

# PUBLIC SUBMISSION

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<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0003

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Dana Collins

**Email:** dcollins@aasc.org

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## General Comment

Appalachian Agency for Senior Citizens is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Appalachian Agency for Senior Citizens strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0007

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Peter Hansel

**Email:** phansel@calpace.org

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## General Comment

CalPACE, representing 23 PACE organizations that provide services to PACE participants in California, is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

CalPACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0010

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Susan Decker

**Email:** sdecker@thomepace.org

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## General Comment

The Cascade PACE, Inc. d/b/a Thome PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Thome PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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<b>Tracking No.</b> kzo-6rfl-7t2v
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0009

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Jed Geyerhahn

**Email:** jgeyerhahn@challiance.org

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## General Comment

CHA PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements. Specifically, an impact analysis of 50% of charts is an unrealistic time burden on POs. The impact analysis requires a manual review of charts that requires substantial labor from the PO. POs don't have staff for these substantial impact analyses, requiring the assignment of clinical staff to the chart reviews and taking those clinical staff away from regular care duties. A random sampling of a manageable number of records would further demonstrate any identified issue without overburdening the PO. We cannot overemphasize the immense burden on a PO resulting from impact analyses. Also of note, upgrades to an EMR in response to CMS audit protocol changes take a year or more to implement (including IT changes, training, etc.). PACE programs are not large institutions with substantial IT resources and often rely on EMR vendors for changes and updates. CMS must consider the considerable burden EMR changes to meet the requirements of audit protocols puts on POs.

CHA PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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<b>Tracking No.</b> kzy-czi6-gix4
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0049

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Jasmine Pablo

**Email:** jpablo@stpaulspace.org

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## General Comment

Community Eldercare of San Diego dba St. Paul's PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Community Eldercare of San Diego dba St. Paul's PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0006

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Michelle Mazzacco

**Email:** Michelle.Mazzacco@sphp.com

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## General Comment

Eddy SeniorCare/PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Eddy SeniorCare strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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<b>Comments Due:</b> February 22, 2022
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0045

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Amie Schippa

**Email:** amies@ichs.com

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## General Comment

ICHS PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

ICHS PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0012

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** susan panah

**Email:** SPanah@lifepittsburgh.org

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## General Comment

LIFE PITTSBURGH is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

LIFE PITTSBURGH strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.



# PUBLIC SUBMISSION

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<b>Tracking No.</b> kzo-61iy-sezm
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0008

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Bridget Hartnett

**Email:** bhartnett@lifepittsburgh.org

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## General Comment

LIFE Pittsburgh is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

LIFE Pittsburgh strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0038

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Joyce Alexander-Hines

**Email:** joyce.alexander-hines@trinity-health.org

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## General Comment

[LIFE St. Joseph of the Pines] is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

LIFE St. Joseph of the Pines strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0047

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Meagan Moody

**Email:** mmoody@trinity-health.org

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## General Comment

Mercy LIFE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Mercy LIFE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0017

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Emmanuel Cheo

**Email:** emmanuel.cheo@trinity-health.org

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## General Comment

Mercy LIFE of Massachusetts is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Mercy LIFE of Massachusetts strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0044

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** suzanne Januszeski

**Email:** sjanuszeski@trinity-health.org

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## General Comment

Mercy LIFE of PA] is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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<b>Status:</b> Draft
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<b>Comments Due:</b> February 22, 2022
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0023

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Johanna Yurkow

**Email:** jyurkow@trinity-health.org

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## General Comment

Mercy LIFE of Pennsylvania is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Mercy LIFE of Pennsylvania strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:38 PM
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<b>Tracking No.</b> kzs-plnu-xsu6
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0036

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Anne Gibbons

**Email:** agibbons@trinity-health.org

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## General Comment

Mercy Life Of Philadelphia is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Mercy Life Of Philadelphia strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0029

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** John Mikus

**Email:** JMikus@trinity-health.org

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## General Comment

Mercy LIFE of Trinity Health PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Mercy LIFE of Trinity Health PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.



# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:40 PM
<b>Received:</b> February 18, 2022
<b>Status:</b> Draft
<b>Tracking No.</b> kzs-t5n7-zfk4
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0039

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Evelyn Dobson

**Email:** dobsone@comcast.net

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## General Comment

Mercy LIFE PACE - Valley View Residential Location for the Deaf and Deaf/Blind is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:34 PM
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<b>Status:</b> Draft
<b>Tracking No.</b> kzs-nh20-2zd3
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0032

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Molly Crumley

**Email:** mcrumley@trinity-health.org

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## General Comment

Mercy LIFE West Philadelphia is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Mercy LIFE West Philadelphia strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:15 PM
<b>Received:</b> February 17, 2022
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<b>Tracking No.</b> kzr-ksol-yzvh
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0016

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Kimberly Hampton

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## General Comment

Mercy LIFE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Mercy LIFE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:26 PM
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<b>Tracking No.</b> kzs-n0bo-i98q
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0026

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Sherray Gould-McDonald

**Email:** Sherraydgould@hotmail.com

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## General Comment

Mercy Life/PACE/Sepa is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Mercy Life/PACE/Sepa strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/22/22 10:42 AM
<b>Received:</b> February 20, 2022
<b>Status:</b> Draft
<b>Tracking No.</b> kzv-johl-2vez
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0042

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Pamela Henderson

**Email:** Pamela.henderson@mercyhealth.org

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## General Comment

[NAME OF YOUR ORGANIZATION] is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:25 PM
<b>Received:</b> February 18, 2022
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<b>Tracking No.</b> kzs-mwgh-yqm4
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0025

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Nadjie Pierre

**Email:** npierre@trinity-health.org

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## General Comment

MLOP is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:36 PM
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<b>Status:</b> Draft
<b>Tracking No.</b> kzs-nwhm-mesc
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0034

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Nichol McCleary

**Email:** Nichol.McCleary@trinity-health.org

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## General Comment

MLOP is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:38 PM
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<b>Status:</b> Draft
<b>Tracking No.</b> kzs-pao3-ua77
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0037

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Nikisha Corprew-Mintz

**Email:** ncorprew-mintz@trinity-health.org

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## General Comment

MLOP is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.



# PUBLIC SUBMISSION

<b>As of:</b> 2/22/22 10:44 AM
<b>Received:</b> February 21, 2022
<b>Status:</b> Draft
<b>Tracking No.</b> kzw-s0vh-2675
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0043

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Patricia Westerfer

**Email:** PWesterfer@Trinity-health.org

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## General Comment

MLOP is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

MLOP strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:24 PM
<b>Received:</b> February 18, 2022
<b>Status:</b> Draft
<b>Tracking No.</b> kzs-mv6a-aap5
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0024

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Lesly Ortiz

**Email:** lortiz@trinity-health.org

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## General Comment

MLOP is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:29 PM
<b>Received:</b> February 18, 2022
<b>Status:</b> Draft
<b>Tracking No.</b> kzs-n6r0-54sk
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0028

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Jennifer Bijou

**Email:** jennifer.bijou@trinity-health.org

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## General Comment

MLWP is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

MLWP strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/15/22 12:24 PM
<b>Received:</b> February 14, 2022
<b>Status:</b> Draft
<b>Tracking No.</b> kzn-50eh-ogz8
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0004

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Mary Kiefert

**Email:** mary.kiefert@msmc.com

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## General Comment

[Mount Sinai Eldercare is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.



February 14, 2022

Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development  
Attention: CMS—10630/OMB Control Number: 0938-1327  
Room C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: CMS—10630—The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460**  
*Submitted electronically via: <http://www.regulations.gov>*

On behalf of the National PACE Association (NPA) and its 144 PACE organization (PO) members in 30 states, we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment on the 2023 PACE Audit Protocol. Our comment is based on a detailed review of the proposed 2023 audit protocol materials released in connection with the 60-day notice published in the Federal Register on December 21, 2021.

In submitting this comment, NPA would like to express its longstanding and continued commitment to ensuring that PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high standards. We appreciate the importance of CMS' ongoing monitoring and recognition of practices that require correction, and the substantial resources that CMS dedicates to these activities. We have concerns, however, about the burden inherent in several aspects of both the current 2020 and proposed 2023 audit protocols and their data collection requirements. NPA encourages CMS to consider opportunities to reduce burden in ways that will not sacrifice auditors' identification of issues that must be addressed, and we respectfully offer recommendations consistent with this objective.

In developing our comment, we have focused not only on the proposed revisions to the 2020 audit protocol and new and modified data collection instruments proposed for 2023, but also on the 2023 PACE audit materials in their entirety. This review was undertaken in close consultation with POs represented on the audit and compliance subcommittee of NPA's Quality Committee. Our comment also reflects feedback NPA has received from POs on their experiences under the current 2020 PACE audit protocol.

Below NPA offers general comments on the audit protocol overall followed by detailed comments and recommendations related to CMS' burden estimates, and individual data collection instruments and information collection requirements in the proposed 2023 audit protocol. We respectfully request that

CMS staff keep our general comments top-of-mind when considering our detailed comments and recommendations.

### **General Comments**

The proposed 2023 PACE audit protocol revises the audit approach that CMS implemented for POs beginning in 2017 and updated in 2020. This approach requires the following of POs being audited:

- Submission of detailed data universes and documentation prior to audit field work;
- Submission of documentation related to auditors' selection of sample cases for review during audit field work;
- Ongoing data submissions in response to auditors' requests during and following audit field work;
- Completion of Root Cause Analyses (RCAs) and Impact Analyses (IA), if applicable, in response to auditors' requests during and following audit field work;
- Review of the draft audit report and submission of comments;
- Submission of a voluntary PACE Audit Survey; and
- Submission and implementation of Corrective Action Plans (CAPs), as needed.

Consistent with comments NPA submitted on the proposed revisions for the 2020 PACE audit protocol (dated May 21, 2019), NPA continues to have substantial concerns about the use of an audit process for PACE that was developed for Medicare Advantage Organizations (MAOs) and Part D Prescription Drug Plans. While POs are similar to MAOs and Part D plans in some respects and, like these insurer-based plans, maintain databases for service determination requests, appeals and grievances, they are fundamentally health care providers. Those aspects of PACE that are "plan-like" are better suited to CMS' approach than those aspects of PACE that are "provider-like." CMS' approach to auditing the provider aspects of POs' operations is extremely data intensive and assumes POs can readily extract enormous amounts of information from participant medical records. As clinical documentation generally takes narrative form, it is not the case that data are easily extractable. Instead, sizeable data demands built into the 2020 audit and proposed 2023 audit must be addressed largely through manual review of PACE participants' medical records. While POs' data systems continue to improve, EMRs are primarily designed to capture clinical information necessary to document and coordinate assessment and treatment. Substantial amounts of data requested during the audit process divert clinical staff whose primary responsibilities are to provide participant care to the manual review of medical records. We are not aware of any examples in which this volume of detailed information is required on a per enrollee/patient/beneficiary basis to monitor MAOs, or other Medicare or Medicaid provider types.

POs should not be expected to be able to retrieve data from their electronic medical record (EMR) systems in the same manner that MAO/Part D plans access their administrative databases. While EMRs are designed to provide immediate and ongoing access to all information contained in the health record to improve patient care, they are not designed to produce data reports representing all the information documented in the EMR. There is a significant difference between the information entered into the EMR for access by other providers and data that can be extracted for the purposes of auditing. We request

that CMS' approach to auditing the provision of services and coordination of care in PACE take this into consideration to a much greater degree. CMS' expectations of insurer-based plans' claims-based data systems are not a sound basis for determining appropriate expectations of PACE organizations' care planning and service delivery data.

The most significant example of this relates to CMS' newly proposed requirement for the submission of reports detailing the PO's monitoring and tracking of all services across all care settings that were ordered, approved, or care planned during the data collection period. This reporting requirement is of enormous concern to many PACE organizations consulted by NPA in the development of this comment. PACE organizations utilize a variety of systems to monitor, track and ensure the provision of ordered, approved and care planned services. These systems include scheduling systems for multiple types of services, e.g., PACE center attendance, home care, specialist appointments, meals, etc.; participant-level calendars; orders tracking modules, service determination requests and appeals tracking; chart audits; care plan audits; audits of specialist services ordered; and more. While these and other systems are designed to ensure provision of services, in many cases they are not designed to enable POs to generate the reports that CMS is proposing to require of POs audited under the proposed 2023 protocol.

This is true, in part, due to the narrative nature of the information documented in the EMR rather than data entered into predetermined fields, particularly for care planned services. For many care planned services, automatic retrieval may not be possible, thereby requiring manual review of care plan changes over time and progress notes that detail both the service provided and participant condition. Services provided by providers and entities contracted by the PO and billed by these providers are more easily identified via the claims submitted by the contracted providers; however, a detailed review of the service documentation is still required to assure the services were provided as ordered or authorized. In addition, consistent with NPA's comments on the 2020 audit protocol, many of the data fields included in the List of Participant Medical Records (LOPMR), the Observation Participant List, and the impact analyses require medical record reviews to complete. To our understanding, this is a level of burden that significantly exceeds that imposed by audits of other provider types. More importantly, it will detract from participant care by diverting the time of health professionals away from delivering care to conduct significant and comprehensive medical record reviews to meet the audit requirements. Notably, PACE participants' care will be harmed by this diversion at a time when existing direct care workforce challenges are already impacting PACE organizations.

In its Supporting Statement for the proposed revisions to the PACE audit protocol, CMS states that one of its objectives in modifying the 2023 audit protocol is to incorporate lessons learned from CMS' audit experiences in 2020 and 2021. We suggest that due to the COVID-19 public health emergency (PHE), auditors' experiences in 2020 and 2021 may not have been representative in two significant ways. First, CMS' use of the 2020 PACE audit protocol was not as extensive as it otherwise would have been because audits were largely limited to smaller, less experienced POs still in their trial period. In addition, during the period of the COVID-19 PHE, POs, like all providers, faced enormous challenges to protect their participants and staff from infection with implications for program operations. We ask CMS to weigh

these points more heavily before modifying the 2023 audit protocol in ways that will impose significantly more burden on POs.

Lastly, NPA believes the objective of several of CMS' extensive audit data requirements is to identify all instances of possible non-compliance and human error rather than to create a focused audit sample from which CMS can identify significant and recurring systems failures. We believe this approach results in an excessively burdensome and costly audit process for both POs and CMS. This is the basis for our recommendations below to substantially reduce the burden of the audit in ways we believe will not prevent auditors from identifying practices that need correction. These recommendations include, but are not limited to, an alternative approach to demonstrating how POs monitor and track services, and use of a sampling approach for those data collection instruments including the LOPMR data universe and numerous impact analyses that require data that are maintained in participants' medical records and cannot be readily extracted. If these recommended processes identify significant non-compliance or systems failures, we appreciate that more data may be needed from individual POs to fully understand and correct these issues, and to mitigate their impact. We respectfully request CMS' consideration of the detailed comments and recommendations below.

#### **Detailed Comments on CMS' Burden Estimates and Recommendations to Reduce Burden and Enhance Quality, Utility and Clarity of Proposed Information Collection**

Referring to the burden estimates in Supporting Statement A, we believe CMS has significantly underestimated the burden of the 2023 PACE Audit Protocol on POs, particularly for medium- and large-size POs with which auditors may have had less experience in 2020 and 2021. General explanations for this are included in the preceding section: 1) CMS' use of an audit approach that was developed for insurer-based plans rather than providers; and 2) the assumption that POs' medical records are databases from which enormously detailed data being required of POs undergoing audits can be retrieved easily. Below we offer a more detailed analysis and recommendations for reducing burden in ways that we believe do not compromise CMS' ability to identify systemic noncompliance.

An important assumption underlying CMS' burden estimates relates to the number and types of PACE staff that are required for an audit. Referring to p. 5 of Supporting Statement A, these include: 1) Medical and Health Services Managers; 2) Executive Secretaries and Executive Administrative Assistants; 3) Medical Records Specialists, and Health Technologists and Technicians; and 4) Compliance Officer. In addition to these staff, POs have routinely reported to NPA that they also need to involve their program and medical directors; numerous individual IDT members/clinical staff needed for medical record review; PACE center managers to assist with activities related to the participant observations; quality managers/staff to provide information on POs' quality improvement activities and who also may be involved in compliance oversight activities; network or contract services managers; and human resources staff. The involvement of substantially more than four staff is often necessary for all four phases of the PACE audit lifecycle: pre-audit activities; audit administration; responding to documentation requests, particularly if impact analyses are required; and for audit close out activities.



Below we identify components of the proposed 2023 PACE audit protocol that NPA believes are especially burdensome along with recommendations to reduce burden without sacrificing auditors' ability to identify significant lapses in compliance. We focus on opportunities to limit data requests that require the participation of clinical staff. We have organized our comments according to the four phases of the PACE audit life cycle with the majority focusing on documentation and data requirements during the "pre-audit" phase and requests for impact analyses (IAs) following audit fieldwork.

- 1) **Activities prior to the audit start.** The burden estimate of a total of 100 hours for the pre-audit period is substantially underestimated and proposed to increase by just 20 hours in 2023 despite CMS' proposal to substantially increase the volume of information required of POs. Most significantly, the proposed 2023 audit protocol includes: 1) reports logging the provision of all services ordered, approved, or care planned for the six-month data collection period; 2) numerous additional fields in the List of Participant Medical Records (LOPMR) data universe; 3) a new Contracted Entities and Providers (CEP) data universe; and 4) new documentation and report requirements related to the PO's compliance oversight program. After consulting with NPA's PO members, we offer the following comments and recommendations related to several of the initial or pre-audit documentation requests. For a number of these, we ask CMS to reconsider the necessity and utility of the proposed documentation request; in others, we ask CMS to enhance the clarity of the proposed data collection.

The following comments/recommendations on the data collection instruments for the pre-audit period are listed in order of their importance in alleviating the burden of the proposed 2023 audit protocol on PO staff and resources. Numerous POs consulted in the development of our comment expressed that the proposed reports detailing their monitoring and tracking of all services across all care settings is of greatest concern followed by proposed changes to the LOPMR, Personnel and CEP data universes.

Reports that detail the PO's monitoring and tracking of all services across all care settings that were ordered, approved, or care planned during the data collection period. More specifically, CMS is requesting the following data elements for each service ordered, approved, or care planned:

- Participant first and last name
- Medicare Beneficiary Identifier (MBI) (if applicable)
- Participant ID
- Date the service was ordered, approved, or care planned
- Description of the service ordered, approved or care planned
- Date the service was provided

NPA believes that CMS' request for these reports will impose a very substantial burden on many POs far exceeding the total 100 hours of PACE staff time estimated by CMS for this portion of the audit. Based on input from numerous POs we strongly disagree with CMS' assertion in Supporting Statement A that all POs would have the requested information tracked and maintained in their

records in a manner that would allow them to generate the reports that CMS is proposing to require.

Although POs must meet PACE regulatory requirements in §460.98(b)(5) to document, track and monitor the provision of services across all care settings, compliance with this requirement would not necessarily enable a PO to generate the requested reports. We believe that CMS is requesting POs provide a log of all services ordered, approved, or care planned. CMS clarified in the preamble to the January 19, 2021, final rule (CMS-4190-F2) that PACE organizations would not be required to maintain logs in response to requirements in §460.98(b)(5) and “should have flexibility in how they operationalize the requirement to track, monitor and document the provision of services.” (Federal Register, Jan. 19, 2021, p. 6036). Requiring POs to provide the monitoring report described in the audit protocol does not reflect this flexibility.

As explained above, a huge volume of information is being requested of POs in these reports. Because POs are responsible for the provision of all Medicare - and Medicaid-covered services and more, for a medium-size program, e.g., 500 participants, these reports could include tens of thousands of entries for a six-month data collection period. A preliminary estimate from a PO with approximately 800 participants suggested well over 20,000 “ordered” services that do not include entries for substantial categories of services, e.g., home care, and many care planned services which the PO tracks and monitors through other systems. Just transferring the ordered services into CMS’ requested format would be extremely time consuming and pulling in other approved and care planned services is considered overwhelming. In consulting with POs, we also identified other issues related to these reports. For example, a participant’s care plan may include PACE center attendance two days a week. Inherent in a day of PACE center attendance are numerous services including activities, personal care, meals, transportation, etc. Is the expectation that each of these services is listed individually? This is a level of detail that a PO could not electronically extract from a participant’s EMR and maintenance of a parallel database that is not needed for purposes of participant care would be enormously costly and labor intensive. This is just one example of the challenge inherent in a report like this for PACE services that are provided throughout the day in the PACE center.

The enormous amount of time and effort required to comply with CMS’ pre-audit data request for these reports does not imply that services are not tracked and monitored by POs. There are multiple means by which POs document, track, and monitor services and ensure they are provided which do not necessarily lend themselves to making data available in the way they are required in the proposed 2023 audit protocol. Referring to the discussion on p. 3 of this comment, these include scheduling systems for multiple types of services, participant-level calendars, orders tracking modules, and a variety of auditing activities.

To account for allowable variation in how POs track and monitor the services, NPA requests CMS implement a much less burdensome approach to auditing POs’ compliance with requirements to monitor and track services to ensure ordered, approved, care planned services are provided. More

specifically, we strongly recommend that auditors require POs to provide documentation describing their process(es), policies and procedures for monitoring and tracking of all ordered, approved, and care planned services across all care settings. This would allow auditors to evaluate a PO's systems against its policies and procedures rather than a set of data of such complexity that it may not accurately reflect the outcomes of the PO's policies and procedures. Any auditor concerns identified through the review of the PO's processes with respect to how the PO effectuates all ordered, approved and care planned services could be pursued in their review of the targeted medical records selected for the Provision of Services audit element. Additionally, any related self-evaluations or audits conducted as part of the PO's compliance or quality programs would be provided consistent with the audit's initial documentation and data submission requirements on pp. 4-5 of the proposed 2023 audit protocol. If additional documentation is required, it can be requested of POs during the audit fieldwork period. If concerns regarding noncompliance are identified with respect to either the requirement in §460.98(b) to document, track and monitor services or with a PO's provision of all required services, these concerns can be pursued further, e.g., the auditor can request additional information on the PO's processes for tracking and monitoring the provision of services, or one or more related impact analyses may be requested, e.g., HomeCare1P02, ProvisionofServices1P021P81, SvcRestrict1P90, RequiredServcies1P93, SpecialistRecommendations1P14, CoordinationofCare1P95.

If CMS is unable to eliminate the reports detailing monitoring and tracking of services from the audit protocol entirely, NPA strongly recommends that the scope of the reports be limited to a probe sample of participants, for example a sample of 10-15 participants chosen randomly by auditors from the PO's participant list. Probe samples are a common tool used to improve audit efficiency and to reduce administrative burden, and a probe sample would be an effective means of identifying risk and evaluating whether more information is required, e.g., by expanding the sample or through additional documentation requests or the impact analyses noted above. The results of this much more limited sample, in combination with the PO's processes, policies and procedures for monitoring and tracking services, would provide auditors with sufficient information needed to identify a systemic issue, if any, that may need to be pursued.

List of Participant Medical Records (LOPMR) Record Layout: CMS is proposing numerous revisions to the LOPMR data universe for 2023. In the crosswalk of changes to the LOPMR proposed for the 2023 audit, CMS specifies that 12 new data fields have been added to the LOPMR and 10 removed. While this is technically accurate, four of the dropped fields asking for diagnostic information have been incorporated into Diagnoses (Column T). Further, Diagnoses (Column T) has been expanded further to request information for additional diagnoses: Cellulitis, Cerebrovascular Accident, Human immunodeficiency virus (HIV), Mental Illness of any type, Pneumonia and Sepsis. A single diagnosis, Hunter's Syndrome, was dropped from this field. Proposed Hospitalization/Emergency Room Reason (Column P) has been expanded to request information on whether a participant who went to the ER or was admitted to the hospital had one of the following additional diagnoses: internal bleeding, sepsis, medication overdose. In total, the addition of a substantial number of new data fields and

expansions to others would substantially increase the time and effort required of PACE organizations to complete the LOPMR.

More significantly, for many if not all POs, numerous fields in the LOPMR require manual medical record review by clinical staff because data cannot be readily extracted from the medical record or other data sources, e.g., Change in Living Situation (Column L), Received Comfort Care (Column X), Date Comfort Care Began (Column Y), Date Comfort Care Ended (Column Z). These are in addition to fields carried over from the 2020 audit protocol that also may require medical record review, e.g., Assistance with Administering Medications (Column AB), Functional Decline (Column AH), Indwelling Catheter (Column AK), Significant Weight Loss (Column AL), Restraints (Column AM), etc. We are not implying that this information is not available to providers for purposes of addressing participants' needs, but it may not be readily extracted for purposes of completing the LOPMR. Requiring clinical staff to review hundreds, possibly thousands, of medical records to complete these fields is unduly burdensome. A sampling approach would significantly relieve the burden, most importantly for POs' clinical staff.

NPA's overarching recommendation is to implement a sampling approach for the LOPMR data universe for the same reasons noted above for the monitoring and tracking reports. Rather than requiring PACE organizations to report data for all participants enrolled at some point during the data collection period, we recommend that POs provide LOPMR information for a random sample of their participants. The proportion of a PO's census included in the random sample would decrease with program size consistent with standard sampling methodologies. We believe that an effective sampling methodology can be devised to balance the demands on POs to provide the detailed data included in the LOPMR with auditors' needs for representation of various types of participants' medical, functional, and social needs from which to select the targeted medical records. Within the science of auditing, when it is not practical to examine all available evidence and occurrences due to volume and the low return on investment of effort and time, a sample is selected to evaluate against the audit criteria and to develop the audit conclusion. We understand CMS' goal is to have a high level of confidence that the audit objectives can be met, and we believe this goal can be achieved with a statistically valid sample for the LOPMR rather than a review of 100% participants, which for some programs is well in excess of 1000 individuals. We believe a statistically valid sample would reduce the effort for both the PO and CMS and prevent distraction from providing participant care while assuring confidence in audit conclusions. A sample size assuring a statistically valid sample with a sufficient level of confidence can be determined for each PO that takes into account differences in programs' census.

In addition to the above overarching recommendation to utilize a sampling methodology for the LOPMR, we have the following comments on specific LOPMR fields. Adoption of these recommendations is even more important if CMS does not implement NPA's recommendation for a sampling strategy for the LOPMR data universe.

- Change in Living Situation (Column L) (new): The data needed to complete this field would require many POs to undertake a retrospective review of their participants' medical records to determine if there was a change that occurred during the six-month data collection period. Information included in the medical record on the participant's current living situation would not be sufficient to complete this field. NPA recommends this field be dropped. While we understand auditors might use this information to identify participants for whom care needs change over the course of the audit review period, other fields are sufficient for this purpose, e.g., Number of Hospital Admissions/Observations (Column M), 30-Day Hospital Readmission (Column N), Number of Emergency Room Visits (Column O), Number of SNF/ICF Admissions (Column Q), Direct SNF Admission (Column R).
- Hospitalization/Emergency Room Reason (Column P) (modified): POs have asked if it would be possible for CMS to provide the ICD-10 codes for the diagnoses included in this field, i.e., hypoglycemia, hyperglycemia, internal bleeding, sepsis, medication overdose and decreased oxygen saturation. This would prevent each individual PO from having to undertake this exercise and would ensure uniformity in reporting.

Further, we seek clarification regarding CMS' use of the term, "medication overdose." Is the intent to identify medication errors, intentional overdoses to cause self-harm, unintentional overdoses of medication related to system or human error, or all of the above? Each described scenario may be recorded differently by diagnosis by a hospital/ER or other primary care provider; therefore, it may be difficult to capture all the scenarios listed here. Clarity in terms of the specific needs would help in understanding how POs can capture the desired information.

- Diagnoses (Column T) (modified): POs' concerns regarding this field are not related to its contents as much as the time required to type each diagnosis and, when applicable, specific types of diagnoses. We ask CMS to consider ways to reduce the burden of entering this data into the record layout considering that a PO may have to complete this field for hundreds, even thousands, of participants if NPA's recommendation to allow sampling for the LOPMR is not adopted.

In addition, consistent with our comment on Hospitalization/Emergency Room Reason (Column P), POs have asked if it would be possible for CMS to provide ICD-10 codes for the diagnoses referenced in this field. This would prevent each individual PO from having to undertake this exercise and would ensure uniformity in reporting.

- CHF Exacerbation (Column U) and COPD Exacerbation (Column V) (new): To reduce burden and need for medical record review, we recommend these fields be dropped from the LOPMR. Participants with CHF and COPD are identifiable based on diagnostic data requested in Diagnoses (Column T). This information in combination with data in other fields, e.g., Number of Hospital Admissions/Observations (Column M), 30-Day Hospital Readmissions (Column N),

Number of Emergency Room Visits (Column O), Specialist/Consultation Visits (Column S) will assist in identification of participants who may have experienced CHF or COPD exacerbation .

- Received Comfort Care (Column X) (new): We are concerned that the term “comfort care” is subject to different interpretations and recommend that this field focus exclusively on end-of-life care as defined by the PO with the name of the field changed accordingly.
- Date Comfort Care Began (Column Y) (new) and Date Comfort Care Ended (Column Z) (new): We request these fields be dropped. The dates such care started and stopped are accessible to all care providers involved in the participant’s plan of care; however, the dates are not typically recorded in a data field that can be used to generate a report reflecting the date range for all participants. If chosen for a targeted review, auditors would be able to identify this information in the medical record of participants receiving such care. Again, we are hopeful that CMS will focus on “End-of-Life Care” as recommended above.
- Current Center Attendance (Column AC) (modified): POs report to us that information on PACE center attendance would be easier to report in terms of days per week rather than days per month, and we request that this field be modified accordingly.

Once the 2023 data universes are finalized, it would be extremely helpful for CMS to provide POs with updated Excel templates for the LOPMR (as well as the other data universes). Ideally, this would happen by July 2022, but no later than October 2022 to provide POs a minimum of three months to work with the new templates prior to audits beginning in early 2023 under the revised protocol.

Personnel Record Layout: CMS is proposing that POs provide “Date of Initial Participant Contact” (Column E) and “Date Individual Began Providing Care Independently (Column F) in place of “Direct Participant Contact” (Column H in 2020 Personnel Data Universe). While we understand that POs must have processes in place to ensure that certain conditions are met before staff have direct participant contact or provide participant care, providing these dates for all employed and contracted staff included in the Personnel data universe will be very time consuming. Alternatively, we request that CMS retain the “Direct Participant Contact” field and have auditors review the targeted sample cases to ensure that requirements related to the timing of initial participant contact and independent provision of care are met. In addition, we note that if a PO is required to complete the Personnel impact analysis, this IA has been revised to include “Date of Initial Participant Contact” and “Date Individual Began Providing Care Independently.”

Contracted Entities and Providers (CEP) Record Layout: CMS is proposing the addition of a new data universe to the audit protocol to gather information on POs’ contracted provider network. With respect to the proposed CEP data universe, NPA requests confirmation that CMS’ intent with this data universe is to obtain information on the PO’s contracted entities which in some cases may be individual providers but may also include group practices in which multiple providers practice.

Therefore, we request that CMS change the field name of “Provider/Facility Name” (Column A) to “Provider/Practice/Facility Name” and allow for POs to provide the practice name if that is the contracted entity. Accordingly, “Specialty or Facility Types” (Column C) should allow for multiple specialty types to accommodate a multi-specialty group practice. NPA’s recommendations are consistent with the narrative in Supporting Statement A describing the CEP universe as having a narrow scope and consistent with PACE requirements for POs to maintain a list of contractors.

In addition, NPA requests that “Limitations/Restrictions” (Column G) be further clarified. Except for this field, the CEP data universe can be completed by the PO’s contracting staff. As currently described, identification of “any” limitations or restrictions could be interpreted to require input from clinical staff interacting with contracted entities in the day-to-day scheduling of appointments which may not be immediately available but for which access is not limited or restricted. Also, no contractors can provide an unlimited amount of service due to their own capacity in terms of staff, beds, etc., and again, we are concerned about the reference to “any” limitation or restriction. We ask that this field be clarified to focus on situations in which the contractor has communicated a specific limitation or restriction on the availability of services for PACE participants that could result in a lack of access to needed care and services.

On-Call Record Layout: CMS is proposing to add “Call Category” (Column H) to this data universe. We request that this field be dropped as it is duplicative of information already available to auditors in “Call Description/Reason for Call” (Column I).

Service Determination Requests Record Layout: Referring to “Immediate Approval” (Column R), should POs also enter “N” if the service determination request was approved in full by the entire IDT? Alternatively, would it be clearer to simply require “N” if a member of the IDT was not able to approve the service determination request in full at the time the request is made. The preceding field provides information on Request Disposition.

Appeal Requests Record Layout: Referring to CMS’ request for “Third-party reviewer or committee credentials” (Column M), PACE organizations may use IDT members employed by other PACE organizations as third-party reviewers. In situations when an individual IDT member (as opposed to multiple IDT members) is used as the third-party reviewer, e.g., a primary care provider, should PACE organizations provide the individual-specific credentials or should this individual be identified as “Another PO’s IDT”? We request CMS’ clarification.

Documentation demonstrating the measures developed as part of the PO’s compliance oversight program to prevent, detect, and correct noncompliance with regulatory requirements and fraud, waste, and abuse. NPA requests further clarification of this documentation request. More specifically, we would like to confirm that POs are being asked for a description of their compliance oversight activities consistent with requirements in §460.63 and not the additional compliance oversight activities required of POs in §423.504(b)(4)(vi)(F) for their Part D benefit which we



understand are reviewed in the context of CMS' 1/3 financial audits.<sup>1</sup> Under §460.63, required activities include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, and correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

Assuming that CMS' expectation here is for the PO to submit existing documentation of its compliance oversight program and that this information is not being required in a specific format, NPA does not anticipate substantial additional burden resulting from this new documentation request. NPA has received feedback from its members that some compliance activities may be included in a PO's quality improvement program because of how the PO's operations are organized, e.g., activities focused on regulatory compliance with requirements for service determination requests. To reduce unnecessary burden on the PO, we request that the PO be able to include a broad range of applicable materials in response to this documentation request and that auditors consider them in their entirety.

Submission of results of all self-evaluations and audits conducted in the PO's compliance oversight program that may have impacted PACE operations and services during the data collection period. Consistent with our preceding comment, NPA would appreciate CMS' clarification that this documentation request is limited to self-evaluations and audits that the PO may have undertaken as required by §460.63 and that it does not include the results of routine internal monitoring and auditing activities related to its Part D benefit. Consequently, in responding to this documentation request, we would expect POs to submit the results of self-evaluations and audits they conduct in responding to compliance issues as they are raised and, to varying degrees across POs, additional self-evaluations and audits undertaken proactively. We want to confirm that there is no expectation inherent in this documentation request that POs must submit the results of routine auditing and monitoring activities required under §423.504(b)(4)(vi)(F) or that CMS requires POs to undertake routine monitoring and auditing for their operations as a whole.

For many of the reasons outlined above, NPA is extremely concerned that the burden on POs of the data collection requirements in the pre-audit phase will far exceed the estimate of 100 hours and very much appreciates CMS' consideration of its recommendations to reduce considerably the demands on PO staff. Although we appreciate consideration of each individual recommendation, we consider those related to the services tracking and monitoring reports, and the LOPMR, Personnel and CEP data universes to be most important.

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<sup>1</sup> Under §423.504(b)(4)(vi)(F), for their Part D benefit, PACE organizations must establish and implement an effective system for routine monitoring and identification of compliance risks which includes internal monitoring and audits and, as appropriate, external audits to evaluate compliance with CMS requirements and the overall effectiveness of the compliance oversight program.



- 2) **Actual administration of the audit** for activities that take place during the audit fieldwork. We appreciate CMS' recognition of the substantial staff time involved in this aspect of the audit as reflected in the increase in CMS' burden estimate from 160 to 320 hours. We believe this increase adjusts for additional time needed for POs to provide significantly more documentation for the Service Determination Requests, Appeals and Grievances (SDAG), Provision of Services, and Compliance and Quality Improvement audit elements, and for additional staff to participate in interviews related to the PO's compliance oversight and quality improvement activities.

We remain concerned, however, that this estimate does not adequately account for the time required of POs to complete the Observation Participant List. As proposed, completion of the list requires significant PO staff time to review participants' medical records to extract and report detailed information on medication administration, wound care, home care and specialized diets for participants who receive these services. We note here that we understand from PACE organizations that the Observation Participant List has not been utilized for audits conducted in 2020 and 2021 to identify participants for observation. Instead, as we understand it, participants have been identified from the sample cases drawn for the Provision of Services audit element. We suggest that information on the participants included in the sample cases and data drawn from the LOPMR are sufficient resources from which to select five participants for observation rather than having a PO complete the Observation Participant List for as many as 150 participants, a rough estimate of the number of participants assigned to one IDT at a specific center.

If use of the information obtained in the medical record review and LOPMR is not acceptable, NPA suggests that POs be able to provide lists of participants assigned to an IDT at a specific center who receive wound care, medication administration, home care and/or a specialized diet during the week of the participant observation review. Based on the lists of participants who receive wound care, medication administration, home care or specialized diets, the auditors can work with PO staff to identify individual participants with the specific type(s) of wound care, medication administration, home care or specialized diet needs they would like to observe. We believe this approach strikes a more appropriate balance between the needs of the auditors and demands placed on PO staff.

Another opportunity to reduce burden on POs during the audit fieldwork arises when an Audit Team member asks PO staff to upload medical record documentation to HPMS because he/she cannot locate it in the medical record. From the PO's perspective it would be more efficient for the Audit Team member to provide PO staff the opportunity to direct him/her to the appropriate place in the record. We believe this would reduce the burden POs experience responding to requests to upload documentation while still assuring auditors' access to the information they need and improving the efficiency of their efforts in reviewing the medical records.

- 3) **Reviewing and responding to documentation requests, compiling and submitting root cause analyses and impact analyses, and responding to draft audit report.** CMS has not modified its burden estimate of 160 hours for this portion of the audit although the number of impact analyses (IAs) is proposed to increase from 16 to 18 and additional columns are proposed for several of the remaining IAs. Based on feedback from POs, for this portion of the audit, NPA is most concerned

about the staff time and resources required to complete the IAs. We note that CMS' experience with the IAs included in the 2020 audit protocol has been limited largely to PACE organizations in their trial period, and the burden estimate for this portion of the 2023 audit protocol is very unlikely to be representative of the experiences of PACE organizations with larger censuses if one or more IAs is requested of them.

Feedback from POs on the staff time required to complete the three newly proposed IAs is illustrative. One PO estimates completion of RequiredServices1P93 would take 40 hours for 100 participants and involve its home care staff extensively, including the IDT's home care coordinators. For a program with a census of 750, if required to undertake this IA for 50% of its participants, completion of RequiredServices1P93 alone could consume upwards of 150 hours. A similar estimate was provided for CoordinationofCare1P92. This PO estimated SpecialistRecommendations1P14 would take 225 hours to complete for 375 participants.

Although CMS' decision in 2020 to reduce the scope of numerous IAs from 100% to 50% of participants and personnel was welcome, the burden of completing the IAs continues to be very substantial and often only can be accomplished by clinical staff engaged in medical record review, thereby straining a PO's clinical capacity. At a minimum, we expect all the following IAs would require detailed medical record reviews focusing on 50% of a PO's enrollment:

Assessments1P491P501P82, SDRIdentification1P76, EmergencyCare1P07, Grievances1P311P751P77, HomeCare1P02, Provision of Services1P021P81, SrvcRestrict1P90, AlertIDT1P14, RequiredServices1P93, SpecialistRecommendations1P14, CoordinationofCare1P95. For medium- and large-size POs, the time required to perform one or perhaps two of these IAs could easily exceed the total 160 hours of PO staff time estimated for this portion of the audit. We are not aware of other provider types for which a comparable audit protocol is used and, consistent with comments above, believe that an audit protocol developed for insurer-based plans that rely on claims and other databases is excessively burdensome in the context of the PACE provider model. If fundamental modifications are not made to the audit protocol itself, then we ask that CMS implement it differently to more accurately account for its burden on POs and their care providers.

To this end, NPA strongly recommends a sampling approach for IAs which takes into account the PO's census in determining the scope of the impact analysis. While a sample of 50% of participants may be appropriate for small POs, as program size increases, smaller but statistically significant proportions of participants should be sufficient to identify systemic issues. Further, for those POs required to undertake more than one IA requiring medical record review, NPA also strongly recommends that the participant samples chosen for the IAs overlap to the greatest extent possible to limit the total number of records to be reviewed. NPA recommends a similar sampling approach for impact analyses for which the scope of the IA is personnel, grievances, service determination requests and appeals when their numbers suggest that a sample would be sufficient to identify systemic issues. As noted earlier, sampling is a well-recognized and generally accepted for various

types of organizational audits to determine compliance with accounting, financial, and other significant regulatory requirements involving risk to individuals and organizations.

In recommending use of a sampling approach for IAs, NPA understands that if the results of an IA identify a widespread or systemic issue of significant concern, auditors may need the PO to expand its focus to include a larger number of participants/personnel/SDRs/grievances/appeals. A more comprehensive review could be included as part of the PO's corrective action plan.

In addition to implementation of a sampling approach, it is critical that auditors implement reasonable thresholds for requiring POs to undertake IAs. More specifically, when an auditor's analysis of sample cases identifies potential instances of non-compliance, if an RCA, together with dialogue between the auditor(s) and PO staff, expose the scope of the issue and the means by which it should be addressed, auditors should not proceed to request an IA. RCAs alone, together with dialogue between auditors and PO staff, can provide POs and their auditors considerable insight into the scope of an issue. For example, the requirements of POs to maintain medical record documentation are extensive, including documentation of services furnished across all settings, 24/7, 365 days a year. Thresholds for IAs related to medical record documentation should take into account the comprehensiveness of POs' documentation requirements and the threshold for an IA should be adjusted accordingly so that minor omissions without consequences for participant care do not lead to IAs consuming hundreds of hours of staff time. We do not believe that such discretion would jeopardize participant experiences or outcomes.

The three new IAs proposed for the 2023 audit process (RequiredServices1P93, SpecialistRecommendations1P14 and CoordinationofCare1P95) will be extremely labor intensive for POs to complete. In addition to NPA's overarching recommendations to utilize a sampling methodology for IAs and for auditors to implement reasonable thresholds in requiring POs to initiate IAs, we encourage CMS to consider additional ways to limit the magnitude of these (and other) IAs that include detail that may not be critical to the specific issue(s) identified by auditors. That said, NPA has several specific recommendations:

**RequiredServices1P93.** We recommend that this IA be modified to reduce the level of detailed information being requested of POs and to clarify CMS' expectations of POs completing this IA. We understand that one objective of this IA is to ensure that 1) a participant's caregiver assists with ADLs/IADLs or supervision only if he/she is willing and capable of doing so, and 2) if a participant's caregiver is unwilling or unable to assist with ADLs/IADLs or supervision, services are provided in full by the PO. This objective can be met without requiring all the detailed information requested in the IA as proposed. For example, we suggest the questions in Columns I and J be changed to Y/N questions. Further, the detailed information requested in Columns L, M, O, P and Q can be limited to situations in which the PO did not provide the services in full if a participant's caregiver expressed unwillingness or the IDT determined caregivers were unsafe. By doing so, the request for detailed

information will be limited to situations in which there is a question that the PO did not act appropriately.

In addition, our understanding is that a PO would not need to complete Columns K-T if responses to the questions in Columns I and J are “No.” Please clarify.

**SpecialistRecommendations1P14.** For this IA we would like to confirm CMS’ expectations regarding services “recommended or ordered by the specialist, emergency room provider, or hospital provider” in Field J. More specifically, we want to confirm that recommendations made by ER or hospital providers are recommendations included in the discharge summary documentation for ER visits and hospitalizations. Participants experience many evaluations, procedures, and consultations throughout an ER visit or hospital stay. The progress notes documented by each ER or hospital provider may make several treatment recommendations that are later determined to be unnecessary or inappropriate throughout the course of the ER visit or hospitalization. The purpose of the discharge summary is to provide a compilation of the participant’s ER or hospital care and to summarize the recommended treatment post discharge. Relying on the treatment recommendations included in the ER or hospital discharge summary is the most accurate and efficient means of determining services that are recommended or ordered by ER and hospital providers. We request that it be clarified that recommendations made by ER or hospital providers are those included in the discharge summaries for ER visits and hospitalizations.

Several of the questions in this IA appear to be focused on the provision of services as opposed to requirements of POs to remain alert to information from specialists/contracted providers, e.g., questions in Columns N, O, P. We recommend these be deleted from SpecialistRecommendations1P14.

Also, instructions on use of NA appear inconsistent, e.g., in Field L, should NA also be an option consistent with instructions for Field K and others?

**CoordinationofCare1P95.** As proposed this IA focuses on coordination of care for participants who receive care in all contracted facilities, including both residential facilities such as nursing homes and assisted living facilities and acute settings such as hospitals and ambulatory surgical centers. We would appreciate further clarification of CMS’ expectations of POs in completing this IA, in particular for participants receiving care in acute settings. We support CMS’ intent to ensure that the PACE IDT retains its responsibility for management and oversight of a participant’s care regardless of setting, but the IDT/PACE PCP do not necessarily authorize specific services in these settings. Participants who receive care in hospitals, ambulatory surgical centers, etc. are under the care of attending physicians and staff in those settings. While coordination of care occurs, it is not to the level of detail that we believe is implied by this IA. We recommend modifying this IA to focus on whether the IDT ensured that care provided in the acute setting was consistent with the participant’s care

plan and the participant's wishes/goals for care. For participants residing in residential care settings where the IDT is responsible for coordinating day-to-day treatment and care, the IA is a better fit.

For the reasons provided above, NPA is extremely concerned that the burden of responding to document requests during this third phase of the audit will far exceed CMS' estimate of 160 hours and appreciates CMS' consideration of its overarching recommendations for sampling and implementation of appropriate thresholds for all IAs, as well as for specific changes to the IAs newly proposed for 2023.

- 4) **Implementation of corrective action and audit close out activities.** CMS estimates a total of 200 hours of staff time are required for this portion of the audit. We concur with this estimate. Further, we appreciate CMS' addition of Attachment VI: Corrective Action Plan (CAP) Process to the protocol documentation which is a helpful description of the CAP process and the role of the PO's account manager in overseeing implementation of the CAP.

#### **Additional Comments**

Finally, we have several additional comments that are not nearly as important as those in the preceding sections of our comment but may be helpful to CMS in finalizing the audit protocol:

- Referring to p. 4 of the proposed PACE Audit Protocol and the reference to the Pre-Audit Issue Summary, NPA notes that CMS eliminated the language from the 2020 PACE Audit Process and Data Request document (p. 4) explaining that CMS will not apply the ICAR condition classification in situations when disclosed issues were promptly identified and corrected and the risk to participants was mitigated. Because these are situations in which the issue has already been corrected and participant risk mitigated, we assume this will continue to be the case and would appreciate CMS' clarification of this.
- Analysis of Potential Non-Compliance (p. 20). We appreciate the additional clarification provided in this new section of the proposed PACE Audit Protocol.
- On p. 14 of the proposed PACE Audit Protocol, referring to "Documentation of recommendations for care or services by IDT team members, participants, caregivers, PO employees, contractors, specialists, and designated representatives," we are unclear as to why participants, caregivers and designated representatives are included in this list. Referring to §460.210(b), our understanding is documentation is required for recommendations for services made by "employees or contractors of the PACE organization, including specialists." We are assuming a participant/caregiver/designated representative would make a service determination request rather than a recommendation. If this is the case, CMS is requiring documentation of these communications in a subsequent bullet.

NPA and its members appreciate CMS' consideration of the full range of comments and recommendations offered above. We are hopeful that this input will lead to CMS' reconsideration of several key aspects of the proposed PACE 2023 Audit Protocol. If there is any need for additional information or dialogue, please reach out to me ([shawnb@npaonline.org](mailto:shawnb@npaonline.org)) or Chris van Reenen ([chrisvr@npaonline.org](mailto:chrisvr@npaonline.org)), NPA's vice president of regulatory affairs. We would very much appreciate the opportunity for continued engagement with CMS staff on this critical issue.

Sincerely,



Shawn M. Bloom  
President and CEO

# PUBLIC SUBMISSION

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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0051

Comment on CMS-2021-0193-0001

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## Submitter Information

**Email:** jchau@onlok.org

**Organization:** On Lok Senior Health Services

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## General Comment

On Lok Senior Health Services is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) request for comment on the 2023 PACE Audit Protocol published in the Federal Register on December 21, 2021. We share the same commitment to ensuring PACE participants access to high-quality care consistent with PACE regulatory requirements. With this being our primary focus, we appreciate the opportunity to provide feedback on the proposed audit protocol, related burden estimates, and supporting documentation.

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## Attachments

On Lok Comments\_2023 PACE Audit Protocols\_2022.02.22

# PUBLIC SUBMISSION

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The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0048

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Stephanie Buttong

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## General Comment

PACE CNY is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. We appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

PACE CNY has significant concerns related to the revised requirements on the monitoring and tracking of all services, across all care settings that were ordered, approved or care planned. One of the greatest strengths of the PACE model is the opportunity for continuous care planning to meet participant needs. As you know, PACE organizations serve frail elders with multiple comorbidities which contribute to ever-evolving needs. A PACE participant's plan of care may change multiple times in a week, or even a day, as the Interdisciplinary Team works to meet the participant's holistic needs. The volume of wrap-around services furnished under the PACE model, through the process of continuous care planning, is exceptional. While we understand and appreciate the need for oversight, we believe that instituting the proposed requirements to capture the necessary information for all services provided would pose an incredible burden on PACE staff, both administratively and operationally. Our concerns are comprehensively expressed in comments submitted by the National PACE Association (NPA). We respectfully request that CMS consider these comments and recommendations to the greatest extent when finalizing the aforementioned changes to the 2023 PACE Audit Protocol.

PACE CNY has additional concerns related to changes in the requirements for Personnel Audits, specifically the revisions capturing "Date of Initial Participant Contact" (Column E) and "Date Individual Began Providing Care Independently" (Column F) in place of "Direct Participant Contact" (Column H in 2020 Personnel Data Universe). Implementing this change will require manual review and, again, place a significant time burden on PACE staff. We again request that CMS review and consider the comments and recommendations expressed in NPA's statement which promote oversight while maintaining operational balance.

As a whole, PACE CNY strongly supports the comment and recommendations submitted by NPA on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and, again, respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.





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The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0015

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Mary John-Williams

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## General Comment

PACE North is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

PACE North strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

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The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

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The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0011

Comment on CMS-2021-0193-0001

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## Submitter Information

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## General Comment

PACE of the Southern Piedmont is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.



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**Pontiac Center**  
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February 22, 2022

Submitted via CMS portal

**Re: The PACE Organization (PO) Monitoring and Audit Process in Part 460 of 42 CFR; CMS-10630, OMB 0938-1327**

Attention CMS:

PACE Southeast Michigan appreciates the opportunity to submit comments in response to the 2023 proposed audit protocol.

PACE Southeast Michigan has been caring for senior participants in southeast Michigan for almost 30 years. We serve seniors in Wayne, Oakland, and Macomb Counties at our six centers located in Detroit, Southfield, Dearborn, Sterling Heights, Eastpointe, and Pontiac with plans to open a second center in Detroit in May of this year. The need for PACE in our community is vast. We currently have a census of almost 1,400 participants and have a net growth rate of, on-average, 26% each consecutive year since 2015 with the exception of 2020 and 2021 due to the COVID pandemic. This growth has ranked us as the largest, fastest-growing PACE program in Michigan and among the top five fastest-growing in the nation. We are a non-profit organization jointly sponsored by Henry Ford Health System and Presbyterian Villages of Michigan.

After reviewing the proposed audit protocols, PACE Southeast Michigan has some concerns regarding the level of burden that will be placed on PACE organizations. Specifically, in the following areas:

**CMS-10630, OMB 0938-1327:**

The data requested for wage estimates does not coincide with our experience in previous audits. Doubling the hourly wage for secretaries, administrative assistants, or health technologists is not a realistic expectation. The staff listed in the CMS wage estimate do not use the electronic medical record (EMR) and cannot audit charts for an impact analysis involving clinical documentation. The staff who perform impact analyses must be trained on regulation and understand what they are looking for in the chart. The impact analyses are a manual chart audit. We were given 780 hours to complete the impact analyses, which was not enough time, especially for multiple-impact analyses.

**Our experience with impact analyses (IA):**

PACE Southeast Michigan will not be able to electronically extract the data requested in the proposed audit protocols from our medical records. We will need to manually review six months of notes in every chart to be able to answer the questions in the assigned IA files.

Manual reviews of participants' medical records diverts too many clinical staff members from participant care and adds an excessive burden to PACE programs as evidenced from our past experience mentioned below. Further, our program cannot contract staff to perform our audit.

As mentioned above, most of the IA required a manual clinical chart review which must be performed by a clinician with knowledge of Excel. In past audits, each chart took two hours, on average, to review and answer the questions in the five assigned IA files where the 100% chart review is required to answer the questions.

For example, seven clinical staff were pulled from patient care to perform clinical IAs. We trained them on how to perform this task which took 4.5 hours of the 10 business days we were given to complete the task. The rest of the training day was spent walking through charts together as a team, so questions could be answered before continuing the review on their own. When we realized we weren't getting enough charts completed, we trained another group of four clinicians.

14 clinical staff (includes three quality staff) were unable to complete five impact analyses on 1,099 participants' medical charts. We were only able to complete 415 chart reviews at 2 hours per chart for a total of 830 hours for the impact analyses alone. (This 830-hour estimate does not include the manual population of all universes by the quality team (three staff) prior to audit and the responses to documentation requests during audit, nor the corrective action plan (CAP). The proposed audit protocols reduce the IAs required to 50% of census. Even at this reduction, larger PACE programs such as ours will be unable to complete the IA due to the amount of time these manual reviews take while detracting time spent on participant care, which is our priority. We recommend that larger PACE programs have a smaller census requirement for IAs.

The document summary states that CMS, while they will increase the hours allocated for administration of the audit from 160 to 320 total per PO, they also maintain that they "...will maintain the estimate of 40 hours per person or 160 hours total per PO for responding to documentation following audit fieldwork." These statements are misaligned if there is recognition that the original estimate of time was wrong, plus there are additional forms and data fields. Some of the key additions are as follows to show them in aggregate:

- Universe Preparation: 3 additional documents requested
- SDAG: Added new documentation requests and compliance standards
- Provision of Services: Added new documentation requests and compliance standards
- Quality of Assessment: Added new documentation requests and compliance standards

#### Appendix A:

Table 1: Net 7 additional fields

Table 2: Net 3 additional fields

Table 3: Net 1 additional field

Table 4: Net 2 additional fields

Table 5: Net 2 additional fields

Table 6: Net 2 additional fields

Finally, and perhaps most important, is the lack of acknowledgement that there is a scaled impact related to program size that is not acknowledged anywhere in this protocol. The burden of data collection/documentation requirements is very directly related to volume – in this case driven by program size (census). A program of 1,500 participants would, logically, have a 5-fold increase in their burden when compared to a program of 300.

This is not acknowledged or calculated in the estimate, placing undue hardship on any program of substantial size or complexity.

The cost estimate by CMS for 2023 proposed audit does not represent the cost and burden of the audit to POs. We do not have 17 extra staff to assign to audit work without compromising care to participants as a result of clinical staff being temporarily reassigned. Our commitment to participant care is in line with CMS' "Patients over Paperwork" initiative. Four staff is not enough unless you are identifying four staff per PACE center rather than program. Reducing the IA to 50% of census is not enough for large PACE organizations. A more reasonable IA expectation would be 30% of the census. We are confident with a  $\pm 5$  margin of error, the results in the IA will not change if we audit 30% of the charts instead of 50%.

With PACE programs growing across the country as seniors prefer care that allows them to age in place, expecting PACE programs to perform IAs on 50% of census will become more and more unrealistic. We therefore respectfully request you reduce the IA audit to a reasonable number of charts – 30% of census is a more reasonable number.

PACE Southeast Michigan will continue to "increase efficiencies and improve the beneficiary experience." Please help us fulfill that by keeping the audit burden sustainable for all PACE programs.

If you have any questions, please contact me at 313-229-6266 or [Tracey.Diroff@pacesemi.org](mailto:Tracey.Diroff@pacesemi.org).

Sincerely,

A handwritten signature in black ink that reads "Tracey Diroff". The signature is written in a cursive, flowing style.

Tracey Diroff

Director, Quality and Compliance

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The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0013

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Michael Walker

**Email:** mwalker@pace-ri.org

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## General Comment

PACE-RI is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

PACE-RI strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

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**Document:** CMS-2021-0193-DRAFT-0018

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Bobbie Costigan

**Email:** bobbie.costigan@trinity-health.org

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## General Comment

Saint Joseph PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Saint Joseph PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.





RE: **CMS-10630- OMB Control Number: 0938-1327**—The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460 via Regulations.gov

Senior LIFE appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment on the proposed revisions to the PACE Audit Protocol. Senior LIFE refers to 6 mutually exclusive health plans, including H3925 Pennsylvania PACE, Inc.; H2992 Senior LIFE Washington, Inc.; H0819 Senior LIFE York, Inc.; H2937 Senior LIFE Greensburg, Inc.; H5902 Senior LIFE Altoona, Inc.; and H5978 Senior LIFE Lehigh Valley, Inc. These plans operate 12 PACE centers serving 13 counties and over 2,200 frail and elderly participants in Pennsylvania. Our collective comment is based on a review of the proposed 2023 audit protocol materials released in connection with the 60-day notice published in the Federal Register on December 21, 2021.

Senior LIFE would like to express our commitment to providing the highest quality of care and services to the participants that we are fortunate to serve while remaining in compliance with the regulations set forth by CMS. Quality improvement efforts are continuous, and we appreciate the importance of CMS' ongoing monitoring activities as a part of this process. As a member of the National PACE Association, Senior LIFE largely echoes the comments submitted by the NPA and offers additional insights from the perspective of a PACE Organization.

### **General Comments**

Senior LIFE strongly agrees with the NPA comments related to the concerns about the use of an audit process developed for insurer-based plans to audit PACE programs as health care providers. The end result of this discrepancy is an extremely labor intensive process that requires both administrative and direct care staff to be pulled from program and participant care responsibilities to address large data requests requiring manual chart review. Senior LIFE continues to work on IT solutions to assist with these types of data requests, including investigation into new EMR options, but at this point much data continues to require manual tracking, manual extraction, and manual review which all require a great deal of time and labor. Senior LIFE echoes the NPA's request that CMS provide consideration to the auditing of provision of services and coordination of care in PACE to a much greater degree.

Senior LIFE also agrees with the NPA comments and recommendations related to the burden estimates for all aspects of audit implementation being severely underestimated. During previous audit experiences, the Senior LIFE programs have typically scored below or around the average national audit scores during the reporting year. With average audit scores, the time demands placed on both administrative and direct care staff far exceeds the time frame estimates outlined in the audit protocol.

## **Specific Comments**

### *1. Request for reports that detail monitoring and tracking of service provision*

Senior LIFE especially expresses significant concern with relation to CMS' newly proposed requirement for the submission of reports detailing the PO's monitoring and tracking of all services across all care settings that were ordered, approved, or care planned during the data collection period. Since we are required to coordinate the care and services needed to meet participant medical, physical, emotional, and social needs 24 hours/day, 7 days a week, every day of the year, this task is nearly impossible to be completed for all participants for a 6 month period within 20 business days in the requested format. Senior LIFE reiterates the NPA comments regarding this data request not providing the flexibility with how requirements to track, monitor, and document the provision of services are operationalized by POs as stated in the preamble to the final rule in January 2021. Senior LIFE uses a variety of systems to monitor, track, and ensure the provision of approved and ordered services, but this data request would require a great deal of manual data collection to submit in the request format.

Due to the all-inclusive nature of this data request, POs would be tasked with providing documentation that may not be meaningful to the PACE audit. The broad nature of this request also could lead to inconsistencies in the audit protocol from program to program, as POs may not interpret the request the same way. For example, the request includes reporting of the date a service was ordered, approved or care planned and also the date the service was provided. Many services are provided on a recurrent basis. One PO may interpret this request to be the first time the service was provided, but another PO may interpret this to be every time the approved service is provided in the 6 month audit review period. Some of this request is also duplicative, as the data in this request is also requested on other data universes, i.e. the date an approved service determination request is provided.

Senior LIFE strongly recommends that CMS consider streamlining this data request to clarify CMS expectations, ensure CMS receives information from POs in a consistent and meaningful manner, and that ensure POs do not waste time on data collection that is not meaningful to the PACE audit. One reasonable alternative as presented by the NPA is to require that POs provide documentation describing processes in place for monitoring, tracking, and documenting all ordered, approved and care planned services across all care settings. If issues are later identified with service provision through auditing of SDAG or provision of services elements, more focused requests could be made at that time in regards to the tracking and monitoring of those specific services.

### *2. Submission of self-evaluations and audits*

The NPA comments and requests for clarification on this section are consistent with Senior LIFE's comments on this section.

### *3. Universes*

#### *Service Determination Requests (SDR)*

Senior LIFE recommends the removal of columns M through O. Since there is no regulatory requirement to complete an assessment except for any denied or partially denied service, these columns add unnecessary burden in collection for data that is already captured.

The protocol recommends:

- M=Date of the first assessment completed in response to the service determination request
- N=Date of the last assessment completed in response to the service determination request
- O=How many assessments were completed in response to the service determination request?

The current protocol has a column for Date(s) assessment(s) performed. The current protocol would meet data reporting elements in less entries. If all assessment dates are entered, then date of first and last would be included, as well as the number of assessments completed.

#### *Grievance (GR)*

Senior LIFE recommends consolidation of the Grievance Universe with the quarterly grievance reporting requirements in HPMS. Since different data is requested by CMS at different collection points, this requires POs to track and report grievances separately. Consistent reporting requirements would decrease PO burden, improve transparency, and enhance quarterly account management and technical assistance activities outside of the PACE audit process.

#### *List of Personnel (LOP)*

Senior LIFE concurs with NPA recommendations related to the revisions to the LOP universe.

#### *List of Participant Medical Records (LOPMR)*

Senior LIFE shares all NPA concerns and recommendations related to the LOPMR universe, which appears to get larger and more intensive with every revision. While Senior LIFE continues to work on IT solutions to assist with the gathering of this comprehensive and specific data, a great deal of manual chart review is necessary to capture the necessary information. Completing 42 cells of data for 850 different participants to enable CMS to choose a sample of 30 medical records is an intensive time burden on administrative and clinical teams which will directly impact the time sensitive needs of our participants.

#### *Contracted Entities and Providers (CEP)*

Senior LIFE proposes that CMS eliminate this universe. POs are required to maintain a list of contractors. CMS could alter this request to have POs submit a copy of the contracted provider network to meet this data request. Additional requests could be made at any time during the audit if issues are identified through auditing of SDAG or provision of services elements.

#### *On-call (OC)*

Senior LIFE agrees with NPA comments regarding recommendations to remove the Call Category field, as this information is duplicative.

### *4. Observation Participant List*

Senior LIFE echoes the NPA's concerns with the Observation Participant List that would require unnecessary manual data collection. The suggestion of the provision of a list of participants at a particular PACE center scheduled to receive the services during the week of the observations would significantly decrease the burden associated with this request.

### *5. Documentation uploads*

Senior LIFE also agrees with the NPA's comments regarding documentation requests during the medical record reviews. In 2017, we were informed by the audit team that only documentation being used to support a potential condition of noncompliance would be requested to be uploaded into HPMS. During

this timeframe, auditors would ask PO staff if they were unable to locate or had a question about something specific in the EMR during a review, which eliminated the need for unnecessary documentation uploads. Since 2017, the engagement with the audit team has trended to be more in the form of documentation requests and daily debriefs where potential conditions of noncompliance were reported, rather than conversation or direct communication with the PO staff. The average number of audit uploads per audit reflects this experience, as it was about 127 uploads in 2017 and about 427 uploads in 2019 without a significant change in the audit scores (1.8 to 2.5). Of specific note is that audits administered by CMS contractors tended to have the highest data upload requests. In one particular audit, the auditor requested Senior LIFE to upload an entire chart, as the auditor ran out of time to complete the chart review prior to the last day of the on-site review, and this was prior to the sample size being increased to 30. Senior LIFE recommends adding clarification in the audit protocol to streamline reason for documentation upload requests.

#### *6. Root Cause Analyses and Impact Analyses*

Senior LIFE seconds the comments submitted by the NPA related to concerns, burdens, and recommendations related to RCAs and IAs.

#### *7. Notification of Audit Results*

Previous audit protocol outlined the audit process in full, which included calculation of audit score and informing PO of audit results. The 2023 Audit Protocol omits the process for notifying the PO of audit results. There appears to be a gap in the proposed protocol between the submission of Impact Analyses and the CAP process.

Previously, POs were issued a Draft Audit Report that contained the preliminary conditions of noncompliance, their classifications, and the overall audit score. POs then had 10 business days to respond to the Draft report prior to CMS reviewing, responding, and issuing the Final Audit Report. Senior LIFE recommends including the notification of audit results to the PO in the Audit Protocol document. It is unclear in the 2023 Audit Protocol whether POs will continue to receive a draft report and have the opportunity to respond to the findings to CMS prior to being issued the Final Report. Through this process, Senior LIFE has experienced reconsideration of findings based on PO input. Since opportunities for PO input during the audit protocol are minimal, it is concerning if the intent is to remove this from the audit process.

Additionally, Senior LIFE requests clarification on scoring of the audits. The audit scores provided a method of comparison to other PACE programs providing similar services to similar population under the same regulations. Previously, findings were classified as ICARs, CARs, or observations, which contributed to the audit score and had different requirements for corrective action. The revised CAP process outlines the process for identified issues of noncompliance, which appears to be inclusive of all issues identified.

As a result of the gap in the protocol between the IAs and the CAP process and changes from current process to revised process that is not addressed in the Supporting Statement or crosswalk, Senior LIFE recommends the addition of a section in the protocol to plug the gap related to notification and scoring of PACE audits.

Thank you for your consideration. If you have questions or need for follow-up, please do not hesitate to contact me at [mgarrity@pace-cs.com](mailto:mgarrity@pace-cs.com) or (814) 535-5433.

Sincerely,  
Michele Garrity, Quality Analyst  
PACE Consulting Solutions  
Senior LIFE

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:18 PM
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<b>Tracking No.</b> kzs-twv2-6gm1
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0019

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Stephanie Winslow

**Email:** swinslow@pacemichigan.com

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## General Comment

The PACE Association of Michigan is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

The PACE Association of Michigan strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/22/22 10:47 AM
<b>Received:</b> February 22, 2022
<b>Status:</b> Draft
<b>Tracking No.</b> kzy-80o2-qwxm
<b>Comments Due:</b> February 22, 2022
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0046

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Margaret Sullivan

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## General Comment

Trinity Health LIFE New Jersey is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Trinity Health LIFE New Jersey strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:19 PM
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<b>Tracking No.</b> kzs-ffir-f2yr
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0020

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Martha Sheely

**Email:** msheely@trinity-health.org

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## General Comment

Trinity Health PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Trinity Health PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.



# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:20 PM
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<b>Tracking No.</b> kzs-ftoi-7mwr
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0021

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Marybeth Hlavac

**Email:** Mhlavac@trinity-health.org

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## General Comment

Trinity Health PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Trinity Health PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:22 PM
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<b>Tracking No.</b> kzs-hkq8-kn55
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<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0022

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Colleen Alles

**Email:** colleen.alles@trinity-health.org

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## General Comment

Trinity Health PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Trinity Health PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:28 PM
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<b>Tracking No.</b> kzs-n2wj-8vfr
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0027

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Robert Murphy

**Email:** robert.murphy@trinity-health.org

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## General Comment

[NAME OF YOUR ORGANIZATION] is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:31 PM
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<b>Tracking No.</b> kzs-namn-pgcw
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<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0030

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Kelly Parks

**Email:** kelly.parks@trinity-health.org

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## General Comment

[NAME OF YOUR ORGANIZATION] is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:35 PM
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<b>Tracking No.</b> kzs-nkwz-umv6
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0033

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** David Schmotzer

**Email:** David.Schmotzer@trinity-health.org

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## General Comment

Trinity Health PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Trinity Health PACE Mid-Atlantic (Mercy LIFE PA, LIFE St. Mary and St. Francis LIFE, Delaware) strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/18/22 5:37 PM
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<b>Tracking No.</b> kzs-olnf-k3ig
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0035

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Joanne Graham

**Email:** joanne.graham@trinity-health.org

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## General Comment

[NAME OF YOUR ORGANIZATION] is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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<b>Tracking No.</b> kzs-u4dp-9xpm
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**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0040

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Lynn Purvis

**Email:** lynn.purvis@trinity-health.org

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## General Comment

[NAME OF YOUR ORGANIZATION] is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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<b>Tracking No.</b> kzs-xc73-yk4r
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0041

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** MLOP MLOP

**Email:** cindy.dekraft@trinity-health.org

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## General Comment

[NAME OF YOUR ORGANIZATION] is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.



# PUBLIC SUBMISSION

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<b>Tracking No.</b> kzq-332v-wza1
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0014

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Carrie Hays McElroy

**Email:** carrie.haysmcelroy@trinity-health.org

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## General Comment

Trinity Health PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

[NAME OF YOUR ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

<b>As of:</b> 2/15/22 12:20 PM
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<b>Status:</b> Draft
<b>Tracking No.</b> kzn-2ni2-z597
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0002

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Luke Reynolds

**Email:** lreynolds@umrc.com

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## General Comment

United Methodist Retirement Communities and Porter Hills, the sponsoring agency of 4 PACE organizations in Michigan, including LifeCircles PACE Huron Valley PACE, Thome PACE, and Senior Community Care of MI PACE, is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

United Methodist Retirement Communities and Porter Hills strongly support the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

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<b>Status:</b> Draft
<b>Tracking No.</b> kzy-q3qn-utx
<b>Comments Due:</b> February 22, 2022
<b>Submission Type:</b> API

**Docket:** CMS-2021-0193

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0050

Comment on CMS-2021-0193-0001

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## Submitter Information

**Name:** Nancy Roach

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## General Comment

Upham's Corner Health Committee, Inc. is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Upham's Corner Health Committee, Inc. ORGANIZATION] strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Upham's Corner Health Committee, Inc. d/b/a/ Upham's PACE, located at 500 Columbia Road, Dorchester MA 02125 fully supports the principles addressed by Shawn Bloom, President and CEO of the National PACE Association regarding the proposed CMS updates to the PACE audit protocol and data collection instruments. PACE is a unique model of care, authorized a provider organization rather than an insurance organization. As such, we take tremendous pride in the work that we do to keep our participants living in the community by providing quality care. We want to share what we perceive as potential consequences for our own organization if these audit protocols and data collection requirements are implemented completely. Upham's PACE feels the 2023 proposed audit requirements will greatly impact our ability to provide adequate resources for both direct and personal care as we will also be required to staff appropriately for the increasing number of audit and data requests coming our way. In previous years, we have drawn from existing staff to support CMS audits but as the audits become more data driven, we will need to expand our team to include compliance staff, project managers, clinical informatics' staff, etc. These positions, except for compliance do not exist in our current structure. Our organization has always applied our resources back to our participants by keeping our administrative structure lean.

We understand the reason and the need for CMS to develop different audit measures and protocols but would like to suggest that you work with NPA and several representative organizations to develop appropriate audit materials for a provider organization. Our organization would happily volunteer to work with CMS to help develop such protocol.

Thank you in advance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.

# PUBLIC SUBMISSION

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The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Comment On:** CMS-2021-0193-0001

The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630)

**Document:** CMS-2021-0193-DRAFT-0005

Comment on CMS-2021-0193-0001

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## Submitter Information

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## General Comment

Valir PACE is committed to ensuring that its PACE participants receive access to all the benefits to which they are entitled through enrollment in PACE and that their care meets the PACE program's high quality standards. Further, we appreciate the importance of CMS' ongoing monitoring of PACE organizations and recognition of practices that require correction. We are concerned, however, about the burden on PACE organizations and their staff of several aspects of the current and proposed PACE audit protocols and their data collection requirements.

Valir PACE strongly supports the comment and recommendations submitted by the National PACE Association (NPA) on CMS' proposed 2023 PACE audit protocol and data collection instruments (CMS-10630) and respectfully requests that CMS consider these recommendations to the greatest extent possible in finalizing the 2023 PACE Audit Protocol. We believe NPA's recommendations, if adopted, will reduce the burden of the audit process on our health care staff in ways that will not sacrifice auditors' access to necessary information for effective monitoring of PACE program operations and compliance.

Thank you for CMS' consideration of this and NPA's comment on proposed revisions to the 2023 PACE Audit Protocol.