



March 5, 2018

Submission via <https://www.regulations.gov>
Demetrios Kouzoukas
Principal Deputy Administrator and Director
Center for Medicare
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd
Baltimore, MD 21244

Re: Docket # CMS-2017-0163: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter - Comments

Dear Principal Deputy Administrator:

Thank you for the opportunity to comment on the 2019 draft call letter. We appreciate CMS consideration of industry feedback with respect to these very important items. We specifically provide feedback on Validation Audit Proposals as described below:

BluePeak supports the following proposals without qualification.

1. *Creation of “a validation work plan template that sponsoring organizations undergoing independent validation audits in 2019 would be required to submit.”*

We believe that the provision of a template will provide clarity to validation auditors, ensuring that CMS expectations are met in certifying all corrective action. We also believe this will encourage industry consistency and better outcomes across sponsoring organizations and validation auditors alike.

2. *“The sponsoring organization [must] to submit its independent auditing firm’s validation report to CMS but would also be required to copy the independent auditor on the submission. The report should be submitted to CMS as received from the independent auditing firm (i.e., without modification by the sponsoring organization).”*

We appreciate this point of clarity as it ensures that BluePeak’s work product remains intact when presented to CMS, notwithstanding any concerns or rebuttals which may also be presented (separately) by the sponsoring organization.

3. *“Sponsoring organizations would have 180 days from the date that CMS accepts their program audit CAPs to undergo a validation audit and submit the independent audit report to CMS for review.”*

We agree that this extra 30 days is helpful for plans to accumulate a sufficient clean period for validation testing and we support this extension.

4. *CMS intends [in an upcoming Federal Register proposed information collection] to require a listing of validation auditor staff used to complete the validation audit. CMS will “clarify which sections of the audit require registered clinicians (physician, RN, pharmacist). A minimum of two auditors per program area would be required in order to satisfy the requirement that a complete and full independent review be performed.”*

We support this clarity as it helps to create consistency and a level playing field for validation auditor bidding. We encourage CMS to consider the use of RNs in addition to physicians for validating ODAG/CDAG conditions. We believe these professionals have sufficient clinical knowledge to evaluate appropriate decision making. Including RNs as potential validating clinicians will also afford sponsoring organizations cost savings in the validation audit process.

BluePeak submits the following additional comments for consideration.

We believe that an effective compliance program is fundamental to the success of any health plan. A well-organized compliance program will monitor operations for proper functioning; mandate reporting of potential noncompliance and fraud, waste, and abuse; and promptly respond to and remediate any issues. The CMS compliance program effectiveness (CPE) program audits are designed to ensure that a sponsor’s compliance program functions to prevent, detect, and correct potential instances of Medicare noncompliance and fraud, waste, and abuse.

***Item 1** - CMS is seeking comments on “whether this threshold [for hiring an independent auditing firm] should be increased or decreased, or limited to conditions that may cause adverse impacts to beneficiaries. [The] proposal . . . aims to exclude a category of conditions from consideration in the threshold because they do not directly and adversely impact beneficiaries . . . CMS intends to exclude Compliance Program Effectiveness (CPE) conditions from the threshold calculation.*

Comment 1 - As compliance effectiveness is so crucial to a sponsor’s success, we do not support the proposal to exclude the count of CPE conditions from the proposed threshold determination with respect to hiring an independent validation firm. Neglecting to take these findings into consideration when planning for and engaging said auditor would suggest that compliance program effectiveness is inconsequential to the proper functioning of all other operational areas. In fact, experience with program audits and validation would suggest that most CPE conditions are integrally tied to the detected operational failures. Said failures do have a direct adverse impact on beneficiaries and will not be fully remediated without fixing the related compliance findings as well. We recommend that all findings, including those related to CPE, are including in the proposed threshold counts.

We also caution that excluding CPE conditions will decrease the number of validation audits performed leaving a risk for audit findings to remain un-remediated, or the resolution to remain un-validated. We recommend that CMS does not proceed with the recommended threshold exclusions.

Item 2 - “During the validation listening session, sponsoring organizations requested flexibility regarding the threshold for requiring an independent audit, asserting that there were challenges with hiring an independent auditing firm when only a limited number of conditions required validation.”

Comment 2 - BluePeak does not agree with this comment and we believe we stated this on the call. While the larger audit firms, such as the “Big 3” refuse to provide bids for small validation audits due to their significant overhead, there are several firms that do bid for the smaller validations audits due to their lower overhead and fixed cost. This should not be a roadblock for plans to meet the CMS requirement to hire an outside auditor to perform a validation audit of any size. BluePeak believes it is reasonable for CMS to require sponsoring organizations with more than five program audit conditions (from any subject matter area) in their final audit report to hire an independent auditing firm to conduct a validation audit.

Item 3 - *CMS is seeking comment on allowing sponsoring organizations that have undergone a program audit to treat the program audit as meeting the annual compliance program audit requirement in 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F) for one year from the date of the CMS program audit.*

Comment 3a - Given the time that it takes for CMS audit reports to be generated and finalized, and the proposed extended period for the validation findings to be completed (180 days rather than 150 days), we caution that the time-period between the CMS audit and the next independent evaluation could be over one year and result in inconsistent lapses between audits across all sponsors. This does not equip the sponsor to maintain an accurate pulse of their compliance program effectiveness.

We seek clarity on what is meant by “one year from the date of the CMS program audit.” Specifically, does this mean the date of the audit start notice, the date of the draft or final report, or the date that validation activities are concluded? Depending on how this is defined, there may be inconsistency in annual reviews among all sponsors. We would recommend that if CMS finalizes this proposal it reflects the following: i) the program audit must have included a full CPE review, and ii) the one year “clock” begins from the date of the final report (still pending independent validation activities). Even with these points of clarity, CMS should note that a sponsor may defer a previously planned annual CPE review upon receipt of an audit notice from CMS. This may also create a longer lapse between review cycles. We recommend that CMS provide clarification on the implications of an audit start notice with respect to previously scheduled audit activity.



Comment 3b - We recommend that when a sponsoring organization receives a finding that it has failed to perform annual reviews of its compliance program effectiveness, that CMS permit the remedy for this finding to be an anticipatory audit work plan reflecting an annual CPE review scheduled for one year after the CMS program audit. We find that it places undue burden on a sponsor to conduct its own internal CPE review directly after a CMS program audit.

Thank you for your consideration of the above comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Babette Edgar", is written over a light blue rectangular background.

Babette Edgar
Principal, BluePeak Advisors