DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health Care Finance (DHCF), pursuant to the authority set forth in An Act to enable the District of Columbia (District) to receive federal financial assistance under Title XIX of the Social Security Act for a medical assistance program, and for other purposes, approved December 27, 1967 (81 Stat. 744; D.C. Official Code § 1-307.02 (2016 Repl. & 2019 Supp.)) and Section 6(6) of the Department of Health Care Finance Establishment Act of 2007, effective February 27, 2008 (D.C. Law 17-109; D.C. Official Code § 7-771.05(6) (2018 Repl.)), hereby gives notice of the proposed adoption of a new Chapter 88 (Program of All-Inclusive Care for the Elderly) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR).

This proposed rulemaking implements the requirements of the Program of All-Inclusive Care for the Elderly Establishment Act of 2018, effective March 13, 2019 (D.C. Law 22-246; D.C. Official Code § 7-571 (2019 Supp.)), which authorizes the establishment of a Program of All-Inclusive Care for the Elderly (PACE) in the District. These rules establish standards governing eligibility criteria for participants, covered services, conditions of participation for providers, reimbursement, data collection, reporting requirements, and quality improvement for the District PACE program. The estimated four-year (FY 2019 - FY 2022) total cost associated with the implementation of PACE is $42,180,543, which was included in the District's local budget for Fiscal Year 2019.

PACE is a nationally recognized model of care that integrates Medicare and Medicaid benefits in order to provide beneficiaries with the entire continuum of necessary medical care and support services. PACE beneficiaries are eligible for a broader array of benefits than is typically available under either Medicaid or Medicare programs and their care is managed by a comprehensive, interdisciplinary team of clinical professionals working to deliver highly coordinated, quality care. To be eligible for PACE, an individual must be fifty-five (55) years of age or older, in need of a nursing home level of care, able to live safely in the community, and residing in a designated PACE service area. The blended PACE payment model includes both Medicare and Medicaid financing and all regularly covered Medicare and Medicaid services are integrated at a community-based PACE center.

This proposed rulemaking corresponds to a related State Plan Amendment (SPA), which requires approval by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS). Accordingly, these rules shall become effective for PACE established on either January 1, 2020, or the effective date established by CMS in its approval of the corresponding SPA, whichever is later. Once approved by CMS, the corresponding SPA will be added to the District's Medicaid State Plan, which can be found on DHCF's website at https://dhcf.dc.gov/page/medicaid-state-plan.

The Director also gives notice of the intent to take final rulemaking action to adopt these rules not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

A new Chapter 88, PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY, of Title 29 DCMR, PUBLIC WELFARE, is added to read as follows:

CHAPTER 88 PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

8800 GENERAL PROVISIONS

8800.1 This chapter establishes standards governing enrollment eligibility, conditions of participation for providers, and program requirements of the District of Columbia's (District) Program of All-Inclusive Care for the Elderly (PACE).

8800.2 DHCF, in coordination with the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), shall serve as the designated District agency responsible for administering the PACE program in the District, and shall adhere to all applicable requirements set forth at 42 CFR Part 460.

8801 PARTICIPANT ENROLLMENT

8801.1 To be eligible to enroll in PACE, an individual shall meet the following requirements, as determined by the PACE organization:

(a) Be fifty-five (55) years of age or older;

(b) Reside in the designated service area of the PACE organization;

(c) Meet the level of care required under the District's State Medicaid Plan for coverage of nursing facility services as determined by the Department of Health Care Finance (DHCF) or its designated agent, in accordance with 29 DCMR § 989.12; and

(d) At the time of enrollment, be able to live in a community-based setting without jeopardizing his or her health or safety, as determined using the criteria specified in the PACE program agreement.

8801.2 Eligibility to enroll in PACE is not limited to individuals who are eligible for or enrolled in either Medicare or Medicaid.

8801.3 If an individual is denied enrollment based on a determination that his or her health or safety would be jeopardized by living in a community-based setting, the PACE organization shall do the following:

(a) Notify the individual in writing of the denial and reason for the denial, in accordance with 42 CFR § 431.210;

(b) Refer the individual to alternative services, as appropriate;

(c) Maintain supporting documentation of the reason for the denial;

(d) Provide the individual with information regarding the process for requesting reconsideration of the denial;

(e) Provide the individual with information regarding the right to appeal the denial by filing a fair hearing request with the Office of Administrative Hearings, in accordance with 1 DCMR § 2971; and

(f) Notify the Medicaid Centers for Medicare and Medicaid Services (CMS) and DHCF of the denial and make all relevant documentation available for review by CMS, DHCF, and the individual.

8802 PARTICIPANT DISENROLLMENT

8802.1 A PACE participant may voluntarily disenroll from the program without cause at any time, in accordance with the following:

(a) Requests for voluntary disenrollment from PACE shall be initiated by the PACE participant or the participant's authorized representative;

(b) A PACE participant's voluntary disenrollment is effective on the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment; and

(c) The PACE organization shall ensure that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status.

8802.2 A PACE participant may be involuntarily disenrolled from the program for any of the following reasons:

(a) The participant, after a thirty (30) day grace period, fails to pay or make satisfactory arrangements to pay any premium due the PACE organization;

(b) The participant, after a thirty (30) day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spenddown liability or any amount due under the post-eligibility treatment of income process, as permitted under 42 CFR §§ 460.182 and 460.184.

(c) The participant moves out of the PACE organization service area or is out of the service area for more than thirty (30) consecutive days, unless the PACE organization agrees to a longer absence due to extenuating circumstances;

(d) The participant is determined to no longer require a nursing facility level of care as described in 29 DCMR § 989.12;

(e) The participant engages in disruptive or threatening behavior, which means that he or she exhibits either of the following:

(1) The participant's behavior jeopardizes his or her health or safety, or the safety of others; or

(2) The participant has decision-making capacity but consistently refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement;

(f) The participant's caregiver engages in disruptive or threatening behavior, which means that he or she exhibits behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others;

(g) The PACE program agreement with CMS and DHCF is not renewed or is terminated; or

(h) The PACE organization is unable to offer health care services due to the loss of District licenses or contracts with outside providers.

8802.3 The involuntary disenrollment of a participant shall not be effective until:

(a) After the PACE organization has notified DHCF and, based on its review, DHCF has determined in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment consistent with § 8802.4; and

(b) The first day of the next month that begins thirty (30) days after the date the PACE organization sends notice of the disenrollment to the participant.

8802.4 Prior to the involuntary disenrollment of a participant based on the disruptive or threatening behavior of the participant or the participant's caregiver, the PACE organization shall document the following information in the participant's medical record:

(a) The reasons for proposing to disenroll the participant; and

(b) All efforts made to remedy the situation.

8802.5 The PACE organization may not disenroll a participant on the grounds that the participant engaged in noncompliant behavior if the behavior is related to a mental or physical condition of the participant, unless the participant's behavior jeopardizes his or her health or safety, or the safety of others. For the purposes of this section, noncompliant behavior includes repeated noncompliance with medical advice and repeated failure to keep appointments.

8802.6 In disenrolling a participant, the PACE organization shall take the following actions:

(a) Use the most expedient process allowed under Medicaid and Medicare procedures, as set forth in the PACE program agreement;

(b) Coordinate the disenrollment date between Medicaid and Medicare, if a participant is eligible for both;

(c) Give reasonable advance notice to the participant, in accordance with § 8802.3(b).

8802.7 To facilitate a disenrolled participant's reinstatement in other Medicaid and Medicare programs, the PACE organization shall do the following:

(a) Make appropriate referrals and ensure medical records are made available to new providers within thirty (30) days; and

(b) Work with CMS and DHCF to reinstate the participant in other Medicaid and Medicare programs for which the participant is eligible.

8802.8 Until the effective date of the disenrollment, the PACE organization and participants shall meet the following requirements:

(a) The PACE organization shall continue to furnish all needed services; and

(b) PACE participants shall continue to use PACE organization services and remain liable for any premiums.

8802.9 A previously disenrolled participant may be reinstated in the PACE program.

8802.10 If the reason for a PACE participant's disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant shall be reinstated in the PACE program with no break in coverage.

8802.11 The PACE organization shall have a procedure in place to document the reasons for all voluntary and involuntary disenrollments, and shall make this documentation available for review by CMS and DHCF.

8803 PARTICIPANT RIGHTS

8803.1 The PACE organization shall have a written participant bill of rights designed to protect and promote the rights of each participant, which include, at minimum, the rights specified at 42 CFR § 460.112.

8803.2 The PACE organization shall inform each participant and his or her authorized representative, if any, upon enrollment, in writing, of his or her rights and responsibilities, and all rules and regulations governing participation.

8803.3 The PACE organization shall fully explain these rights to each participant and his or her authorized representative, if any, at the time of enrollment in a manner understood by the participant.

8803.4 The PACE organization shall display the participant rights in accordance with the requirements set forth at 42 CFR § 460.116.

8803.5 The PACE organization shall have established documented procedures to respond to and rectify a violation of a participant's rights, in accordance with 42 CFR § 460.118.

8803.6 The PACE organization shall establish a written process to evaluate and resolve participant complaints expressing dissatisfaction with service delivery or the quality of care furnished, in accordance with the requirements set forth at 42 CFR § 460.120.

8803.7 The PACE organization shall establish a written appeals process to address the PACE organization's noncoverage of, or nonpayment for, a service, including denials, reductions, or termination of services, in accordance with the requirements set forth at 42 CFR § 460.122.

8803.8 The PACE organization shall inform a participant and his or her authorized representative, if any, in writing of his or her appeal rights under Medicare or Medicaid managed care, or if both are applicable, assist the participant in choosing which to pursue, and forward the appeal to the appropriate external entity, in accordance with 42 CFR § 460.124.

8803.9 The PACE organization shall also provide a Medicaid beneficiary participant and his or her authorized representative, if any, with information regarding the right to appeal any decision referenced in § 8803.7 by filing a hearing request with the District of Columbia Office of Administrative Hearings.

8804 PACE ORGANIZATION APPLICATION PROCESS

8804.1 To be eligible to become a PACE organization, an entity shall be, or be a distinct part of, one of the following:

(a) An entity of city, county, state, or tribal government;

(b) A private not-for-profit entity organized for charitable purposes under Section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger corporation, or a department of a corporation; or

(c) A private for-profit entity.

8804.2 An entity that is interested in becoming a PACE organization shall submit a response to a Request for Proposals (RFP) issued by DHCF by no later than the established deadline published in the *D.C. Register*. The RFP response shall include the following:

(a) A description of the entity's experience delivering or contracting with PACE programs or other home- and community-based services and supports;

(b) A description of the proposed PACE program model, including an explanation of how the entity meets all the requirements to be a PACE organization;

(c) A description of the proposed service area and the entity's experience and familiarity with it;

(d) A description of the entity's financial capacity to operate a PACE program and fiscal readiness to implement its proposed program model;

(e) A PACE program development timeline; and

(f) Any additional information requested in the published request for Proposal (RFP).

8804.3 Prior to the submission to CMS of an application to become a PACE organization, the interested entity shall:

(a) Respond to all DHCF requests for additional information necessary to assess whether the entity is qualified to be a PACE organization;

(b) Complete and submit a District Medicaid provider enrollment application in accordance with Chapter 94 of Title 29 DCMR;

(c) Make its facilities available to onsite visit(s) by DHCF staff; and

(d) Obtain written assurances from DHCF that DHCF:

(1) Considers the entity to be qualified to be a PACE organization; and

(2) Is willing to enter into a PACE program agreement with the entity.

8804.4 Following CMS approval of an application to become a PACE organization, the entity shall enter into a three-way agreement with CMS and DHCF for the operation of a PACE program. The PACE program agreement is effective for one (1) contract year, with the option to extend the agreement on a yearly basis for up to five (5) option years unless any of the three (3) parties chooses to terminate the agreement.

8804.5 The PACE program agreement shall comply with federal requirements at 42 CFR §§ 460.30 – 460.34.

8805 PACE ORGANIZATION REQUIREMENTS

8805.1 The PACE organization shall comply with the federal organizational, administrative, and governance requirements at 42 CFR §§ 460.60 – 460.86.

8805.2 The PACE organization shall comply with the District requirements for Adult Day Health Program providers, as applicable, at 29 DCMR §§ 9702.2 – 9704.3, 9708, and 9713.

8805.3 The PACE organization shall ensure that it has sufficient protections against insolvency in place by demonstrating compliance with provisions set forth in D.C. Official Code § 31-3412.

8806 INTERDISCIPLINARY TEAM

8806.1 The PACE organization shall meet the following requirements:

(a) Establish an interdisciplinary team, in accordance with § 8806.2, at each PACE center to comprehensively assess and meet the individual needs of each participant; and

(b) Assign each participant to an interdisciplinary team functioning at the PACE center that the participant attends.

8806.2 The interdisciplinary team shall be composed of members qualified to fill, at minimum, the following roles:

(a) Primary care provider;

(b) Registered nurse;

(c) Master's-level social worker;

(d) Physical therapist;

(e) Occupational therapist;

(f) Recreational therapist or activity coordinator;

(g) Dietitian;

(h) PACE center manager;

(i) Home care coordinator;

(j) Personal care attendant, or his or her representative; and

(k) Driver, or his or her representative.

8806.3 Primary medical care shall be furnished to a participant by a primary care provider. The primary care provider shall be one of the following:

(a) Primary care physician;

(b) Community-based physician;

(c) A physician assistant licensed in the District and practicing within the scope of practice as defined by District laws; or

(d) A nurse practitioner licensed in the District and practicing within the scope of practice as defined by District laws.

8806.4 Each primary care provider is responsible for the management of a participant's medical situations and the oversight of a participant's use of medical specialists and inpatient care.

8806.5 The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of twenty-four (24) hour care delivery. Each interdisciplinary team member is responsible for the following:

(a) Regularly informing the interdisciplinary team of the medical, functional, and psychosocial condition of each participant;

(b) Remaining alert to pertinent input from other team members, participants, and caregivers; and

(c) Documenting changes of a participant's condition in the participant's medical record consistent with documentation polices established by the medical director.

8806.6 The PACE organization shall ensure that all members of the interdisciplinary team have appropriate licenses or certifications under District law, act within the scope of practice as defined by District laws, and meet the requirements for direct participant care set forth in 42 CFR § 460.71.

8806.7 The PACE organization shall establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, participants, or participants' authorized representatives, and caregivers consistent with the requirements for confidentiality set forth in 42 CFR § 460.200(e).

8807 PARTICIPANT ASSESSMENT AND PLAN OF CARE

8807.1 The interdisciplinary team shall conduct an initial in-person comprehensive assessment of each participant following enrollment. The assessment shall be completed in a timely manner in order to comply with the plan of care development requirements at § 8807.7. As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team shall evaluate the participant in person and develop a discipline-specific assessment of the participant's health and social status:

(a) Primary care provider;

(b) Registered nurse;

(c) Master's-level social worker;

(d) Physical therapist;

(e) Occupational therapist;

(f) Recreational therapist or activity coordinator;

(g) Dietitian; and

(h) Home care coordinator.

8807.2 At the recommendation of the interdisciplinary team, other professional disciplines (*e.g.*, speech-language pathology, dentistry, or audiology) may be included in the initial comprehensive assessment process.

8807.3 The initial comprehensive assessment shall at a minimum include the evaluation of:

(a) Physical and cognitive function and ability;

(b) Medication use;

(c) Participant and caregiver preferences for care;

(d) Socialization and availability of family support;

(e) Current health status and treatment needs;

(f) Nutritional status;

(g) Home environment, including home access and egress;

(h) Participant behavior;

(i) Psychosocial status;

(j) Medical and dental status; and

(k) Participant language.

8807.4 At least once every six (6) months, or more often if a participant's condition dictates, the following members of the interdisciplinary team shall conduct an in-person reassessment:

(a) Primary care provider;

(b) Registered nurse;

(c) Master's-level social worker; and

(d) Other team members actively involved in the development or implementation of the participant's plan of care, as determined by the primary care provider, registered nurse, and Master's-level social worker.

8807.5 If the health or psychosocial status of a participant changes, the members of the interdisciplinary team listed at § 8807.4 shall conduct an in-person reassessment.

8807.6 If a participant, or his or her authorized representative, makes a request to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, shall conduct a reassessment in accordance with the following:

(a) The reassessment may be conducted via remote technology when the interdisciplinary team determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant, or his or her authorized representative, agrees to the use of remote technology.

(b) An in-person reassessment must be conducted:

(1) When the participant, or his or her authorized representative, declines the use of remote technology; and

(2) Before a PACE organization can deny a service request.

(c) The PACE organization must have explicit written procedures for timely resolution of requests by a participant, or his or her authorized representative, to initiate, eliminate, or continue a particular service.

(d) Except as permitted under § 8807.6(e), the interdisciplinary team must notify the participant, or his or her authorized representative, of its decision to approve or deny the request as expeditiously as the participant's condition requires, but no later than seventy-two (72) hours after the date the interdisciplinary team receives the request for reassessment.

(e) The interdisciplinary team may extend the seventy-two (72) hour timeframe for notifying the participant, or his or her authorized representative, of its decision to approve or deny the request by no more than five (5) additional days for either of the following reasons:

(1) The participant, or his or her authorized representative, requests the extension; or

(2) The interdisciplinary team documents its need for additional information and how the delay is in the interest of the participant.

(f) For any denial of a request to initiate, eliminate, or continue a particular service, the PACE organization must take the following actions:

(1) Explain the denial to the participant, or his or her authorized representative, orally and in writing;

(2) Provide the specific reasons for the denial in understandable language;

(3) Inform the participant, or his or her authorized representative, of the right to appeal the decision as specified in 42 CFR § 460.122;

(4) Describe both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in 42 CFR § 460.122; and

(5) Describe the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in 42 CFR § 460.122(e).

(g) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with 42 CFR § 460.122.

8807.7 The interdisciplinary team shall develop a plan of care for each PACE participant in accordance with the following requirements:

(a) Within thirty (30) days of the date of enrollment in PACE, the interdisciplinary team must consolidate discipline-specific assessments

into a single plan of care for the participant through team discussions and consensus of the entire interdisciplinary team;

(b) If the interdisciplinary team determines that certain services are not necessary to the care of the participant, the reasoning behind this determination must be documented in the plan of care;

(c) The plan of care must include all of the following:

(1) Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment;

(2) Identify measurable outcomes to be achieved;

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome; and

(4) Identify each intervention, how it will be implemented, and how it will be evaluated to determine progress in reaching specified goals and desired outcomes.

(d) Female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services;

(e) The interdisciplinary team must implement, coordinate, and monitor the plan of care, whether the services are furnished by PACE employees or contractors. The team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants, and/or participants' authorized representatives, and caregivers, and communications among members of the interdisciplinary team and other providers;

(f) At least once every six (6) months, the interdisciplinary team must reevaluate the plan of care, including defined outcomes, and make changes as necessary;

(g) The interdisciplinary team must develop, review, and reevaluate the plan of care in collaboration with the participant, and/or his or her authorized representative, and caregiver, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed; and

(h) The interdisciplinary team must document the plan of care, and any changes made to it, in the participant's medical record.

8808 PACE SERVICES

8808.1 If a Medicare beneficiary or Medicaid beneficiary enrolls in the PACE program, the following conditions apply:

(a) The participant is not subject to Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing; and

(b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.

8808.2 The PACE benefit package for all participants must include the following:

(a) All Medicare-covered items and services;

(b) All Medicaid-covered items and services, as specified in the District's approved Medicaid state plan; and

(c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

8808.3 The PACE benefit package for Medicare-enrolled participants must also meet the requirements at 42 CFR § 460.94.

8808.4 The following services are excluded from coverage under PACE:

(a) Any service that is not authorized by the interdisciplinary team, even if it is a required service, unless it is an emergency service;

(b) In an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the interdisciplinary team as part of the participant's plan of care);

(c) Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy;

(d) Experimental medical, surgical, or other health procedures; and

(e) Services furnished outside of the United States, except when in accordance with 42 CFR §§ 424.122 and 424.124.

8808.5 The PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings twenty-four (24) hours a day, every day of the year.

8808.6 The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care. These services must be furnished in at least the PACE center, the home, and inpatient facilities.

8808.7 The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, gender, age, sexual orientation, mental or physical disability, or source of payment.

8809 PACE CENTER

8809.1 PACE centers must be operated in accordance with the following requirements:

(a) The PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.

(b) The PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, the PACE organization must increase the number of PACE centers, staff, or other PACE services.

(c) If the PACE organization operates more than one PACE center, each center must offer the full range of services and have sufficient staff to meet the needs of participants.

8809.2 The PACE organization must ensure that each PACE center is in compliance with safety and accessibility standards for disabled persons in accordance with the Americans with Disabilities Act of 1990 (ADA), as amended and supplemented by the American Disabilities Amendments Act of 2008, approved September 25, 2008, and its implementing federal regulations, ADA standards for accessible design, 28 CFR Ch. I, parts 35 and 36.

8809.3 The PACE organization must maintain a Certificate of Occupancy from the Department of Consumer and Regulatory Affairs (DCRA) to ensure that the PACE center is in compliance with the applicable zoning regulations and construction codes including electrical, plumbing, mechanical, and fire prevention requirements in accordance with the Construction Codes Supplement of 2013 under Title 12 DCMR.

8809.4 At a minimum, the following services must be furnished at each PACE center:

(a) Primary care, including services furnished by a primary care provider as defined at § 8806.3 and nursing services;

(b) Social services;

(c) Restorative therapies, including physical therapy and occupational therapy;

(d) Personal care and supportive services;

(e) Nutritional counseling;

(f) Recreational therapy; and

(g) Meals, which must be prepared and served in accordance with the food safety requirements set forth in Title 25 DCMR.

8810 EMERGENCY CARE

8810.1 The PACE organization must establish and maintain a written plan to handle emergency care in accordance with the following requirements:

(a) The plan must ensure that CMS, DHCF, and PACE participants are held harmless if the PACE organization does not pay for emergency services; and

(b) The plan must provide for the following:

(1) An on-call provider, available twenty-four (24) hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post-stabilization care services following emergency services; and

(2) Coverage of urgently needed out-of-network and post-stabilization care services when either:

(A) The services are preapproved by the PACE organization; or

(B) The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within one (1) hour after being contacted or cannot be contacted for approval.

8810.2 Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that are:

(a) Furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization's service area; and

(b) Necessary to evaluate or stabilize an emergency medical condition, as defined at 42 CFR § 460.100(c).

8810.3 The PACE organization must ensure that each participant, and his or her authorized representative, and caregiver, understand when and how to get access to emergency services and that no prior authorization is needed.

8811 REIMBURSEMENT

8811.1 Under the PACE program agreement and 42 CFR § 460.180, CMS will make a prospective monthly payment to the PACE organization of a capitation amount for each Medicare participant.

8811.2 Under the PACE program agreement and 42 CFR § 460.182, DHCF will make a prospective monthly payment to the PACE organization of a capitation amount for each Medicaid participant.

8811.3 The monthly capitation payment amount is negotiated between the PACE organization and DHCF, and specified in the PACE program agreement.

8811.4 The PACE organization must accept the capitation amount as payment in full for Medicaid participants and may not bill, charge, collect, or receive any other form of payment from DHCF or from, or on behalf of, the participant or authorized representative, except as follows:

(a) Payment with respect to any applicable spend-down liability and any amounts due under the post-eligibility treatment of income process;

(b) Medicare payment received from CMS or from other payers, in accordance with 42 CFR § 460.180(d).

8812 DATA COLLECTION, RECORD MAINTENANCE, AND REPORTING REQUIREMENTS

8812.1 The PACE organization must collect data, maintain records, and submit reports in accordance with the following:

(a) The PACE organization must collect data, maintain records, and submit reports as specified in the program agreement and as otherwise necessary to enable DHCF and CMS to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates;

(b) DHCF and CMS must be granted free access to PACE organization data and records including, but not limited to, participant health outcomes data, financial books and reports, medical records, and personnel records; and

(c) The PACE organization must submit financial records and reports to DHCF according to the format and frequency specified by DHCF in the PACE program agreement.

8812.2 The PACE organization must establish written policies and implement procedures to safeguard all data, records, and financial books against loss, destruction, unauthorized use, or inappropriate alteration.

8812.3 The PACE organization must establish written policies and implement procedures to protect the privacy of participant records and any information that identifies a particular participant, in accordance with the following requirements:

(a) Information from, or copies of, records may be released only to authorized individuals. Original medical records may be released only in accordance with federal or District law, court orders, or subpoenas; and

(b) The PACE organization must abide by all federal and District laws regarding confidentiality and disclosure for medical records, mental health records, and other participant health information.

8812.4 The PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards and the following requirements:

(a) The medical record for each participant must be complete, accurately documented, readily accessible, systematically organized, available to all staff, and maintained and housed at the PACE center where the participant receives services;

(b) At minimum, the medical record must contain the following:

(1) Appropriate identifying information;

(2) Documentation of all services furnished, including but not limited to, a summary of emergency care and other inpatient or long-term

care services; services rendered by employees of the PACE center; and services rendered by contractors and their reports;

(3) Interdisciplinary assessments, reassessments, plans of care, treatment and progress notes that include the participant's response to treatment;

(4) Laboratory, radiological and other test reports;

(5) Medication reports;

(6) Hospital discharge summaries, if applicable;

(7) Reports of contact with informal support (*e.g.*, caregiver, legal guardian, or next of kin);

(8) PACE enrollment agreement;

(9) Physicians orders;

(10) Discharge summary and disenrollment justification, if applicable;

(11) Advance directives, if applicable; and

(12) A signed release permitting disclosure of personal information;

(c) The PACE organization must promptly transfer copies of medical record information between treatment facilities;

(d) All entries in the medical record must be legible, clear, complete, and appropriately authenticated and dated. Acceptable types of authentication include signatures or secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry; and

(e) The PACE organization must retain each participant medical record for the period of time required under § 8812.6.

8812.5 A participant must be granted timely access, upon request, to review and copy his or her own medical records and to request amendments to those records.

8812.6 The PACE organization must retain records for the longest of the following periods:

(a) For medical records of participants, ten (10) years from the last entry date;

(b) For medical records of disenrolled participants, ten (10) years from the date of disenrollment from PACE; and

(c) For all other records, ten (10) years from the last entry date.

8812.7 The PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care provided to participants. The PACE organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by CMS and DHCF in the PACE program agreement.

8812.8 The PACE organization must participate in the District's Health Information Exchange (DC HIE) as specified in the PACE program agreement.

8813 QUALITY IMPROVEMENT

8813.1 The PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality improvement program. The program must include all services provided by the PACE organization, and the PACE organization must take actions that result in improvements in its performance in all types of care.

8813.2 The PACE organization must have a written quality improvement plan, which is reviewed, and revised if necessary, annually by the PACE organization's governing body. The plan will be incorporated into the PACE program agreement and must specify how the PACE organization proposes to:

(a) Identify areas to improve or maintain the delivery of services and patient care;

(b) Develop and implement plans of action to improve or maintain quality of care; and

(c) Document and disseminate to PACE staff and contractors the results from the quality improvement activities.

8813.3 The quality improvement program must include the use of objective measures to demonstrate improved performance in the areas identified in 42 CFR § 460.134.

8813.4 Outcome measures must be based on current clinical practice guidelines and professional practice standards applicable to the care of PACE participants. The PACE organization must ensure that all data used for outcome monitoring are accurate and complete.

8813.5 The PACE organization must meet or exceed minimum levels of performance on standardized quality measures, as established by CMS and DHCF in the PACE program agreement.

8813.6 The PACE organization must comply with the internal quality improvement activities requirements described in 42 CFR § 460.136.

8813.7 The PACE organization must establish one or more committees with community input. Duties of the committee(s) shall include:

(a) Evaluate data collected pertaining to quality outcome measures;

(b) Address the implementation of, and the results from, the quality improvement plan; and

(c) Provide input related to ethical decision-making, including end-of-life issues and implementation of the Patient Self-Determination Act (42 U.S.C. §§ 1395cc(f) and 1396a(w)).

8813.8 The PACE organization must meet external quality assessment and reporting requirements, as specified in the PACE program agreement, in accordance with 42 CFR § 460.202.

8814 SANCTIONS, ENFORCEMENT ACTIONS, AND TERMINATION

8814.1 If CMS determines that the PACE organization has committed any of the violations set forth at 42 CFR § 460.40(a), or CMS or DHCF makes a determination that could lead to a termination of the PACE program agreement under 42 CFR § 460.50, CMS has the authority to impose the following sanctions:

(a) Suspend enrollment of Medicare beneficiaries or suspend Medicare payment to the PACE organization, in accordance 42 CFR § 460.42;

(b) Impose civil money penalties, in accordance with 42 CFR § 460.46; or

(c) Pursue any other remedies authorized by federal or District law.

8814.2 If CMS, after consultation with DHCF, determines that the PACE organization is not in substantial compliance with program requirements, CMS or DHCF has authority to take one or more of the following actions:

(a) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan;

(b) Withhold some or all payments under the PACE program agreement until the PACE organization corrects the deficiency; or

(c) Terminate the PACE program agreement.

8814.3 CMS or DHCF has the authority to terminate a PACE program agreement at any time for cause, including, but not limited to the circumstances set forth in paragraphs (a) or (b) of this subsection:

(a) CMS or DHCF has authority to terminate a PACE program agreement if a determination is made that both of the following circumstances exist:

(1) Either:

(A) There are significant deficiencies in the quality of care furnished to participants; or

(B) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under 42 CFR Part 460, or with terms of its PACE program agreement, including making payment to an individual or entity that is included on the preclusion list, defined at 42 CFR § 422.2.

(2) Within thirty (30) days of the date of the receipt of written notice of a determination made under § 8814.3(a)(1), the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies or failed to continue implementation of the plan of correction.

(b) CMS or DHCF has authority to terminate a PACE program agreement if CMS or DHCF determines that the PACE organization cannot ensure the health and safety of its participants. This determination may result from the identification of deficiencies that CMS or DHCF concludes cannot be corrected.

8814.4 The PACE organization has authority to terminate a PACE program agreement after giving timely written notice to CMS, DHCF, and participants. Notice shall be timely if the PACE organization:

(a) Submits written notice to CMS and DHCF at least ninety (90) days before the proposed effective date of the termination; and

(b) Submits written notice to participants at least sixty (60) days before the proposed effective date of the termination.

8814.5 The PACE organization must develop a written plan detailing how, in the event of termination, the organization will complete the following actions:

(a) Give written notice to participants, the community, CMS, and DHCF about termination and transition procedures;

(b) Assist participants with reinstatement of conventional Medicare and Medicaid benefits;

(c) Transition participants' care to other providers; and

(d) End all marketing and enrollment activities.

8814.6 A PACE organization whose PACE program agreement is in the process of being terminated must assist each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers.

8899 DEFINITIONS

8899.1 When used in this chapter, the following terms and phrases shall have the meanings ascribed:

Contract year - The term of a PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from twelve (12) to twenty-three (23) months, as determined by CMS.

PACE center - A facility operated by an approved PACE organization, which includes a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.

PACE organization - An entity as defined in 42 CFR § 460.6 that has in effect a PACE program agreement to operate a PACE program in the District.

PACE program - A program of all-inclusive care for the elderly that is operated by an approved PACE organization and that provides comprehensive healthcare services to PACE enrollees in accordance with a PACE program agreement.

PACE program agreement - An agreement between a PACE organization, CMS, and DHCF for the operation of a PACE program.

Post-stabilization care – Non-emergency services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized.

Program of All-Inclusive Care for the Elderly (PACE) – A jointly administered capitated Medicare/Medicaid program providing medical and long-term care services to individuals fifty-five (55) years of age and older who require a nursing home level of care.

Urgent care – The care provided to a PACE participant who is out of the PACE service area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or function is not in severe jeopardy.

Comments on these rules should be submitted in writing to Melisa Byrd, Senior Deputy Director/State Medicaid Director, Department of Health Care Finance, Government of the District of Columbia, 441 4th Street N.W., Suite 900, Washington, D.C. 20001, via telephone at (202) 442-8742, or via email at DHCFPubliccomments@dc.gov, within thirty (30) days of the date of publication of this notice in the *D.C. Register*. Additional copies of these rules are available from the above address.