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Centers for Medicare & Medicaid Services

Office of Strategic Operations and Regulatory Affair

Division of Regulations Development

Attention: Document Identifier/OMB Control Number ll

Room C4–26–05

7500 Security Boulevard

Baltimore, Maryland 21244–1850.

Re: CMS-10599

To whom it may concern,

The following are the comments of the National Association for Home Care & Hospice (NAHC) regarding the Proposed Collection, CMS-10599, as published in the Federal Register, 83 Fed. Reg. 25012 (May 31, 2018). NAHC is the leading national trade association representing the interests of home health agencies (HHA) across the nation. NAHC members include thousands of HHAs of all types—nonprofit, proprietary, health-system-based and freestanding. The proposed collection published by the Centers for Medicaid and Medicare Services (CMS) greatly impacts NAHC members.

CMS has proposed a program integrity effort entitled "Review Choice Demonstration for Home Health Services" (RCD). Under RCD, home health agencies in five targeted states (IL; OH: NC; TX: and FL) will have all claims subject to a complex medical review either on a pre-claim or post-payment basis. Alternatively, the home health agency can elect to take a 25% reduction in the amount paid for services while still being subject to claims review by the Recovery Audit Contractor (RAC). RCD follows the Pre-

Claim Review Demonstration (PCRD) that was administered in Illinois from August 2016 until its suspension in March 2017.

RCD will cost CMS $400 million over 5 years to administer. In addition, the PCRD experience indicates that HHAs will incur significant costs as well to submit and manage the exponentially increased paperwork that PCRD/RCD requires. While HHAs strongly support sensible program integrity measures, better alternatives to RCD readily exist. Further, CMS appears tp have taken few if any steps to study the operation, focus, and outcome of PCRD before launching the instant proposal. PCRD was a demonstration program that provides the opportunity for gaining insights that would be extremely helpful in crafting program integrity measures such as the one proposed here and for doing so in ways that bring efficiency and success. Accordingly, NAHC recommends that CMS undertake a full review of PCRD before proceeding with RCD.

CMS should suspend RCD until its need and value are fully evaluated, using PCRD as the basis for the evaluation, and viable alternatives are utilized first.

The purpose of any Medicare demonstration program is to learn what works and what does nor work. For many years, Medicare has relied on demonstration programs to determine the best course of action that should be applied on a program-wide basis. PCRD was a valuable learning experience for CMS. However, CMS has not taken advantage of that learning opportunity in crafting the proposed RCD. Essentially, RCD simply repeats PCRD and adds some other claim review options for HHAs without consideration of what happened in PCRD. The proposed options—100% post-payment review or a 25% payment rate reduction plus claim reviews by a RAC—are in no way related to anything that could be learned from PCRD. What has been learned from PCRD indicates that further analysis could provide exceptionally important information that might avoid a $400 million expenditure by CMS along with the costly administrative burden by the HHAs in the five targeted states. We know the following from PCRD:

1. CMS did not identify any fraud through PCRD, the virtual twin predecessor to RCD. However, the CMS proposal continues to advance that the program will be used to "develop or demonstrate improved methods for the investigation and detection of fraud" under the authority of Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 USC 1395b-1(a)(1)(J)). Given that result, there are important questions as to whether CMS has the authority for the proposed program.
2. PCRD showed that there are common characteristics of HHAs at risk of improper claims that would permit efficient targeting of claims reviews. Over the term of PCRD and the months that followed PCRD, it is clear that claims review does not affect all HHAs uniformly. Instead, the data shows that HHAs are broken up into three classes: HHAs with significant claim volume reduction; HHAs with an increase in claims volume; and HHAs with claim volume equivalent to pre-PCRD periods. The HHAs with claim volume decline are generally newer and smaller HHAs.

Further study can be useful to determine if predictive modeling is possible, allowing for an efficient targeting of RCD at the outset.

3. Thousands of Medicare beneficiaries in Illinois lost home health care during PCRD and CMS has not evaluated what harm that may have caused them or what increase in Medicare expenditures occurred in other Medicare service sectors. These patients presumably do not just simply disappear. However, if these individuals truly did not need home health services or any other health care services as alternatives to home care, CMS can determine if there are any common characteristics for purposes of looking any one of a wide range of program integrity options rather than proceed with the most expensive one available, PCRD/RCD. For example, if the reduced patient population comes primarily from certain Home Health Resource Groupings (HHRG), CMS could easily target those patient categories with a highly efficient effect comparable to the shotgun approach used in PCRD and planned in RCD—100% of claims.

NAHC conducted an initial review of data from the 2016 and 2017 Medicare beneficiary claim file to determine if common characteristics exist for the HHAs involved in PCRD that experienced significant claim reductions during and after PCRD. The following represents the findings from that review:

- 57 IL agencies voluntarily closed or exited the Medicare home health business during the life of PCRD or shortly thereafter. This represents a 9% decline in the state's home health providers.

- The impact on beneficiaries is not fully known. However, monthly claim volume dropped from an average of 25,223 during March through July 2016 to 19,706 during PCRD (8/16-3/17) and 20,948 over the last 6 months of 2017. Based on a national average of 1.7 claims per beneficiary, the claims volume translates to a reduction of 18,800 beneficiaries receiving home health services as a result of PCRD. CMS has not evaluated, at least publicly, what impact PCRD may have had on beneficiaries.

- The volume of paid Medicare episodes declined by 17% between January 2016 and December 2017. Much of the overall volume loss attributable to PCRD was never recovered.

- The reimbursement and cash flow loss to IL home health agencies appears to be in the range of $114 Million to $122 Million over the course of PCRD.

- HHAs located in the six Chicago-area counties constitute 85% of the State's total provider count. These HHAs accounted for $57 Million of the statewide $57.8 post-PCRD volume decline.

- Small HHAs represented the bulk of the decline. Approximately 60% of small or very small providers experienced declines in volume of 25% or more during the last six months of 2017. For a third of those providers, volume dropped in excess of 50%.

The enlightenment that can be gained though a deep evaluation of PCRD cannot be understated. Certainly, it makes eminent sense to do so prior to committing $400 million to administer its virtual twin in RCD. The lessons learned from PCRD can be used to determine if less costly, less burdensome alternatives would be better choices for home health programs integrity action. These alternative have been presented to CMS in the past.

PCRD confirmed what had been found in home health audits, CERT reviews, and OIG studies that the vast majority of "improper payments" are due to correctable documentation deficiencies rather than unnecessary care or fraudulent claims. Most of the documentation deficiencies relate to the face-to-face physician encounter/physician certification documentation regulatory requirements that remain difficult to manage for physicians, home health agencies, and Medicare contractors. There are better, more efficient and effective alternatives than PCRD for addressing the root cause of documentation deficiencies nationwide.

The Pre-Claim Review Demonstration project (PCRD) was in operation in Illinois from August 3, 2016 through March 31, 2017. Over that time, the acceptance rate of submissions rose from 40% to over 90%. In fact, the affirmation rate effectively translates to a nearly 100% acceptance as resubmissions that result in affirmations are counted as separate submissions.

The PCRD project established that the central issue is not fraud or claims for non-covered care. Instead, the near perfect affirmation rate is due to improved documentation practices within home health agencies and improved reviews by Medicare contractors. As such, PCRD has established documentation errors and deficiencies as the root cause of an increased claims error rate. CMS officials had expected that to be the finding. The next generation PCRD should be built on these lessons learned not simply restarting PCRD with the minor tweaks and labeling changes that is RCD.

We strongly believe that PCRD has served its purpose that it does not need be reinstated in the form of RCD. The PCRD project was highly costly to CMS, heavily burdensome to HHAs, and confusing to patients and physicians. Multiple alternatives exist that can more efficiently correct the well-identified and common documentation errors. Further, these alternatives can be employed nationally rather than on the limited basis used in PCRD. That change would lead to corrective action across HHAs, bringing the CERT improper payment rate down nationwide.

The common documentation errors and deficiencies are a result of a combination of causes. Illinois PCRD established that HHAs are a partial source of the errors. In addition, PCRD also confirmed that the documentation standards for compliance with the physician face-to-face encounter and physician certification requirements are unmanageable for all parties involved. Limiting reviews to documentation solely in the physician's record predictably results in partial information and erroneous conclusions on a patient's coverage eligibility. The CERT error rate dramatically increased concurrent with reviews of face-to-face (F2F)/certification documentation. When CMS examined the full record as part of PCRD, the affirmation rate rose significantly. However, CMS requires physicians to acknowledge, sign, and date virtually every page of records transmitted from an HHA to them in order to include consideration of these records in a review. CMS has now proposed to combine consideration of the physician and HHA record in the recently issued Notice of Proposed Rulemaking in the 2019 rate NPRM.

Beyond the physician record issues, the common HHA documentation errors include simple correctable elements such as:

1. Plans of Care that are unsigned or undated
2. Physician Certification statements that are not properly signed and dated
3. Physician change orders not timely signed and dated
4. Absence of a physician's statement on expected length of care in recertification
5. Absence of measurable goals in therapy records
6. Appropriate OASIS submissions consistent with the claim
7. Missing documents (these may have been submitted, but missed by the MAC)

The development of corrective measures can be greatly aided by the knowledge gleaned from detailed data regarding the reasons that PCRD-IL submissions were rejected in the early months of the project. We request that CMS provide that detailed data as part of the collaborative effort to achieve claim compliance. With such data, precisely focused and targeted actions in terms of policy guidance, education, process improvement, and auditing are more feasible.

The CERT "improper payment rate" represents a nationwide finding. It is heartening that the rate has dropped from 59% to 32%, but the home health community is committed to reducing it significantly further. To do so, corrective actions must be nationwide, effective in the short-term, and operate with great efficiency. Most importantly, these corrective actions must prevent errors rather than simply respond to them with post-error corrections. As such, we suggest that CMS first consider the use of measures to prevent errors as the better approach to a effective and efficient, nationwide corrective action plan. Only after these measures are applied should CMS consider reactive steps that utilize costly and burdensome claims oversight such as occurred with PCRD-IL. It may be that PCRD-IL is viewed by some as effective, but it came with a significant price for all and did not serve to achieve the needed nationwide corrective action. Nevertheless, CMS should move forward relying on what can be learned from PCRD, not simply redoing PCRD.

Based on the learnings of PCRD, the following alternatives would provide preventive, effective and significantly more efficient corrective action. The following outline of corrective action alternatives can be expanded with greater detail if CMS is interested in any of the concepts.

PREVENTATIVE ACTION STEPS

1. The single, most important reform would be to revise regulatory standards on physician certification and face-to-face encounter documentation to integrate the physician record with the HHA and other provider records into a single review for a complete, rather than partial record review to establish eligibility. The PCRD demonstrated that physician certification and F2F compliance determinations should be based upon a full record review if an accurate eligibility decision is to be reached. Currently, CMS medical reviews require that the physician's record must be sufficient, on its own, to establish eligibility. Physicians can effectively document the clinical status and needs of a patient, but a full record is needed to determine whether the practical limitations triggered by the patient's condition render the patient homebound under

Medicare coverage standards. This would be done with existing documentation and would not require any new paperwork from physicians or HHAs thereby limiting burdens. The CMS proposal for combined review of the certifying physician record and the HHA record falls somewhat short of a simple combination review as it requires HHAs to incorporate the HHA record into the physician record. Such is unnecessary if CMS instead checks the HHA record for consistency with the physician record.

2. Development of model documentation forms. The CMS 485 form can be easily modified to accommodate all of the needed elements. This modification should, at a minimum, include the needed elements to demonstrate compliance with the F2F and physician certification requirements. The electronic templates for documentation are nothing more than the equivalent of blank forms in an electronic format.

3. Implementation of a documentation certification by the HHA that would employ a checklist of the required documentation needed to support a claim. For example, this approach would require that an HHA specifically confirm/certify that it has checked compliance with the various documentation requirements such as physician signed and dated certifications. The confirmation could be an internal process or can be considered as a formal element to the claim submission.

4. Clarified guidance on existing documentation requirements for such as when, where, and how a physician must sign required documentation. The home health community can work collaboratively with CMS to construct the guidance. Areas of need under current rules include: physician F2F documentation; eligibility documentation; patient goals; and homebound status.

5. Targeted education directed to both HHAs and physicians using the tools referenced in 1-4 above. Physician education has been extremely limited. HHA education has fallen short of effectiveness. An educational partnership with the no more than simple blank forms in an electronic format. home health care community and physician groups would be more effective.

6. Detailed and specific explanations provided with adverse claim determinations. Current determinations use boilerplate explanations that are merely conclusory, e.g. the physician's record is insufficient to establish eligibility.

7. MAC education and oversight by CMS specific to documentation standards. The PCRD-IL established that MAC errors exist and are correctible with proper attention.

CLAIM REVIEW ALTERNATIVES

100% proclaim review of post-payment review can help bring about corrections of HHA errors, but it will work best in a modified, scaled-back form. However, claims review should be employed only after the remedies referenced above have been utilized and demonstrated as not fully effective. The options in that regard are:

1. An optional preclaim review—- CMS has already indicated that an optional PCR is a better way to go. NAHC agrees. However, 100% post-payment review in not a first line alternative option. A 25% rate reduction option is not a valid option. In fact, NAHC believes that any HHA that accepts a 25% rate reduction should be immediately investigated.
2. Automated review of claims on a prepayment basis using edits related to the billing form and OASIS. The billing form can be modified to incorporate essential eligibility data fields, which in conjunction with an interoperable OASIS review, can demonstrate eligibility.
3. Random, ongoing application of preclaim review where a small percentage of RAP submissions trigger the potential for a preclaim review. With this approach, an HHA prepares every patient record with the potential of its selection for review. However, the reviews occur randomly so as to reduce the overall volume.
4. Targeted reviews based on performance, statistical aberrancies, or nature of the claim, e.g., outliers. Performance-based exemptions should occur through a defined process that sets out the testing period and the performance standard required to qualify for the exemption. The CMS proposal for performance-based exemptions is discussed below. NAHC is grateful for the CMS consideration of this recommendation.
5. Reduced percentage of claims subject to PCR. This approach would bring about efficiencies for all stakeholders while likely achieving comparable effectives with HHAs and MACs learning from the claims subject to review and applying the learning to all claims.
6. Use of a process similar to an Independent Review Organization where the HHA selects a compliance organization that does a claims audit and certifies, consistent with CMS-approved standards, that the HHA reached an acceptable level of claim accuracy. Such providers would be exempt from any MAC process, prepayment review, or post-payment review outside of allegations of fraud for a period of time. Periodic follow-up audits would be preformed to determine whether the exemption continues. CMS/OIG uses this type of process for corporate integrity agreements. Further, CMS utilizes private accrediting entities with "deemed status" for purposes of determining compliance with the Conditions of Participation. This process would be the claim compliance equivalent to "deemed status." The process would be integrated with an OIG-consistent corporate compliance plan. However, this process should be viewed, at most, as an optional process for HHAs as it is very costly. It would be expected that only a few entities would utilize such.

The home health community can be an effective partner with CMS in developing and implementing corrective actions. A high improper payment rate as a result of documentation errors or otherwise is detrimental to all Medicare stakeholders. NAHC is ready, willing and able to be such a partner with CMS as we believe the above demonstrates that we can provide constructive contributions to the development of solutions. The alternatives to RCD set out above warrant CMS's serious consideration as they can be both effective and efficient.

In the event that CMS does choose to suspend its plans for RCD, NAHC offers the following recommendations.

<u>Implementation Timing</u>

CMS should publish a timetable for implementation of RCD that includes the following:

1. A phased-in approach. CMS should pause expansion until a period of time following each state's RCD experience of 3 to 6 months to permit modification based on what is learned in each state.
2. The phase-in should involve at least 3 months between each state.
3. No state should be provided less than a 3 month prior notice.

Streamlined Documentation

CMS should consider a streamlined documentation requirement. For example, CMS could make determinations based on the Plan of Care and the OASIS documentation. In the event that the reviewers conclude more is needed to make a decision in an individual review, the added documentation can be requested by the MAC.

With respect to the post-payment review option, CMS should develop a documentation checklist that focuses the needed to documents rather than seeking everything the HHA has in its patient records. A documentation list of standard key documents can set these out for HHAs in advance of the decision to choose the post-pay option over the preclaim option.

Exemption Standards

The proposal includes a reference to an exemption based on performance of the HHA. However, the detail is very much lacking. RCD should not move forward until there is a full public display of the exemption standards. These standards should include:

1. The minimum number or percentage of claims processed before an HHA becomes eligible for an exemption
2. The minimum time that must occur before an exemption can be established
3. The duration of an exemption
4. The standards for spot checking of claims (not just the 5% sample referenced)
5. Notice and opportunity to comment on proposed standards
6. Permitting Illinois HHAs to be credited with performances in the PCRD demonstration project

Coverage Policy

As previously referenced, CMS should revise its policy that requires that the physician record on its own support Medicare coverage eligibility. It is very evident that physician records are generally insufficient to support homebound status and skilled care need. That occurs because physicians want to be clinicians not paperwork caretakers. Further, CMS and its MACs have done little to educate physicians on Medicare home health documentation requirements. Simply relying on hard to find, internet-based documentation guidance will not succeed.

Instead, CMS should learn from the PCRD experience and automatically evaluate the physician and HHA records in combination. The dramatic increase in review affirmations is a telling sign that the limited record review is the root cause of much of the improper payment rate.

Beneficiary Information Regarding the RCD Process

Illinois HHAs reported numerous concerns with the information provided to Medicare beneficiaries during PCRD. NAHC recommends that CMS engage representatives from the beneficiary community to develop a beneficiary notice that clearly explains rights under RCD. NAHC is available to work with CMS on this element.

Improve the Reliability of the Record Submission Process

PCRD was plagued with ongoing problems with electronic documentation submissions. CMS must fully test MAC capabilities in this regard before proceeding. Further, CMS must require the MAC to maintain an inventory record of all HHA submissions as too frequently in PCRD the MAC alleged that records had not been sent on particular claims while the HHA assured that such had been sent.

MAC Reviewer Capability and Competence

Early claims reviews during PCRD demonstrated that the MAC was insufficiently prepared to handle the workload or to bring necessary competence to claims reviews. At one point, CMS deemed it necessary to audit the MAC performance and to correct review errors. CMS should take all necessary steps to ensure that the MAC is ready for RCD. Quality not volume should be the performance measure.

HHA Training

The PCRD experience demonstrated that HHA training by MACs fell short of adequacy. MACs should rely upon CMS direction to devise and present detailed HHA training prior top the start of RCD reviews. CMS should audit the MAC presentation off HHA training to determine whether quality standards are achieved. The HHA training should precede RCD reviews by at least one month.

Protection Against Further Claim Review

The main benefit of 100% review for HHAs should be the assurance that approved claims will not ever be subject to any later review by a Medicare integrity contractor, CMS, OIG, or others with the exception of fraud investigations that are focused on fraudulent documentation. CMS should issue a formal regulation to that effect for RCD reviews. An FAQ alone does not create binding policy.

Reimbursement for Increased HHA Costs

RCD is an extraordinary action for HHAs. CMS will be providing additional reimbursement to the MAC to cover its extraordinary costs. CMS will cover its own added costs as well. However, there is no indication that any HHA will be entitled to increased reimbursement, directly or indirectly, for the added costs that the HHAs will experience.

The cost of RCD is not within the current episode or per visit rates applied to home health services. Further, the annual inflation update, Market Basket Index, will not account for the added costs. Unless CMS provides an add-on in reimbursement with each claim or provides a mechanism for direct cost

reimbursement, HHAs in the targeted states will be relegated to a national payment rate that is not adjusted for the unique and costly experience of participating in the RCD demonstration program.

CMS may be correct that RCD HHAs will only be providing the same record that all HHAs must compile. However, the costs of concern go far beyond customary record processing. Typical claims reviews for. HHAs is a small percentage of their annual claim volume with many HHAs subject to little or no claims reviews for years. It is the expanded claim review process, not the original record composition that brings the new costs of concern.

The additional actions required of HHAs in PCRD/RCD include:

1. Record assembly for transmission to the MAC
2. Record review by health professionals prior to transmission
3. Development of a record summary to highlight eligibility (a very necessary action to protect the HHA from a wrongful rejection)
4. Actual transmission of record to the MAC
5. Tracking of the status of claim reviews
6. Responding to MAC inquiries on submitted claims
7. Resubmission upon erroneous rejection

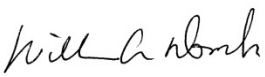
During the PCRD project, NAHC gathered cost increase information. Overall, HHAs estimated that the added cost of PCRD was 1 hour of skilled health professional time and 1 hour of administrative time per claim review to accomplish items 1-7 above. These metrics stayed fairly steady throughout PCRD with the exception of the volume of resubmissions when a claim was initially rejected. Such costs add up to $75-100 per claim.

It should be noted that HHAs will be doubling the volume of claims beginning in 2020 when proposed payment reforms take effect. CMS must also account for this added cost for RCD participants.

HHAs should not suffer unnecessary costs for a CMS demonstration program CMS should use its demonstration project authority to account for and reimburse HHAs for added costs the same way it provides added payment tp MACs handling their part of the project. To do otherwise raises serious questions about the validity of the project.

Thank you for the opportunity to submit these comments. NAHC is available at your convenience to discuss any aspect of these comments or the RCD proposal.

Very truly yours,



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