October 14, 2016

Andrew Slavitt, Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-4168-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

RE: CMS-4168-P - Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Federal Register Vol. 81, No. 158, p. 54666 (August 16, 2016).

Submitted electronically via www.regulations.gov

Dear Mr. Slavitt:

UnityPoint Health (UPH) and Siouxland PACE are pleased to provide input in response to the Centers for Medicare & Medicaid Services’ (CMS) proposed rule relating to the Programs of All-Inclusive Care for the Elderly (PACE). UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 32 hospitals in metropolitan and rural communities and home care services throughout our 9 regions, UPH provides care throughout Iowa, Illinois and Wisconsin. On an annual basis, UPH hospitals, clinics and home health provides a full range of coordinated care to patients and families through more than 4.5 million patient visits. In addition, UPH is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. Siouxland PACE started in 2008 with assistance from a CMS Rural PACE Development grant. Since 2011, Siouxland PACE has been under the ownership of UnityPoint Health – St. Luke’s, a UPH senior affiliate in northwest Iowa. Currently, there are 162 Participants receiving PACE services from four northwest Iowa counties.

As an integrated healthcare system, UPH believes that patient-centered care is best supported by a value-based payment structure that enables healthcare providers to focus on population health instead of volume-based episodic care. PACE epitomizes this principle and provides holistic, patient-centric care in a community-based setting. We appreciate the time and effort spent by CMS to update and revise the PACE rules. For the most part, this proposal represents a concerted effort to match regulations with practice and to balance regulatory flexibility required to enable services to meet individual PACE Participant and family needs and goals. We respectfully offer the following comments to the proposed regulatory framework.
PACE ORGANIZATION APPLICATION AND WAIVER PROCESS

Application Requirements (§460.12): The application process is revised to add language to provide for the expansion of an existing PACE service area and/or the addition of a new PACE center site. Whether for a new PACE Organization, service area expansion or an added PACE center site, the application must include an assurance from the State Administering Agency (SAA). For a new PACE Organization, this assurance concerns whether the entity is qualified to be a PACE Organization and whether the SAA is willing to enter into a PACE program agreement with the entity. For expansion service areas or added PACE center sites, this assurance concerns whether the SAA is willing to amend its PACE agreement to include the new site or expand the PACE service area. This proposal conforms regulatory language to the CMS PACE manual.

- **Comment**: We are pleased that CMS has specifically referenced an application requirement for service area expansion and new PACE center sites. While we agree that an application process needs to be in place for these situations, we are concerned that (aside from timeframe) the proposed regulations do not offer specificity related to this process. Any changes or revisions to the SAA Readiness Review are omitted. When a PACE Organization is applying to either expand its service area or add a new site, we would recommend that the Readiness Review be tailored to these situations, which should not be the equivalent of a SAA Readiness Review for a new PACE Organization contained within the PACE Initial Application. Specifically, certain aspects of the Initial Readiness Review should be abbreviated or eliminated as being redundant and causing unnecessary delay. For instance, when a PACE Organization is relocating its PACE center site perhaps due to loss of lease or to accommodate participant growth, this review should focus on the new facility/site, not general written policies and procedures related to overall PACE governance, PACE services, participant enrollment and disenrollment, participant rights, etc. Policies unrelated to the physical facility/site are already subject to biennial reviews from CMS as well as at least annual SAA review and should not be reexamined within the scope of a PACE center site relocation request. We urge CMS to engage stakeholders, including current PACE Organizations, when examining and developing/revising processes in support of these proposed applications.

Submission and Evaluation of Waiver Requests (§460.26) & Notice of CMS Determination on Waiver Requests (§460.28): Section 460.26 provides that waivers must be submitted to the SAA for initial review and the SAA subsequently forwards the waiver to CMS. To clarify current practice, CMS is proposing to add language to allow PACE applicants to apply for waivers separate from their application process. Section 460.28 provides the timeframe for CMS waiver decisions and notifications. CMS proposes to clarify that the 90-day timeframe for decision begins upon receipt of a complete waiver request. Language is also proposed to authorize conditional approvals for pending applicants as well as the process for CMS in consultation with SAA to withdraw waiver approvals.

- **Comment**: Siouxland PACE has submitted two waivers: Nurse Practitioner Waiver to authorize these providers to complete initial, annual, and semi-annual assessments; and Veterans Administration (VA) Partnership Waiver. The VA Partnership Waiver authorizes Siouxland PACE to partner with the local Veterans Administration in Sioux Falls for assistance when Veterans do not meet individual Medicaid requirements, providing an additional effort to serve the area Veterans. We support the waiver process as outlined to promote patient-centered care and to provide administrative relief from
processes that hamper PACE service delivery within our rural service area. We also appreciate that CMS has reviewed prior waiver requests and has incorporated them to provide global procedural relief within these Proposed Rules.

**PACE PROGRAM AGREEMENT AND PAYMENT METHODOLOGY**

**Content and Terms of PACE Program Agreement (§460.32):** Current PACE regulations require that the PACE program agreement contain the methodology used to calculate the Medicare capitation rate as well as the actual amount negotiated between the PACE Organizations and the SAA for the Medicaid capitation rate. CMS is proposing to change the agreement requirement for Medicaid capitation to enable the SAA to include either the Medicaid capitation rates or the Medicaid payment rate methodology.

- **Comment:** We agree with CMS that there are “operational challenges associated with updating the PACE program agreement appendices to reflect changes to the Medicaid rates.” Although the rates expire July 1 under the PACE program agreement, there is a typical delay of at least 3 months before the new Medicaid rates are released. At the time of this comment filing (October 17th), we have not received the 2017 rates from the State of Iowa. In the absence of a set rate, it is difficult to establish budgets and meet fiscal expectations.

As proposed, subsection (b) of § 460.182 reads, “The monthly capitation amount is negotiated between the PACE organization and the State administering agency, and the amount, or the methodology used to calculate the amount, is specified in the PACE program agreement.” Practically, we understand that the proposal to allow the agreement to contain only the Medicaid payment methodology aligns with the requirement for Medicare capitation rates and that the inclusion of a methodology instead of actual amounts will enable SAAs to stay in compliance with the agreement requirements. While this change may reflect SAA timelines, the inclusion of a Medicaid actuarial formula within the program agreement will not readily assist PACE organizations to establish and monitor their budgets. We are concerned that the Medicaid capitation methodology is complex and often confusing and that this change removes any incentive for SAAs to timely “negotiate” with PACE Organizations the monthly capitation amount and produce rate schedules. In addition, we urge CMS to clarify the negotiation requirement to establish the monthly capitation amounts. In Iowa, negotiation is a misnomer as rates are set using the actuarial formula, which takes into account regulatory requirements and State of Iowa priorities. There is a negligible to nonexistent ability by PACE organizations to annually negotiate with the SAA. A signed pricing addendum does not reflect an ability to negotiate. Instead of focusing on regulatory revisions to reflect the status quo, we urge CMS to consider including some language to affirmatively require timely Medicaid rate setting for the PACE program and buttress the ability of PACE Organizations to negotiate rates.

**Medicaid Payment (§460.182):** A state must make a prospective monthly capitated payment for each PACE Participant eligible for medical assistance under the state plan. As referenced above, CMS is proposing that the program agreement must contain the Medicaid capitation amounts or the Medicaid payment rate methodology. CMS is also proposing that the monthly capitated amount be sufficient and consistent with efficiency, economy, and quality of care.
CMS is also soliciting comments for future rulemaking about other rate methodologies appropriate for Medicaid capitation payment amounts for PACE. Specifically, whether there are methodologies used for other programs that provide similar services to similar populations on a capitated basis.

- **Comment:** Historically, rates were set at 95% of Fee-For-Service rates for Home Based Community Services and Skilled Nursing Facilities and taking into account geographic disparity. In terms of future rulemaking, we concur with the Medicare Payment Advisory Commission (MedPAC) comment letter dated September 22, 2016 that urges CMS to reform the PACE payment system. We are concerned that benchmarks have not been updated and do not adequately risk adjust for dual eligible population. To obtain robust feedback to inform the rulemaking process, we urge CMS to develop a workgroup with stakeholders, including individual PACE Organizations and the National PACE Association. As a rural PACE Organization with a relatively small population, our budget margins will not tolerate capitated rates that do not reflect the breadth of services required for the heightened acuity and complexity level of our PACE Participants.

**PACE ADMINISTRATIVE REQUIREMENTS**

**Proposed Compliance Oversight Requirements (§460.63):** CMS is proposing to adopt compliance oversight requirements. These requirements will mirror the Part D compliance program required of PACE Organizations participating in Part D and apply these to the PACE program generally. Compliance oversight must include the prevention, detection and correction of non-compliance with PACE program requirements as well as fraud, waste and abuse regulations. CMS estimates time and effort related to the development, adoption and implementation of these requirements at 150 hours over three years for development and 200 hours annually for ongoing oversight. For each PACE Organization, CMS approximates $8916 total for oversight development ($2972 annually for three years) and $11,888 annually for ongoing monitoring, reporting and implementation / follow up.

- **Comment:** First, we believe that CMS has grossly underestimated the time and effort needed both in the development (150 hours annually or roughly 2.5 hours per week) and ongoing monitoring phases (200 hours annually or roughly 3.5 hours per week). In comparison, CMS estimates the PACE organization cost for a site audit to 240 hours through a combination of 3 FTEs (2 Nurse Managers and 1 Executive Assistance). It would seem that ongoing duties would require more time and effort than site audit hours. In addition, we question CMS’ attribution of these hours to one position and disagree with the position’s classification (“Other Technical Position”). For continuity, it would seem that if this “Other Technical Position” is charged with compliance oversight that it would also be included in any site audit. Also, as recognized in the audit estimates, compliance is a team effort and usually requires training activities as well as consultation with content experts.

  Second, while CMS provides some flexibility regarding who should lead this function, it is unclear how PACE Organizations will staff and implement this requirement. Ultimately we are concerned about the scalability of this proposal and its impact on small rural programs, like Siouxland PACE. CMS has indicated that it is modeled after Medicare Advantage (MA) and Part D programs; however, PACE programs do not have the similar resources. We fear that this will further stretch tight resources intended for direct patient care.

  Third, the timeframe for implementation is unclear and the robustness of any potential Technical Assistance has not be discussed. CMS has estimated a three-year development timeframe, but the
annual expectations for implementation are not specified. In terms of technical assistance, CMS has not offered guidance as to what training and templates may be available in this arena. We urge that CMS work closely with stakeholders to establish an implementation schedule and determine technical assistance needs prior to enacting this provision.

Personnel Qualifications (§460.64): Current regulation requires that all personnel that have direct participant contact must have a minimum of at least one year experience with a frail or elderly population. CMS is proposing to provide an exception to this one-year experience requirement to allow a PACE Organization to provide appropriate training on working with a frail or elderly population upon hire. CMS is also removing the requirement that CMS must approve the PACE Organization’s competency evaluation program for direct participant care staff. These hiring requirements apply whether an individual is a direct employ of the PACE Organization or whether they are an employee of the PACE Organization contractor.

**Comment:** We support the proposed hiring flexibility. As noted in the proposed rule, we have a wide variety of staff that directly touch our participants on a daily basis and, as a rural agency in northwest Iowa, we have a more limited pool of potential staff. The one-year requirement has been problematic for our organization and we appreciate the ability to substitute training for experience with frail and elderly populations.

It appears from the Proposed Rule that this training element is not new, but simply would need to be conducted before direct participant care is delivered. As such, CMS associates no additional training costs with this exception; however, we do believe that PACE Organizations will need to review their written policies and procedures to determine if this exception needs to be referenced, if current orientation training specifically contains elderly and frail population content, and if processes are in place to assure that no direct participant care occurs prior to this training for those hired under this exception. It is possible that some PACE Organizations may need to revise their policies and training curriculum, which will have associated time and effort costs.

Program Integrity (§460.68): This regulation was established to guard against potential conflicts of interest and certain other risks that may impact PACE program integrity. One risk that is regulated involves the employment or contracting with individuals and/or organizations with criminal convictions. CMS is proposing to insert flexibility by allowing PACE Organizations to determine if past convictions are such that they pose a threat of harm to individual participants. Additionally, CMS is imposing two separate limitations on employment which harmonize this regulation to the employment restrictions for Long-Term Care Facilities related to abuse, neglect and mistreatment and to mandatory exclusions from federal health care programs (section 118(a)).

**Comment:** We are supportive of the proposed changes and balance that CMS is attempting achieve to promote the ability of PACE Organizations to hire or contract with only those individuals who have the right skills for the job and those individuals who are legally able to fill the position.

Contracted Services (§460.70): CMS proposes to clarify this regulation by separating contract terms for entities that furnish administrative or care-related services from those contract terms that apply to individuals serving as InterDisciplinary Team (IDT) members or key administrative staff. In addition, CMS is seeking comment for future rulemaking concerning whether contracted or direct PACE Organization
services should comply with the Home and Community-Based Settings regulation when non-institutional settings are used to house and/or provide services to PACE Participants.

- **Comment:** CMS is seeking input on the appropriateness of the Home and Community-Based Settings regulation to PACE Participants in non-institutional settings. By nature, PACE is very much community-based and, in theory, PACE requirements should be consistent with the requirements of the HCBS regulation. We are concerned, however, that a strict application of the HCBS requirements may prevent Siouxland PACE from providing center care, a setting defined in the PACE regulations where PACE Participants receive many of their essential services: primary care, including physician and nursing services; social services; physical and occupational therapies; and personal care and supportive services along with nutritional meals and counseling. Many Siouxland PACE Participants receive their services at the PACE center with the frequency and preferences based on their individual needs. In addition, since the HCBS regulation is subject to further State interpretation and regulations, we are concerned that this regulation will add another layer of uncertainty to our current PACE regulatory framework.

**Oversight of Direct Participant Care (§460.71):** This regulation imposes oversight requirements for employees and contracted staff with direct participant care responsibilities. CMS proposes to clarify orientation requirements and that personnel must be “medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.”

- **Comment:** We are concerned that the medical clearance requirements are more restrictive than needed. For instance, as a rural PACE Organization, transportation is the largest barrier to services for our PACE Participants. Siouxland PACE does have our own transportation fleet; however, the demand for transportation services often exceeds our capacity, particularly in the early morning and late night. The medical clearance requirement creates an additional contracting barrier by severely restricting our ability to contract with experienced transportation providers. Siouxland Regional Transit System is the largest publically sponsored transportation provider in our service area. Despite their extra capacity, we are unable to contract with them because they cannot assure us that all their employees have PACE orientation training and meet medical clearance requirements. Instead of requiring each PACE to submit waivers, we request that CMS allow exceptions for contracted services with publically sponsored transportation systems.

**Marketing (§460.82):** This regulation governs marketing activities related to the PACE program. CMS is proposing revisions to clarify special language requirements, to further prohibit certain marketing practices related to PACE Organization employees and agents, and to eliminate PACE Organization maintenance of a separate documented marketing plan. Prohibitions concern gifts to induce enrollment, contracted services for enrollment outreach, and unsolicited door-to-door marketing.

- **Comment:** PACE guidelines for marketing are consistent with those for Medicare Advantage (MA) plans. Given the discrepancy in scale (PACE programs have many fewer referrals and cover a much smaller area), we question whether CMS should utilize MA as the model for this program. The marketing guidelines are complex and we have found it difficult to submit and approve PACE marketing materials in a timely manner. While we generally support regulations that reinforce the PACE organization’s responsibility to assure prospective participants receive accurate information,
regardless of whether it is provided by employees, or contracted entities or individuals, we oppose any further regulation of PACE marketing and outreach without stakeholder involvement – both PACE Participants and PACE Organizations. This stakeholder engagement needs to focus on PACE Program attributes that differentiate the PACE Program from MA to offer greater outreach flexibility and less rigidity than exists with traditional insurance markets. One significant differentiator is the PACE program’s interaction with Medicaid. Many States, including Iowa, have a role in educating Medicaid beneficiaries regarding Medicaid managed care and long term services and support options. We believe current and proposed PACE regulations may conflict and effectively prevent efforts to inform Medicaid beneficiaries of the PACE option given current MCO/Medicaid enrollment marketing efforts. We urge CMS to reevaluate marketing goals and strategies for the unique PACE population prior to further revision on these regulations.

**PACE SERVICES**

**Service Delivery (§460.98):** This regulation addresses service delivery under the PACE delivery model. The success of this predicated on the combination of the IDT assessment, care planning, and the PACE center. CMS is soliciting comment for future rulemaking related to current PACE center requirements as well as desired regulatory flexibility for other settings in which IDT members provide PACE services.

- **Comment:** While all PACE Participants have access to PACE center services, some participants prefer to receive services at home or in alternative care settings such as adult day care centers, senior centers, or perhaps activity areas in residential communities, etc. We believe it is important to allow greater flexibility with regard to the settings in which PACE Participants receive care as well as participants’ access to care in alternative settings. We concur with the National PACE Association’s recommendation that clarification of how PACE Organizations may utilize alternative care settings should not be delayed until future rulemaking. Fundamentally, we affirm that PACE Participants may access PACE services based on their needs and preferences, without having to demonstrate undue hardship or extraordinary circumstance as indicated in CMS’ 6/30/2016 memorandum to PACE Organizations.

**Interdisciplinary Team (§460.102):** This regulation sets forth requirements for the IDT. Current regulation requires specific IDT membership and lists 11 members. CMS is proposing several revisions to enable flexibility: (1) Allow qualified staff members to fulfill up to two IDT roles; (2) expand primary care services beyond physicians to include physician assistants and nurse practitioners; (3) enable primary medical care to be provided beyond the IDT primary care physician and include non-physician primary care providers or community-based physicians; and (4) permit community-based physicians to contract with PACE Organizations to provide primary medical care for PACE Participants without having to serve primarily PACE Participants.

Aside from the above, CMS is seeking input for future rulemaking on two alternatives to promote IDT flexibility. The first alternative is to delete the specific IDT composition requirements to enable IDT composition to be further tailored to the PACE Participants. The second alternative is to delete the requirement that IDT members must serve primarily PACE Participants. These two alternates would avoid the need to apply for program waivers in these areas.
Comment: We fully agree with the proposal to permit one staff member to fulfill up to two roles on the IDT in accordance with their licensure. Given that there are 11 identified IDT members, this allows our rural area to efficiently operate while serving the unique needs of each PACE Participant. As has long been recognized in the context of Rural Health Clinics, we support PA/ARNP to perform the function of a Participant’s primary care provider and to participate in the IDT. Generally, we support all efforts to give flexibility concerning IDT membership. This would include the two proposed alternatives – removing IDT composition requirements and eliminating restrictions related to service primarily to PACE Participants.

Participant Assessment (§460.104): The regulation sets forth parameters for the initial and ongoing assessments of PACE Participants by the IDT. CMS is proposing several revisions, including: (1) the initial comprehensive assessment must be conducted in-person; (2) the assessment completion timeframe must enable a care plan to be developed within 30 days of enrollment; (3) the term “team meetings” is replaced with “team discussions” to permit convenient IDT consultative formats, including video and/or conference calls; (4) parameters are established for semi-annual and unscheduled reassessments; and (5) references to annual reassessments are deleted.

Comment: As stated previously, we are supportive of all language that embeds flexibility into the IDT process – its membership and roles as well as duties related to the various assessments. We also appreciate the ability to use different formats for team discussions, including phone and video conferencing, which is particularly important to accommodate our IDT members in rural areas. The only area of concern that we have is with the 30-day period to initially assess a Participant and develop a care plan. Although this 30-day period is usually adequate, there are circumstances beyond the control of the PACE Organization that may make this timeframe problematic. For example, these circumstances may include, but are not limited to, hospitalization of the PACE Participant and travel outside the service area by the PACE Participant. We would respectfully request that CMS consider an exception to this timeframe for extenuating circumstances and that the exception be limited to the timeframe for which the extenuating circumstance exists. In the instance that a PACE Participant traveled out of the service area for a siblings funeral, we would suggest that the PACE Organization be permitted to extend the 30-day period for the duration of the out-of-area travel provided that the PACE Organization maintain documentation to show the circumstance / event (such as an obituary) and the number of days impacted.

Plan of Care (§460.106): This regulation sets forth requirements that the IDT establish and monitor the Plan of Care for each PACE Participant. CMS is proposing changes to clarify that the Plan of Care should use the most appropriate intervention, identify each intervention and how it will be implementation, and identify its evaluation method.

Comment: We agree that the IDT is responsible for establishing a single Plan of Care for each PACE Participant. In Iowa, when a PACE Participant (with a PACE Plan of Care) is admitted to a nursing facility, the nursing facility develops its own care plan for the PACE Participant. Nursing facilities are regulated by the Iowa Department of Inspections and Appeals, whereas the PACE SAA is Iowa Medicaid Enterprise. The Iowa Department of Inspections and Appeals does not accept the PACE Plan of Care as meeting nursing facility requirements. Consequently, PACE Participants in nursing facilities...
have two care plans, which follow mostly duplicative care planning processes – PACE staff attend nursing facility care planning activities and nursing facility staff are invited to participate in PACE Plan of Care reviews. This duplicity also creates confusion for the PACE Participant and family and can undermine efforts at care coordination. We urge CMS and the SAA to work with other State regulatory agencies to avoid duplicative processes and educate them regarding the PACE program. In support of this, it would be helpful to have clear statutory and regulatory intent from CMS that PACE Participants have a single Plan of Care developed by the PACE IDT regardless of care setting and that this Plan of Care should serve as a core plan for care and services received from other settings or providers while the PACE Participant is enrolled in the PACE program. We welcome the opportunity to partner with CMS and SAA to identify areas of state regulatory duplication and potential conflict as well as to participate in the examination of alternatives and potential solutions.

PARTICIPANT ENROLLMENT AND DISENROLLMENT

Eligibility to Enroll in a PACE Program (§460.150): To be eligible for the PACE program, individuals must be able to live in a community setting at the time of enrollment without jeopardizing health or safety. To determine if health or safety is in jeopardy, the regulation presently relies upon criteria specified within the program agreement. According to CMS, there is long-standing policy to suggest that this assessment by the PACE Organization involves assessing the individual’s care support network and their health condition based on both the program agreement and SAA criteria. CMS is proposing to revise the regulation to codify this long-standing policy.

- **Comment:** This proposed change assumes that the SAA criteria to determine denial of enrollment due to safety of living in the community is clear and conducive to consistent application. Although CMS considers this to be a long-standing policy, this does little to assist PACE Organizations where SAA eligibility criteria are not clear. We seek clarity as to whether this eligibility standard is the same health and safety standard referenced in the involuntary disenrollment process. Also, since CMS is assigning the establishment of this eligibility criteria to its SAA regulatory partner, we request for consistency that CMS at least establish basic guidelines and definitions to assure overall programmatic direction.

Effective Date of Enrollment (§460.158): CMS has NOT proposed any revision to this regulation, which provides that enrollment is effective the first day of the calendar month following the date of the executed enrollment agreement.

- **Comment:** We urge CMS to revise this provision to enable enrollment to become effective on the date of the signed agreement. This causes delays in obtaining services and PACE Participant and family dissatisfaction. As an alternative to nursing facility care, we firmly believe that this enrollment process should be just as easy as getting admitted into a nursing facility. We encourage CMS to adopt a presumptive eligibility process to permit immediate enrollment of eligible PACE Participants.

Voluntary Disenrollment (§460.162): PACE Participants may disenroll from the program at any time without cause. In alignment with current practice, CMS is proposing to specify the effective date of disenrollment. CMS also proposes to prohibit PACE staff from steering disenrollment due to PACE participant health status.

- **Comment:** Voluntary disenrollment becomes effective on the first day of the month following the date disenrollment is received. We urge CMS to create an exception to this delayed effective date for
PACE Participants electing the Medicare Hospice benefit. Currently, if a Participant makes a Hospice election, the PACE Organization must obtain a signed letter of agreement with the hospice provider, which creates delay. In rural areas, the delay is magnified as Participants prefer a local hospice. In addition, the hand-off at month’s end adds processes that are cumbersome to family that just wants comfort care for their family member (PACE Participant). Overall, effective date for the transition is a dis-satisfier for both the PACE Participant and their family.

Involutary Disenrollment (§460.164): This regulation addresses situations that warrant the PACE Organization to initiate a disenrollment and provide for SAA review and final determination of the disenrollment request. CMS proposes to clarify the timeframe for notice to the PACE Participant, add circumstances that qualify for involuntary disenrollment, including actions of the caregiver, and specify documentation to demonstrate disruptive or threatening behavior.

- **Comment:** While involuntary disenrollment for disruptive or threatening behavior occurs infrequently; when it does, it often raises significant safety and fear concerns for other PACE Participants and staff. We would ask CMS to re-examine the timeframe for these reviews and to establish separate clear and expedited SAA disenrollment review and determination (i.e. not to exceed 30 days). CMS states that they are instituting an extended notice timeframe “to protect participants’ due process, as our regulations and guidance do not currently include an advance notice requirement.” Perhaps CMS should provide advanced notice to PACE Participants when an involuntary disenrollment request is filed with the SAA and the PACE Organization should begin in the process of transferring to Fee-For-Service services pending final SAA determination.

**FEDERAL/STATE MONITORING**

Ongoing Monitoring after the Trial Period (§460.192): This regulation addresses continued oversight, including an onsite review of each PACE Organization on a two-year cycle. CMS is proposing to change the ongoing monitoring to enable CMS in cooperation with the SAA to conduct reviews of PACE Organization operations as appropriate. PACE Organizations will be selected for ongoing audits based on a risk assessment approach utilized for the Medicare Advantage and Part D programs.

- **Comment:** In concept, this general approach appears sound, in that it will place more reliance on PACE Organizations to regulate themselves without perfunctory external audits. Although the Proposed Rule provides some general guidelines to be used in the risk assessment, CMS has not provided enough information for PACE Organizations and stakeholders to make an informed decision about the merits of this proposal. Among our questions are:
  - How will it be developed to determine which PACE Organizations will get on site audits (i.e. what are the specific selection criteria?)?
  - Is there a maximum number of years that a PACE Organization may go without receiving an audit, or will some PACE Organizations never be subject to an audit based on exemplary practices/data?
  - Will the same tool be used in all CMS regions?
  - Will it be uniformly applied?
  - Will there be transparent exit interviews onsite at the conclusion of each audit?
The above represents a sampling of our questions. We would suggest that CMS provide more detailed information about this process and solicit specific stakeholder input prior to implementing this change.

On behalf of our PACE Participants, Siouxland PACE and UnityPoint Health appreciates the opportunity to provide comments to the Proposed Rule. In addition, Siouxland PACE is a member of the National PACE Association (NPA). We support the comments submitted by NPA and are committed to participating with the NPA to further strengthen services and supports for the PACE population. Siouxland PACE and UnityPoint Health look forward to participating in future PACE rulemaking and other stakeholder forums. To discuss Siouxland comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Government & External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,

Randy Ehlers, MSW
Executive Director, Siouxland PACE

Sabra Rosener
VP, UPH Government & External Affairs