Regulatory Analysis

Notice of Intended Action to be published: 441—Chapter 88
"Specialized Managed Care"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 249A.4
State or federal law(s) implemented by the rulemaking: Iowa Code chapter 249A

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 19, 2024 2 p.m.	Microsoft Teams Meeting ID: 222 143 545 89 Passcode: Ythqof

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Victoria L. Daniels
Department of Health and Human Services
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Phone: 515.829.6021
Email: compliancerules@hhs.iowa.gov

Purpose and Summary

This proposed chapter provides for specialized programs of managed care within the Iowa medical assistance program but outside of managed care pursuant to 441—Chapter 73. Managed care providers under these programs are not required to comply with 441—Chapter 73.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

There are no costs associated with the rules themselves.

- **Classes of persons that will benefit from the proposed rulemaking:**

Individuals participating in specialized managed care programs administered by the Department will benefit.

2. **Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:**

- **Quantitative description of impact:**

Currently, the Program of All-Inclusive Care for the Elderly (PACE) provides services to 694 Iowans. This number is expected to grow as three new PACE centers are expected to open in eastern Iowa in 2024.

- **Qualitative description of impact:**

In conjunction with federal regulations, this chapter sets forth eligibility, services provided, enrollment procedures, and other information for the specialty managed care programs administered by the Department.

3. **Costs to the State:**

- **Implementation and enforcement costs borne by the agency or any other agency:**

Personnel and other administrative costs will be borne by the Department.

- **Anticipated effect on state revenues:**

None.

4. **Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:**

Not applicable.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

The Iowa Administrative Code is the appropriate place for this type of guidance and provides a basis for other information shared by the Department.

6. **Alternative methods considered by the agency:**

- **Description of any alternative methods that were seriously considered by the agency:**

None were considered.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

The Iowa Administrative Code is the appropriate place for this type of guidance and provides a basis for other information shared by the Department.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

There is no impact on small businesses.

Text of Proposed Rulemaking

ITEM 1. Rescind 441—Chapter 88 and adopt the following **new** chapter in lieu thereof:

CHAPTER 88
SPECIALIZED MANAGED CARE PROGRAMS

441—88.1(249A) Definitions.

"Alternate PACE service site" means a location outside a primary or alternate PACE center in which one or more PACE services are offered to PACE enrollees.

"Capitation rate" means the fee the department pays monthly to a PHP for each enrolled recipient for the provision of covered medical services whether or not the enrolled recipient received services during the month for which the fee is intended.

"CMS" means the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services.

"Contract" means a contract between the department and a PHP for the provision of medical services to enrolled Medicaid recipients for whom the PHP assumes a risk as defined in the contract.

"Emergency service" means medical services rendered under unforeseen conditions that require hospitalization for the treatment of accidental injury and relief of acute pain, which, if not immediately diagnosed and treated, would result in risk of permanent danger to the patient's health.

"Enrollee" means a person who is enrolled in a PACE program.

"Federal PACE regulations" means the standards published in 42 CFR Part 460, Programs of All-Inclusive Care for the Elderly, as amended to August 1, 2024. These rules shall be interpreted so as to comply with the federal PACE regulations.

"Grievance" means an incident, complaint, or concern that cannot be resolved in a manner satisfactory to enrolled recipients by the immediate response, verbal or otherwise, of the PHP staff member receiving the complaint or any complaint received in writing.

"Interdisciplinary team" means the team designated by the PACE organization to assess the needs of and develop a comprehensive plan of care for each enrollee.

"Managed health care" means any one of the alternative deliveries of regular, fee-for-service Medicaid, such as defined in subrules dealing with health maintenance organizations (HMOs), or PHPs, or Medicaid Patient Access to Service System (MediPASS).

"Managed health care review committee" means a committee composed of representatives from the department. The committee will review and render a decision on all requests for disenrollment that are not automatically approvable.

"Medicare beneficiary" means a person who is entitled to Medicare Part A benefits, is enrolled under Medicare Part B, or both.

"Nonmanaged services" means medical services covered under regular Medicaid that are not covered in the PHP's contract with the department. Payment for nonmanaged services incurred by an enrolled recipient shall be made under regular Medicaid procedures.

"PACE enrollment agreement" means the contract between the PACE organization and the enrollee that includes, at a minimum, all information identified in 42 CFR Section 460.154 as amended to August 1, 2024.

"Participating providers" means the providers of covered medical services that subcontract with or who are employed by the PHP.

"Prepaid health plan" or *"PHP"* means an entity defined in Section 1903(m)(2)(B)(iii) of the Social Security Act as amended to August 1, 2024, and considered to be a PHP by the department based upon criteria set forth in the Code of Federal Regulations at Title 42, Part 434.20(a)(3) as amended to August 1, 2024.

"Primary care" includes all program components in accordance with 42 CFR Section 460.92 as amended to August 1, 2024.

"Recipient" means any person determined by the department to be eligible for Medicaid and for PHP enrollment.

"Routine care" means medical care that is not urgent or emergent in nature and can wait for a regularly scheduled physician appointment without risk of permanent damage to the patient's life or health status. The condition requiring routine care is not likely to substantially worsen without immediate clinical intervention.

"Service area" means the specific counties in which a PACE provider may provide services as identified in the PACE program agreement.

"Urgent, nonemergency need" means the existence of conditions due to an illness or injury that are not life-threatening but that require expeditious treatment because of the prospect of the condition worsening without immediate clinical intervention.

The following definitions have the same meaning as set forth in 42 CFR Section 460.6 as amended to August 1, 2024:

"Contract year"

"Medicaid enrollee"

"Medicare enrollee"

"PACE"

"PACE center"

"PACE organization"

"PACE program"

"PACE program agreement"

"Services"

"Trial period"

441—88.2(249A) Participation.

88.2(1) *Contracts with PHPs.* The department shall enter into contracts for the scope of services specified in 441—Chapter 78, or a part thereof, with a PHP that has verified to the department that the criteria set forth in the Social Security Act have been met. This verification shall be reviewed by CMS staff to ensure that the status of PHP is rightfully conferred. The department may also include the scope of services described in 441—Chapter 74, known as the Iowa Health and Wellness Plan, or part thereof, in contracts with PHPs.

a. The department shall also determine that the PHP meets the following additional requirements:

(1) The PHP shall make the services it provides to enrolled recipients at least as accessible (in terms of timeliness, duration, and scope) to them as those services are accessible to recipients in the enrollment area who are not enrolled.

(2) The PHP shall provide satisfaction to the department that insolvency is not likely to occur and that enrolled Medicaid recipients shall not be responsible for its debts if the PHP should become insolvent.

b. Any protests to the award of contracts shall be in writing and submitted to the director of the department. Prior to termination or suspension of a contract, the department will send a notice to cure to the PHP, specifying the number of days the PHP has to correct the problems. Failure to correct the problems in the time given shall then result in termination or suspension. The PHP may appeal the decision of the department in writing to the director of the department or to the federal Department of Health and Human Services, Centers for Medicare and Medicaid Services, if the appeal documents state violations of federal law or regulation.

88.2(2) *Method of selection of PHP.* In counties served by a single prospective PHP, the department will attempt to negotiate directly with the PHP. In counties where two or more prospective PHPs exist, the department will initiate communication and attempt to negotiate as many contracts as are administratively feasible.

88.2(3) *Termination of contract.* Either party may, by mutual consent, terminate a contract. Either party may give 60 days written notice to the other party. The effective date of termination must be the first day of a month. The department may terminate or suspend a contract if the contract is

determined by the department to be inconsistent with the overall goals and objectives of the Medicaid program.

441—88.3(249A) Enrollment.

88.3(1) *Recipients eligible to enroll.* Any Medicaid-eligible recipient is eligible to enroll in a contracting PHP except for the following:

a. Recipients who are medically needy as defined at 441—subrule 75.1(35).

b. Recipients over the age of 65 and under the age of 21 in psychiatric institutions as defined at 441—Chapter 85.

c. Recipients who are supplemental security income-related case members.

d. Recipients whose eligibility is in the process of automatic redetermination as defined at rule 441—76.11(249A).

e. Recipients who are foster care and subsidized adoption-related case members.

f. Recipients who are Medicare beneficiaries.

g. Recipients who are pregnant women and who are deemed to be presumptively eligible as defined at 441—subrule 75.1(30).

h. Recipients who are Native American Indians or Alaskan natives.

i. Recipients who are receiving services from a Title V provider.

88.3(2) *Enrollment area.* Counties in a PHP enrollment area can be designated as voluntary or mandatory. In voluntary counties, enrollment is not required, but eligible recipients may choose to join the PHP. Recipients not excluded may volunteer to enroll in the PHP. In mandatory counties, enrollment in managed health care is required for eligible recipients.

88.3(3) *Voluntary enrollment.* When only one managed health care option is providing service in a county, enrollment by recipients is voluntary. Applicants and recipients are offered the option of managed health care enrollment or regular Medicaid coverage. Applicants and recipients who do not choose one option or the other will be assigned to a managed health care provider as defined in subrule 88.3(6). These persons have the right to request disenrollment at any time as defined in rule 441—88.4(249A). Applicants or recipients may designate the applicants' choices of providers on a form designated by the managed health care contractor or in writing to or through a verbal request to the managed health care contractor. The form will be available through the county office, the PHP office, provider offices, the managed health care contractor, or other locations at the department's discretion. If the PHP (or any entity listed above other than the managed health care contractor) receives the form, it shall be forwarded to the managed health care contractor within three working days. Recipients shall be accepted by the PHP as the recipients are enrolled by the department unless a maximum limit has been specified in the contract. Recipients who choose not to enroll in a PHP shall be covered under regular Medicaid.

88.3(4) *Mandatory enrollment.* In a county where the department has a contract with more than one PHP, HMO, or other managed health care provider, the department will require whenever it is administratively feasible that all eligible recipients enroll with a managed health care provider of their own choosing. Administrative feasibility is determined by whether the managed health care providers have the capacity to adequately serve all potential enrolled recipients. Recipients may enroll by completing the choice form designated by the managed health care contractor, in writing to or through verbal request to the managed health care offices. Recipients may also contact the managed health care contractor by the publicized toll-free telephone number for enrollment assistance.

88.3(5) *Effective date.* The effective date of enrollment will be no later than the first day of the second month subsequent to the date on which the managed health care contractor receives the form designated by the managed health care contractor.

88.3(6) *Assignment methodology.* When no choice is made, the recipient will be systematically assigned to, between, or among the contracting managed health care providers.

a. Notification. Recipients who are assigned to a managed health care provider will receive notification of the assignment and the name of the provider in a timely fashion prior to the effective date of enrollment.

b. Limitations. Contracting providers may specify in the contract a limit to the number of recipients who can be assigned under this subrule. If a specified limitation is attained, the remaining assignment needs in that county will be met by the other managed health care providers who are contracting with the department in that county.

c. Household member enrollment. When some household members have made a choice and some have not (so that assignment is required), a systematic search of household member choices regarding managed health care options will be completed. Assignment of those who have made no choice will be made whenever possible to the managed health care provider with whom the first household member is already enrolled.

d. Assigned recipients who desire another choice. Recipients who are assigned to a managed health care provider as described in this subrule have at least 30 days in which to request enrollment in a different available managed health care plan. The change of plan is subject to provisions in subrules 88.3(4) and 88.4(2) dealing with effective date.

441—88.4(249A) Disenrollment.

88.4(1) *Disenrollment request.* An enrolled recipient may request disenrollment at any time. In voluntary counties, this request will be approved and acted upon within ten days of receipt without requiring the recipient to demonstrate good cause. In mandatory counties as defined at subrule 88.3(3), the disenrollment will not be acted upon by the health care contractor unless the request includes an alternate choice of managed health care.

88.4(2) *Effective date.* Disenrollment will be effective no later than the first day of the second calendar month after the month in which the department receives a request for disenrollment. The recipient will remain enrolled in the PHP and the PHP will be responsible for services covered under the contract until the effective date of disenrollment which will always be the first day of a month.

88.4(3) *Disenrollment process.* If the recipient is requesting disenrollment, the recipient shall complete the choice form designated by the managed health care contractor that can be obtained through the PHP, the county office, or the managed health care contractor. If the PHP receives a request from the recipient, the PHP shall forward the form to the managed health care contractor within three working days. If the recipient must show good cause for disenrollment, the determination as to whether disenrollment shall occur shall be made within 30 days. If the recipient or the PHP disagrees with the decision, an appeal may be filed under the provisions of 441—Chapter 7. If the PHP is requesting disenrollment, the PHP shall complete a form prescribed by the department. If the county office receives such a completed form from the managed health care provider, the county office will forward the form to the managed health care review committee within three working days.

a. Request for disenrollment by the recipient. In voluntary counties, the request will be approved and acted upon within ten days of receipt by the managed health care contractor. In mandatory counties, a request for disenrollment will be denied unless a choice of another managed health care provider is requested simultaneously or good cause can be demonstrated to the review committee. Examples of good cause include services received that were untimely, inaccessible, of insufficient quality, or inadequately provided by all of the contracting managed health care providers in the recipient's county of residence. If the recipient has not experienced the above conditions in all the other available managed health care programs, enrollment in one of the alternative managed health care programs will be a condition of approving disenrollment.

b. Request for disenrollment by the PHP. With prior approval of the managed health care review committee, a request for disenrollment of an enrolled recipient may be approved when:

(1) There is evidence of fraud or forgery in the use of PHP services or in the choice for PHP services.

(2) There is evidence of unauthorized use of the PHP identification card.

(3) Upon documentation, the PHP has been unable after reasonable efforts to establish or maintain a satisfactory physician-patient relationship with the recipient.

88.4(4) *Disenrollments by the department.* Disenrollments will occur when:

a. The contract between the department and the PHP is terminated.

b. The recipient becomes ineligible for Medicaid. If the recipient becomes ineligible and is later reinstated to Medicaid, enrollment in the PHP will also be reinstated.

c. The recipient permanently moves outside the PHP's enrollment area.

d. The recipient transfers to an eligibility group excluded from PHP enrollment. See definition of recipient in rule 441—88.1(249A).

e. The department has determined that participation in the HIPP (Health Insurance Premium Payment) program as described in rule 441—75.21(249A) is more cost-effective than enrollment in managed health care.

88.4(5) *No disenrollment for health reasons.* No recipient will be disenrolled from a PHP because of an adverse change in health status.

441—88.5(249A) Emergency services.

88.5(1) *Availability of services.* The PHP will ensure that the services of a primary care physician are available on an emergency basis 24 hours a day, seven days a week, either through the PHP's own providers or through arrangements with other providers. In addition, the PHP must provide payment to nonparticipating providers within 60 days of receipt of the bill for all contracted services furnished by providers that do not have contractual arrangements with the PHP to provide services but that were needed immediately because of an injury or illness and in which case the illness or injury did not permit a choice of provider.

88.5(2) *PHP payment liability.* PHP payment liability on account of injury or emergency illness is limited to emergency care required before the recipient can, without medically harmful consequences, return to the enrollment area or to the care of a provider with whom the PHP has arrangements to provide services. If an ambulance is necessary to transport the recipient to follow-up treatment, the PHP shall be financially liable. Benefits for continuing the follow-up treatment are provided only in the PHP's enrollment area.

If an enrolled recipient is injured or becomes ill and receives emergency services outside the PHP's enrollment area, the PHP shall pay the facility or person who provided the emergency care for emergency medical services and medical services, for inpatient hospital services in a general hospital as a result of the emergency, and for emergency ambulance service.

88.5(3) *Notification and claim filing time span.* The PHP may set notification and claim filing time limitations in the event of the provision of care by nonparticipating providers. However, failure to give notice or to file claims within those time limitations will not invalidate any claim if it can be shown that it was not reasonably possible to give the notice and that notice was, in fact, given as soon as was reasonably possible.

441—88.6(249A) Access to service.

88.6(1) *Choice of provider.* Recipients will have the opportunity to choose their health care professionals to the extent possible and medically appropriate from any of the PHP providers participating in the Medicaid contract.

88.6(2) *Medical service delivery sites.* Medical service delivery sites shall have the following specific characteristics:

a. Be located within 30 miles of and be accessible from the personal residences of enrolled recipients.

b. Have sufficient staff resources to adequately provide the medical services for which the contract is in effect including physicians with privileges at one or more acute care hospitals.

c. Have arrangements for services to be provided by other providers where in-house capability to serve specific medical needs does not exist.

d. Meet the applicable standards for participating in the Medicaid program.

e. Be in compliance with all applicable local, state, and federal standards related to the service provided as well as those for fire and safety.

88.6(3) *Adequate appointment system.* The PHP shall have procedures for scheduling patient appointments as follows:

a. Patients with urgent nonemergency needs shall be seen within one hour of presentation at a PHP medical service delivery site.

b. Patients with persistent symptoms shall be seen within 48 hours of reporting of the onset of the persistent symptoms.

c. Patient routine visits shall be scheduled within four to six weeks of the date the patient requests the appointment.

d. Scheduling of appointments shall be by specific time intervals and not on a block basis.

88.6(4) *Adequate after-hours call-in coverage.* The PHP must have in effect the following arrangements for adequate after-hours call-in coverage:

a. Twenty-four-hour-a-day telephone coverage shall exist.

b. If a physician does not respond to the initial telephone call, there must be a written protocol specifying when a physician must be consulted. Calls requiring a medical decision shall be forwarded to the on-call physician, and a response to each call requiring a medical decision must be provided within 30 minutes.

c. Notations shall be made in the patient's medical record of relevant information related to an after-hours call.

88.6(5) *Adequate referral system.* The PHP must have an adequate referral system as follows:

a. A network of referral sources for all services that are covered in the contract but not directly provided by the PHP.

b. Procedures for the return of relevant medical information from referral sources including review of information by the referring physicians, entry of information into the patient's medical record, and arrangements for periodic reports from ongoing referral arrangements.

c. A notation in the medical record for hospitals' patients indicating the reason, date, and duration of hospitalization and entry of pertinent reports from the hospitalization and discharge planning in the medical record.

441—88.7(249A) Grievance procedures.

88.7(1) *Written procedure.* The PHP must have a written procedure by which enrolled recipients may express grievances, complaints, or recommendations, either individually or as a class and that:

a. Is approved by the department prior to use.

b. Acknowledges receipt of a grievance to the grievant.

c. Sets time frames for resolution, including emergency procedures, appropriate to the nature of the grievance and that require that all grievances be resolved within 30 days.

d. Ensures the participation of persons with authority to require corrective action.

e. Includes at least one level of appeal.

f. Ensures the confidentiality of the grievant.

88.7(2) *Written record.* All grievances, including all informal or verbal complaints, that must be referred or researched for resolution must be recorded in writing. A log of the grievances must be retained and made available at the time of audit and must include progress notes and method of resolution.

88.7(3) *Information concerning grievance procedures.* The PHP's written grievance procedure must be provided to each newly enrolled recipient not later than the effective date of coverage.

88.7(4) *Appeals to the department.* A recipient who has exhausted the grievance procedure of the PHP may appeal the issue to the department under the provisions of 441—Chapter 7. Instances where the substance of the grievance relates to department policy shall be appealed directly to the department.

88.7(5) *Periodic report to the department.* The PHP shall make quarterly reports to the department summarizing grievances and resolutions as specified in the contract.

441—88.8(249A) Records and reports.

88.8(1) *Medical records system.* The PHP shall comply with the provisions of rule 441—79.3(249A) regarding maintenance and retention of clinical and fiscal records and, in addition, the PHP must maintain a medical record system that:

a. Identifies each medical record by the departmentally assigned state identification number.

b. Identifies the location of every medical record.

c. Places medical records in a given order and location.

d. Provides a specific medical record on demand.

e. Maintains the confidentiality of medical records information and releases the information only in accordance with established policy pursuant to subrule 88.8(3).

f. Maintains inactive medical records in a specific place.

g. Permits effective professional review in medical audit processes.

h. Facilitates an adequate system for follow-up treatment including monitoring and follow-up of off-site referrals and inpatient stays.

i. Meets state and federal reporting requirements applicable to PHPs.

88.8(2) *Content of individual medical record.* The PHP must have in effect arrangements that provide for an adequate medical record-keeping system that includes a complete medical record for each enrolled recipient in accordance with provisions set forth in the contract.

88.8(3) *Confidentiality of records.* PHPs must maintain the confidentiality of medical record information and release the information only in the following manner:

a. All medical records of enrolled recipients shall be confidential and shall not be released without the written consent of the enrolled recipients or the responsible party acting on behalf of the enrolled recipient.

b. Written consent is not required for the transmission of medical record information to physicians, other practitioners, or facilities that are providing services to enrolled recipients under a subcontract with the PHP. This provision also applies to specialty providers who are retained by the PHP to provide services that are infrequently used or are of an unusual nature.

c. Written consent is not required for the transmission of medical record information to physicians or facilities providing emergency care pursuant to rule 441—88.5(249A).

d. Written consent is required for the transmission of medical record information of a former enrolled recipient to any medical provider not connected with the PHP.

e. The extent of medical record information to be released in each instance will be based upon tests of medical necessity and a "need to know" on the part of the practitioner or facility requesting the information.

f. Medical records maintained by subcontracting providers must meet the requirements of this rule.

88.8(4) *Reports to the department.* Each PHP shall submit reports to the department as follows:

a. Annual audited financial statements no later than 120 days after the close of the PHP's fiscal year.

b. Periodic financial, utilization, and statistical reports as required by the department under the contract.

88.8(5) *Audits.* The department or its designee and the U.S. Department of Health and Human Services (HHS) may evaluate through inspections or other means, the quality, appropriateness, and timeliness of services performed by the PHP. The department or HHS may audit and inspect any records of a PHP, or the subcontractors of a PHP, which pertain to services performed and the determination of amounts paid under the contract. These records will be made available at times, places, and in a manner as authorized representatives of the department, its designee, or HHS may request.

441—88.9(249A) Marketing.

88.9(1) *Marketing procedures.* All marketing plans, procedures, and materials used by the PHP must be approved in writing by the department prior to use. Random door-to-door marketing of low-income families or the offering of financial incentives will not be approved.

88.9(2) *Marketing representatives.* Marketing representatives utilized to market Medicaid recipients must be sufficiently trained and capable of performing marketing activities within the requirements of the contract. The PHP's marketing representatives must represent the PHP in an honest and straightforward manner. In its marketing presentations, the PHP must include information that ensures that the representative is not mistaken for a department employee. Marketing presentations that intentionally belittle or maliciously downplay the benefit package, services, or providers of another participating managed health care option will not be approved.

88.9(3) *Marketing presentations.* The PHP may make marketing presentations in the local office(s) of the department or otherwise include the department in marketing efforts at the discretion of the department.

88.9(4) *Marketing materials.* Written material must include a marketing brochure or a member handbook that fully explains the services available, how and when to obtain them, and special factors applicable to enrolled recipients as specified in the contract.

441—88.10(249A) Patient education.

88.10(1) *Use of services.* The PHP shall have procedures in effect to orient enrolled recipients in the use of services the PHP is contracting to provide. This includes what to do if the recipient requires medical care while out of the enrollment area, a 24-hour-a-day telephone number, appropriate use of the referral system, grievance procedures, and how emergency treatment is to be provided.

88.10(2) *Patient rights and responsibilities.* The PHP shall have in effect a written statement of patient rights and responsibilities which is available upon request as well as issued to all new enrolled recipients. This statement may be part of an informational brochure provided to all new enrollees. The right of the enrolled recipient to request disenrollment must be included.

441—88.11(249A) Payment to the PHP.

88.11(1) *Capitation rate.* In consideration for all services rendered by a PHP under a contract with the department, the PHP will receive a payment each month for each enrolled recipient. This capitation rate represents the total obligation of the department with respect to the costs of medical care and services provided to enrolled recipients under the contract.

88.11(2) *Determination of rate.* The capitation rate is actuarially determined by the department for the beginning of the new fiscal year using statistics and data about Medicaid fee-for-service expenses for PHP-covered services to a similar population during the preceding fiscal year. (For example, fiscal year 2020 rates are predicted with fiscal year 2018 dates of service for Medicaid fee-for-service expenditures.) The capitation rate may not exceed the cost to the department of providing the same services on a fee-for-service basis to an actuarially equivalent nonenrolled population group. A 1 percent incentive will be available to PHPs who contract to cover all services except those excluded by contract. PHPs electing to share risk with the department will have their payment rates reduced by an amount reflecting the department's experience for high-cost fee-for-service recipients.

88.11(3) *Amounts not included in rate.* The capitation rate does not include any amounts for the recoupment of losses suffered by the PHP for risks assumed under the current or any previous contract. The PHP accepts the rate as payment in full for the contracted services. Any savings realized by the PHP due to lower utilization from a less frequent incidence of health problems among the enrolled population shall be wholly retained by the PHP.

88.11(4) *Third-party liability.* If an enrolled recipient has health coverage or a responsible party other than the Medicaid program available for purposes of payment for medical expenses, it is the right and responsibility of the PHP to investigate these third-party resources and attempt to obtain

payment. The PHP shall retain all funds collected through third-party sources. A complete record of all income from these sources must be maintained and made available to the department.

441—88.12(249A) Quality assurance. The PHP shall have in effect an internal quality assurance system that meets the requirements of 42 CFR Section 434.44 as amended to August 1, 2024, and a system of periodic medical audits meeting the requirements of 42 CFR Section 434.53 as amended to August 1, 2024.

441—88.13(249A) PACE.

88.13(1) A PACE organization provides prepaid, capitated, comprehensive health care services in accordance with 42 CFR Section 460.4 as amended to August 1, 2024.

88.13(2) PACE programs may serve Medicaid members, Medicare beneficiaries, persons eligible for both Medicare and Medicaid benefits, and private-pay individuals. Enrollment to receive services from a PACE organization is voluntary. To enroll in a PACE program, an individual must meet eligibility requirements specified in 42 CFR Section 460.150 as amended to August 1, 2024. To continue to be eligible for PACE, an individual must meet the annual recertification requirements specified in 42 CFR Section 460.160 as amended to August 1, 2024.

441—88.14(249A) PACE organization application and waiver process. This rule sets forth the application requirements for an entity that seeks approval from the department as a PACE organization and the process by which a prospective PACE organization may request department review and approval of requests to CMS for waiver of federal requirements.

88.14(1) *Application requirements.* A person authorized to act on behalf of an entity seeking approval as a PACE organization shall prepare an application in the format suggested by CMS in 42 CFR Section 460.12 as amended to August 1, 2024.

88.14(2) *Waiver of federal requirements.* A prospective PACE organization must also receive CMS approval as a PACE organization. A prospective PACE organization must submit any request for waiver of federal PACE regulations to the department for initial review before submitting the request to CMS.

a. The waiver request shall be submitted as a document separate from the application. The request may be submitted:

(1) In conjunction with and at the same time as the application; or

(2) At any time during the approval process.

b. The prospective PACE organization shall submit the waiver request and documentation to the department.

88.14(3) *Review of applications and requests for waiver of federal requirements.* The department may conduct on-site visits and may request additional information from an entity in connection with an application for approval as a PACE organization or a request for waiver of federal requirements.

88.14(4) *Department action on applications.* Upon review of an application for approval as a PACE organization and action by CMS on any request for waiver of federal requirements, the department will determine whether it considers the entity qualified to be a PACE organization and whether it is willing to enter into a PACE program agreement with the entity. If so, the department will complete the application sections designated for the state administering agency and submit the completed application in its entirety to CMS.

441—88.15(249A) PACE program agreement. An entity that has been approved by the department and CMS to be a PACE organization must enter into an agreement with CMS and the department for the operation of a PACE program under Medicare and Medicaid. The agreement must be signed by an authorized official of CMS, the PACE organization, and the department.

88.15(1) *Content and terms of agreement.*

a. Required content. A PACE program agreement must include the information set forth in 42 CFR 460.32 as amended to August 1, 2024. In addition, the agreement must provide a description of

procedures the PACE organization will follow if the PACE program agreement is terminated, including how the organization will:

(1) Inform enrollees, the community, CMS, and the department, in writing, about the organization's termination and transition procedures.

(2) Initiate contact with the local department office and assist enrollees in obtaining reinstatement of conventional Medicare and Medicaid benefits.

(3) Transition enrollees' care to other providers.

(4) Terminate marketing and enrollment activities.

b. Optional content. An agreement may include optional content in accordance with 42 CFR Section 460.32 as amended to August 1, 2024.

88.15(2) *Duration of agreement.* A PACE program agreement will be effective for a contract year but may be extended for additional contract years in the absence of a notice by a party to terminate.

88.15(3) *Enforcement of agreement.* If the department determines that the PACE organization is not in substantial compliance with requirements of the federal PACE regulations or of this division, the department may 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.

c. Terminate the PACE program agreement.

88.15(4) *Termination of agreement by the department.*

a. The department may terminate a PACE program agreement at any time for cause, including but not limited to the circumstances set forth in 42 CFR Section 460.50 as amended to August 1, 2024.

b. Notice and opportunity for hearing. Except as provided in paragraph 88.15(4)*"c,"* before terminating an agreement, the department will furnish the PACE organization with the following:

(1) A reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that are the basis of the department's determination that cause exists for termination.

(2) Reasonable notice and opportunity for hearing (including the right to appeal an initial determination) before terminating the agreement.

c. Immediate termination. The department may terminate an agreement without invoking the procedures described in paragraph *"b"* of this subrule if the department determines that a delay in termination resulting from compliance with those procedures before termination would pose an imminent and serious risk to the health of the enrollees.

88.15(5) *Termination of agreement by PACE organization.* A PACE organization may terminate an agreement after timely notice issued in accordance with 42 CFR Section 460.50(d) as amended to August 1, 2024.

88.15(6) *Transitional care during termination.* A PACE organization whose PACE program agreement is being terminated must provide assistance to each enrollee in accordance with 42 CFR Section 460.52 as amended to August 1, 2024.

441—88.16(249A) Enrollment and disenrollment. A PACE organization must comply with the federal enrollment requirements stated in 42 CFR Sections 460.152 through 460.156 as amended to August 1, 2024.

88.16(1) *Eligibility for Medicaid enrollees.* To enroll in a PACE program as an Iowa Medicaid enrollee, a person must meet the eligibility requirements specified in 42 CFR Section 460.150 as amended to August 1, 2024.

88.16(2) *Effective date and duration of enrollment.* A person's enrollment in the program is in accordance with 42 CFR Sections 460.158 and 460.160 as amended to August 1, 2024.

88.16(3) *Annual recertification.*

a. At least annually, the department will:

(1) Reevaluate whether each enrollee continues to need the nursing facility level of care; and

(2) Review all financial and nonfinancial eligibility requirements for Medicaid enrollees. The enrollee shall complete a form available from the department.

b. Deemed continued eligibility. If the department determines that an enrollee no longer needs the nursing facility level of care, the department, in consultation with the PACE organization, will determine whether, in the absence of continued PACE coverage, the enrollee reasonably would be expected to meet the nursing facility level-of-care requirement within the next six months. This determination will be based on a review of the enrollee's medical record and plan of care, applying criteria specified in the PACE program agreement. If the enrollee reasonably would be expected to meet the level-of-care requirement within six months, the enrollee's eligibility for the PACE program may continue until the next annual reevaluation.

88.16(4) *Involuntary disenrollment.* Involuntary disenrollment will occur for any of the reasons set forth in 42 CFR Section 460.164 as amended to August 1, 2024. An involuntary disenrollment will not become effective until the department has determined that the PACE organization has adequately documented acceptable grounds for disenrollment.

88.16(5) *Disenrollment responsibilities.* In disenrolling a Medicaid enrollee, the PACE organization must take the actions set forth in 42 CFR Section 460.166 as amended to August 1, 2024.

88.16(6) *Documentation of disenrollment.* A PACE organization must meet the disenrollment documentation requirements set forth in 42 CFR Section 460.172 as amended to August 1, 2024.

88.16(7) *Reinstatement in other Medicare and Medicaid programs.* After a disenrollment, the PACE organization shall work with CMS and the department to facilitate the former enrollee's reinstatement in other Medicare and Medicaid programs in accordance with 42 CFR Section 460.168 as amended to August 1, 2024.

88.16(8) *Reinstatement in PACE.* A previously disenrolled enrollee may be reinstated in a PACE program. If the reason for disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant is reinstated in the PACE program with no break in coverage.

441—88.17(249A) Program services. A PACE organization shall furnish comprehensive medical, health, and social services that integrate acute and long-term care.

88.17(1) *Required services.* The PACE benefit package for all enrollees, regardless of the source of payment, must include the services set forth in 42 CFR Section 460.92 as amended to August 1, 2024.

88.17(2) *Excluded services.* The following services are excluded from coverage under PACE:

a. Any service that is not authorized by the enrollee's interdisciplinary team, even if it is a required service, unless it is an emergency service.

b. In an inpatient facility:

(1) A private room and private-duty nursing services unless medically necessary; and

(2) 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 enrollee's plan of care.

c. Cosmetic surgery. "Cosmetic surgery" 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.

e. Services furnished outside the United States, except in accordance with 42 CFR Sections 424.122 and 424.124 as amended to August 1, 2024, or as otherwise permitted under the Iowa Medicaid program.

88.17(3) *Service delivery and operations.* The PACE organization must establish and implement a written plan to furnish care that meets the needs of each enrollee in all care settings 24 hours a day, every day of the year in accordance with 42 CFR Section 460.98(b) as amended to August 1, 2024. In

addition, a PACE organization must ensure accessible and adequate services to meet the needs of its enrollees in accordance with 42 CFR Sections 460.98(d) and (e) as amended to August 1, 2024.

88.17(4) *Minimum services furnished at a PACE center.* A PACE center must, at a minimum, furnish the services outlined in 42 CFR Section 460.98(c) as amended to August 1, 2024.

88.17(5) *Primary care.* Primary medical care must be furnished to an enrollee by a PACE primary care physician in accordance with 42 CFR 460.102(c)(2) as amended to August 1, 2024.

88.17(6) *Out-of-network emergency care.* In accordance with 42 CFR Section 460.100 as amended to August 1, 2024, a PACE organization must pay for out-of-network emergency care when the care is 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 enrollee's health.

441—88.18(249A) Access to PACE services. An enrollee's access to PACE services is governed by a comprehensive plan of care developed for each enrollee by an interdisciplinary team based on a comprehensive assessment of the enrollee's health and social status.

88.18(1) *Interdisciplinary team.* A PACE organization shall establish an interdisciplinary team at each PACE center to comprehensively assess and meet the individual needs of each enrollee.

a. Team composition. The members of the interdisciplinary team must primarily serve PACE enrollees. At a minimum, the interdisciplinary team shall be composed of the members enumerated in 42 CFR Section 460.102(b) as amended to August 1, 2024.

b. The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery for each assigned enrollee. Each interdisciplinary team member is responsible for the following:

(1) Regularly informing the team of the medical, functional, and psychosocial condition of each enrollee.

(2) Remaining alert to pertinent input from other team members, enrollees, and caregivers.

(3) Documenting changes in an enrollee's condition in the enrollee's medical record, consistent with documentation policies established by the medical director.

c. Exchange of information. The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and enrollees and their caregivers consistent with the federal requirements for confidentiality in 42 CFR Section 460.200(e) as amended to August 1, 2024.

88.18(2) *Initial assessment.* The interdisciplinary team must conduct an initial comprehensive assessment of each enrollee promptly following enrollment.

a. Each of the interdisciplinary team members set forth in 42 CFR Section 460.104(a)(2) as amended to August 1, 2024, must evaluate the enrollee, at appropriate intervals, and develop a discipline-specific assessment of the enrollee's health and social status.

b. Other professional disciplines may be included in the comprehensive assessment process in accordance with 42 CFR Section 460.104(a)(3) as amended to August 1, 2024.

c. The assessment of each enrollee must include but not be limited to assessment of the items set forth in 42 CFR Section 460.104(a)(4) as amended to August 1, 2024.

88.18(3) *Plan of care.* In accordance with 42 CFR Section 460.104 as amended to August 1, 2024, the interdisciplinary team must promptly consolidate discipline-specific assessments into a single plan of care for each enrollee through discussion in team meetings and consensus of the entire team.

a. Content. The plan of care must:

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

(2) Identify measurable outcomes to be achieved.

b. Implementation. The interdisciplinary team shall:

(1) Implement, coordinate, and monitor the plan of care, whether the services are furnished by PACE employees or contractors; and

(2) Continuously monitor the enrollee's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from enrollees and caregivers, and communications among team members and other providers.

c. Evaluation. On at least a semiannual basis, the interdisciplinary team shall reevaluate the plan of care, including defined outcomes, and make changes as necessary.

88.18(4) *Reassessment.*

a. Semiannual reassessment. On at least a semiannual basis, or more often if an enrollee's condition dictates, the interdisciplinary team members must conduct an in-person reassessment in accordance with 42 CFR Section 460.104(c) as amended to August 1, 2024.

b. Unscheduled reassessments. In addition to scheduled annual and semiannual reassessments, unscheduled reassessments may be required in accordance with 42 CFR Section 460.104(d) as amended to August 1, 2024.

c. Changes to plan of care. Interdisciplinary team members who conduct a reassessment must meet the requirements of 42 CFR Section 460.104(e) as amended to August 1, 2024.

88.18(5) *Procedures for resolving enrollee request to change the plan of care.* The PACE organization must have explicit procedures for timely resolution of a request by an enrollee or an enrollee's designated representative to initiate, eliminate, or continue a particular service in accordance with 42 CFR Section 460.121 as amended to August 1, 2024.

a. The PACE organization is responsible for:

(1) Informing the enrollee or the enrollee's designated representative of the enrollee's right to appeal the decision as specified in 42 CFR Section 460.122 as amended to August 1, 2024.

(2) Describing both the standard and expedited appeals processes of the PACE organization, including the right to obtain and conditions for obtaining expedited consideration of an appeal of a denial of services as specified in 42 CFR Section 460.122 as amended to August 1, 2024.

(3) Describing the right to and conditions for continuation of appealed services through the period of an appeal as specified in 42 CFR Section 460.122(e) as amended to August 1, 2024.

b. If the interdisciplinary team fails to provide the enrollee with timely notice of the resolution of the request or fails to furnish the services required by the revised plan of care, this failure constitutes an adverse decision. The enrollee's request must be automatically processed by the PACE organization as an appeal in accordance with 42 CFR Section 460.122 as amended to August 1, 2024.

c. The PACE organization must submit all documentation related to an appeal to the department.

441—88.19(249A) Program administrative requirements. A PACE organization shall comply with the federal administrative requirements stated in 42 CFR Sections 460.60 through 460.82 as amended to August 1, 2024, including requirements relating to organizational structure, governing body, qualifications for staff who have direct contact with enrollees, training, program integrity, contracted services, oversight of direct care services, physical environment, infection control, transportation services, dietary services, fiscal soundness, and marketing.

88.19(1) *Enrollee rights.* A PACE organization shall comply with the federal participant rights requirements stated in 42 CFR Sections 460.110 through 460.124 as amended to August 1, 2024. Upon exhaustion of the PACE organization's appeal process, a Medicaid enrollee has the right to appeal to the department any adverse coverage or payment decision regarding any service, including any denial, reduction, or termination of any service, pursuant to 441—Chapter 7.

88.19(2) *Data collection, record maintenance, and reporting.* A PACE organization shall comply with federal data collection, records maintenance, and reporting requirements stated in 42 CFR Sections 460.200 through 460.210 as amended to August 1, 2024.

88.19(3) *Quality assessment and performance improvement.* A PACE organization shall comply with the federal quality assessment and performance improvement requirements stated in 42 CFR Sections 460.130 through 460.140 as amended to August 1, 2024.

88.19(4) *Federal and state monitoring.*

a. The PACE program shall cooperate with federal and state monitoring pursuant to 42 CFR Sections 460.190 through 460.196 as amended to August 1, 2024, including:

(1) Corrective action required pursuant to 42 CFR Section 460.194 as amended to August 1, 2024; and

(2) Disclosure of review results pursuant to 42 CFR Section 460.196(c) and (d), as amended to August 1, 2024.

b. The PACE program is subject to sanctions or termination pursuant to subrules 88.15(3) and 88.15(4).

c. During the trial period, CMS, in cooperation with the department, will conduct comprehensive annual reviews of the operations of a PACE organization to ensure compliance with PACE federal regulations as amended to August 1, 2024, and 441—Chapter 88, Division II.

d. After the trial period, the department, in cooperation with CMS, will conduct on-site reviews of a PACE organization at least every two years.

e. After a review, CMS and the department will report the results of the review to the PACE organization, along with any recommendations for changes to the organization's program.

f. Within 30 days of issuance of the report, the PACE organization shall develop and implement a corrective action plan to address any deficiencies identified through the review.

g. CMS or the department will monitor the effectiveness of the corrective actions implemented.

441—88.20(249A) Liability of Medicaid enrollee. A Medicaid enrollee shall contribute toward the cost of the enrollee's care according to the terms of this subrule. A PACE organization may not charge a premium to a Medicaid enrollee except for any amounts due pursuant to this subrule.

88.20(1) *Institutionalized enrollees.* Medicaid enrollees who reside in a medical facility are liable to the PACE organization for the Medicaid capitation payment to the extent of their total monthly income, with the exceptions allowed by 441—subrule 75.16(1) and the deductions allowed by 441—subrule 75.16(2).

88.20(2) *Noninstitutionalized enrollees.* Medicaid enrollees who do not reside in a medical facility are liable to the PACE organization for the Medicaid capitation payment to the extent of their total monthly income, with the deductions required by 42 CFR Section 435.726(c) as amended to August 1, 2024, with maintenance needs amounts set at the following levels:

a. The amount for the maintenance needs of the enrollee is set at 300 percent of the maximum SSI grant for an individual.

b. The additional amount for the maintenance needs of a spouse at home is set at the Iowa Medicaid program's medically needy income standard for one person.

c. The additional amount for the maintenance needs of a family at home is set at the Iowa Medicaid program's medically needy income standard for a family of the same size, to the extent that amount exceeds any amount allowed for the maintenance needs of a spouse at home.

These rules are intended to implement Iowa Code section 249A.4.