the State agency may instruct the PACE organization to report concurrently to the Centers for Disease Control and Prevention.

The PACE organization must make the notification(s) and take any prescribed actions within the prescribed time frame to comply with applicable statutory or regulatory requirements. Specific requirements can be found on the respective Federal or State agencies' websites.

Transmittals Issued for this Chapter

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R2PACE	06/09/2011	Initial Publication of Manual	06/03/2011	NA
R1_SO	06/03/2011	Initial Publication of Manual - Rescinded and replaced by Transmittal 2	06/03/2011	NA

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