

No. 18-699

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IN THE  
**Supreme Court of the United States**

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BROOKDALE SENIOR LIVING COMMUNITIES, INC., *et al.*,  
*Petitioners,*

v.

UNITED STATES OF AMERICA, *ex rel.*,  
MARJORIE PRATHER,  
*Respondent.*

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**On Petition for Writ of Certiorari to the  
United States Court of Appeals  
for the Sixth Circuit**

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**BRIEF FOR AMICUS CURIAE  
NATIONAL ASSOCIATION FOR HOME CARE &  
HOSPICE INC. IN SUPPORT OF PETITIONER**

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**STATEMENT OF INTEREST OF  
*AMICUS CURIAE*<sup>1</sup>**

The National Association for Home Care & Hospice, Inc. submits this brief for the Court's consideration. The National Association for Home Care & Hospice, Inc. (NAHC) is a not for profit trade association representing the interests of nearly 6,000 home and community based health care providers throughout the nation. NAHC submits this amicus curiae brief in support of the Petitioners.

NAHC members across the United States and the millions of individuals who receive their services face a risk of severe adverse impact if the Court of Appeals decision stands. The decision has the potential to impact over 6.6 million claims submitted for Medicare payment of home health services provided to over 3.4 million Medicare beneficiaries annually by over 12,000 Medicare participating home health agencies. NAHC has directly participated in legislative and regulatory matters involved in the physician certification requirements under the Medicare home health benefit that are at issue in this matter.

**SUMMARY OF THE ARGUMENT**

The Court of Appeals standard of pleading materiality with respect to the Medicare physician certification requirements poses a serious risk to each home health agency as it encourages baseless litigation that

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<sup>1</sup> All parties have consented to the filing of this brief. A blanket consent by the parties has been filed with the Clerk of the Court. *Amicus curiae* certifies that no counsel for a party has authored any part of this brief. No counsel for a party has made a monetary contribution intended to fund the preparation or submission of this brief. Further, no person or entity has made such a monetary contribution other than amicus curiae itself.

triggers unsustainable costs for the vast majority of home health agencies. This litigation and the Court of Appeals ruling are at odds with longstanding Medicare policy practice and application of the physician certification rules. The Medicare administration has had longstanding and continuing knowledge that Medicare claims have been and are continuing to be paid under a standard that requires a signed and dated physician certification prior to final billing in order to comply with 42 C.F.R. § 424.22(c). It has adjudicated claims with that standard since the inception of the Medicare home health benefit in 1967. In fact, Medicare continues to apply that same standard even after the Sixth Circuit's earlier ruling that created a standard that there must be a "valid excuse" for any delay in securing a physician certification "as soon thereafter as possible" beyond the start of care date, continuing to apply a clear "prior to final billing" standard in all claims reviews.

As the relator is a self-proclaimed expert in Medicare standards, it is inconceivable that she is unaware of the actual Medicare practice. She merely offers her conclusory allegation that securing a physician certification "as soon thereafter as possible" means something other than "prior to billing." She alleges only that such vague and generalized standard is material to Medicare's payment of a claim. Such allegation ignores over five decades of consistent practice by Medicare. Given that background, the Court of Appeals allowed the relator to provide nothing more than a bald, unsupported allegation that the Petitioners' submission of claims with physician certifications that were established prior to Medicare billing are noncompliant and material to Medicare's payment of the claims.

The regulation at issue herein, 42 C.F.R. § 424.22(c), requires a very individualized, fact-based assessment



to determine whether there is compliance outside the bright-line “prior to billing” test that has been applied for decades by the Medicare program. Respondent’s reliance on a different interpretation of the “as soon thereafter as possible” standard for compliance requires a deep, fact-based dive into each individual certification to assess, in an individualized proper context, whether the Petitioner was compliant or not. Instead, the Court of Appeals standard of pleading materiality allows for a generalized, universe incorporating allegation that falls far short of a sufficiently pled, specific allegation that specific claims of the Petitioners would be denied payment by Medicare.

Materiality in this matter requires a party to plead that the Petitioner was overpaid by Medicare based on specific facts for each individual physician certification within the universe of claims submitted due to untimely certifications under:

1. the appellate court’s “as soon thereafter as possible” standard;
2. the court’s newly created “valid excuse” for any delayed certification standard; and
3. After application of the “without fault” provision in 42 U.S.C. § 1395gg that permits waiver of recovery of any overpayment.

NAHC urges this Court to grant Petitioners’ Petition for Writ of Certiorari so that this Court may fully review the decision of the Court of Appeals and apply an appropriate standard for pleading materiality in this action.

**ARGUMENT****RESPONDENT HAS NOT PROPERLY PLED THAT PETITIONERS' ALLEGED NON-COMPLIANCE IS MATERIAL TO MEDICARE PAYMENT OF HOME HEALTH SERVICES**

The Medicare home health benefit is unique. It is the only service that is covered by both Medicare Part A and Part B. 42 U.S.C. §§ 1395d(a)(3);1395k(a)(2)(A). In addition, it is one of few Medicare benefits that does not include a deductible or copay as Congress eliminated cost sharing in 1972 to encourage the use of these cost-effective services that are covered under the benefit. 42 U.S.C. §§ 1395l(a)(2); 1395l(b)(2). Finally, it is the only Medicare Part A benefit that is in no way based in an institutional care setting. Instead, it is available only in the patient's place of residence, specifically excluding a residence in a nursing facility. 42 C.F.R. § 409.42(a). It is these elements of uniqueness that are relevant to the instant case.

At issue in this case at present is whether Respondent has sufficiently pled that the "as soon thereafter as possible" element of 42 C.F.R. § 424.22(c) is material to Medicare payment determinations such that Medicare would have denied payment of the claims.

The regulation of concern, 42 C.F.R. § 424.22(c), provides in part, that a home health agency obtain a physician certification of the patient's eligibility for Medicare coverage "at the time the plan of care is established or as soon thereafter as possible." 42 C.F.R. § 424.22(c). However, Medicare has never applied such a vague standard in adjudicating claims. Instead,

Medicare interprets that standard as requiring the objective, clear, and sensible criteria that requires certification “prior to billing.” Further, Medicare knowingly does not apply such requirement other than by using a “prior to billing” interpretation in claims reviewed subsequent to Court of Appeals earlier ruling.

The Respondent’s action only has merit if she can properly allege and establish that her “as soon thereafter as possible” standard under § 424.22(c) and/or the “valid excuse” established by the Court of Appeals in its earlier decision is material to a payment of a claim. No such allegation has been adequately made and no such allegation can be proven. Instead, Respondent would need to allege and prove that Petitioners did not have a signed and dated physician certification prior to submitting the final bill for payment in order to support her action. If her “as soon thereafter as possible” standard is material to Medicare payment of a claim, Respondent also fails to properly plead materiality in that she offers nothing more than a bald allegation, unconnected to any set of facts to support an intensely fact-dependent standard that would need to be evaluated individually on each respective claim submitted to Medicare.

The Court should hold Respondent to a standard for pleading materiality that requires more than a bald statement that alleged regulatory noncompliance is material as the stability of the Medicare payment process nationally is at issue. The Court of Appeals standard for pleading materiality allows for baseless litigation related to alleged regulatory violations that have never been the basis for denial of payment. This litigation may be brought in hopes of exacting concessions out of targeted Defendants who must bear the

burden of a litigation defense until the merits of the allegation can be fully exposed through a trial of the actual facts. The Court of Appeals pleading standard risks diverting precious resources of health care providers away from patients into baseless litigation defense.

A detailed materiality pleading standard is necessary to provide a reasonable balance between the purpose of the False Claims Act and the security of a health care delivery system that must be allowed to rely upon consistent administration of Medicare. The thousands of home health agencies that provide care on a daily basis cannot safely operate if they are at risk of relator-driven lawsuits that hide behind liberal standards of pleading that permit empty, conclusory allegations that a regulation has been violated and that such noncompliance is material to Medicare payment. That is particularly the case where, as here, the rule in issue is vague and fully fact-dependent relative to a compliance standard other than with Medicare's "prior to billing" interpretation. Respondent has not dared to specifically allege that Medicare has ever rejected a claim under the "as soon thereafter as possible" standard she now advances.

Further, if relators are permitted to rely upon a liberal standard of pleading "materiality," the courts are at risk of being flooded with lawsuits under the False Claims Act that are based upon unsubstantiated and conclusory allegations of materiality using any and all regulations that pertain to the conduct involved in a generalized, non-specific manner. A heightened standard of pleading materiality is essential to avoid untold volume of baseless litigation.

### **I. Where Regulatory Compliance Standards are Vague and Highly Fact-Based, A Detailed, Specific Pleading of Materiality Should Be Required**

As discussed below, NAHC strongly contends that the applicable standard of compliance is that timely physician certifications are those that are obtained prior to Medicare billing.<sup>2</sup> It is well within Medicare's interpretive authority to apply that standard in determining whether the "as soon thereafter as possible" element of 42 C.F.R. § 424.22(c) is met. Such a standard presents an objective, bright-line for assessing compliance in contrast to the vague and open standard that exists if "as soon thereafter as possible" is left undefined for Medicare and its contractor to struggle with. That struggle would necessitate a highly fact-based and individualized claim compliance determination. Since the certification requirement is applicable to the claimant home health agency (HHA), it would naturally necessitate an analysis of the circumstances facing that HHA in each instance of every claim where the certification is not obtained immediately at the time the plan of care is established. For example, with a delayed certification, the HHA might have had to deal with a physician who died, a hurricane that swamped its office, a document delivery that was lost by a carrier, a staff shortage, a breakdown in office operations, or

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<sup>2</sup> It is highly notable that Medicare and its counsel appear to have done a litigation dance as to what standard Medicare actually applies. Amicus has worked with Medicare on program integrity and compliance standards since 1982. At no time has Medicare ever applied a standard under 42 C.F.R. § 424.22(c) other than a "prior to billing" standard. Such a standard can be consistently and efficiently administered in contrast to the vague "as soon thereafter as possible" one at issue herein.

one of the many other actual occurrences that routinely happen in home health care. An HHA cannot control the certification timing of a physician's actions any more than it can control the weather.

Here, even the facts alleged by Respondent demonstrate a good faith effort to effectively and efficiently secure valid physician certifications prior billing Medicare. Here, Petitioner established a new system of securing physician certifications after finding that its existing approach was resulting in a backlog that adversely affected the timing of claim submissions to Medicare. Clearly, it is in the strong interests of HHA to secure signed and dated physician certifications as soon as they can manage to do since the HHA is without any payment to cover its incurred care costs until that step is completed. Any delay in obtaining certifications hurts the HHA while Medicare gains the financial advantage of paying later.

Recognizing its need to have compliant physician certifications prior to billing Medicare, Petitioner took extraordinary steps to obtain signed and dated physician certifications by establishing a centralized unit that had a singularly focused responsibility. Petitioner did not sit on unsigned certifications. Instead, it acted responsibly and quickly under the circumstances facing it. All businesses can face breakdowns in their operation that result in less than optimal performance. With the paperwork-intensive Medicare compliance requirements, such is bound to happen frequently. How that organization responds to the inevitable breakdown is relevant as to whether it is getting the physician certifications "as soon thereafter as possible." That action is a purely fact-based one.

A "prior to billing" standard of compliance focuses on a single fact. An undefined "as soon thereafter as

possible” standard requires consideration of a potentially endless myriad of facts that may be relevant.

Did Respondent plead that Petitioners’ actions fell short of what a responsible HHA would do under the circumstances such that its actions or inactions led to a failure to comply with 42 C.F.R. § 424.22(c)? Not even close.

Respondent fell far short of a specific pleading that could connect to the facts herein and the materiality of those facts to a likely finding of noncompliance by Medicare that would result in a rejection of payment. Materiality in this matter means pleading an essential combination of facts and law. In no way did Respondent plead that Petitioner had obtained any physician signature in a specific manner or with a lack of diligence from a perspective of timing that would be material to payment of a Medicare claim. The Court of Appeals did not apply such a necessary pleading standard, permitting Respondent to wrongly rely upon a bald allegation of materiality.

Another missing element in Respondent’s pleading of materiality is the complete failure to plead whether Medicare would have recouped any alleged overpayments resulting from non-compliance with 42 C.F.R. § 424.22(c) under the “without fault” provisions of 42 U.S.C. § 1395gg. Medicare can and does waive recovery of overpayments where a provider of services is “without fault” in receiving the overpayment. With respect to compliance with the “as soon thereafter as possible” requirements, HHAs can certainly present strong arguments that recoupment of any overpayments resulting from alleged non-compliance should be waived where the HHAs complied with the “prior to billing” standard that has been the reality application of 42 C.F.R. § 424.22(c) since its inception. As such, Respondents

fail to meet the requirement of pleading materiality in this case because there is no allegation that Medicare would not have waived the recovery of any overpayment incurred by Petitioner.

This Court should apply a real world standard for pleading materiality, not an empty abstract standard that allows litigants to simply state that a party's action or inaction is material to payment under Medicare. In the real world, facts matter. Under 42 C.F.R. § 424.22(c), highly individualized, claim-specific facts are really all that matters.

## **II. Relator Has Not Properly Pled the Material “Prior to Billing” Standard**

Medicare has reviewed hundreds of millions of claims since the inception of the home health benefit. Medicare operations oversight bodies such as the OIG have also reviewed numerous home health claims. Federal courts have also reviewed Medicare home health claims in False Claims Act prosecutions. Not once has the basis of a claim rejection been a generalized “as soon thereafter as possible” timeliness standard at the heart of the instant case. Respondent has not alleged and cannot allege that anything other than a “prior to billing” standard is material to payment of a claim. The Court should grant the Petition so that this matter not move forward without more than a conclusory allegation of materiality, particularly when a strong showing has been made that the allegation is unfounded.

Medicare has had frequent opportunities to amend its regulations and its policy position on the timeliness of physician certification, but has not done so. It revisited the certification regulation 15 times following its 1976 promulgation, 41 Fed. Reg. 21345 (May



25, 1976), and not once did it remotely consider enforcing a standard like that alleged here or the one established in the earlier Court of Appeals ruling. Medicare had that opportunity in the past and had it again after the Court of Appeals ruling. Instead, Medicare only reaffirmed its longstanding policy position.

Notably, Medicare has not changed its practice of using a “prior to billing” standard for payment with 42 C.F.R. § 424.22(c) since the initiation of this litigation in 2014. To the extent that Medicare could claim that it was not aware of any noncompliance previously, it certainly could not hold to that position after the instant case was filed.

It is also notable, that Medicare regulations set date-specific, objective requirements for inpatient and institutional care. In those settings, the facilities directly employ certifying physicians or experience routine on-site physician-patient encounters that permit ease of access to obtaining signed certifications.<sup>3</sup> CMS has never required pre-discharge certification deadline in home health services. It does not fit within the context of home health services where physician availability is random and distant rather than immediate and close as exists in institutional care. However, Medicare has and continues to employ a comparable date-specific standard—HHAs must have assigned and date physician certification prior to billing for purposes of payment.

The statutory mandate underlying 42 C.F.R. § 424.22(c) presents valuable initial guidance on what Medicare

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<sup>3</sup> Hard, objective deadlines also exist in other health sectors, e.g. 42 C.F.R. § 424.13(b) (inpatient hospital services certification required prior to discharge) and in a manner that is comparable to one based on a specific triggering deadline, e.g. prior to billing.

considers material to payment of a home health services claim in permitting payment even where the certification is obtained after the conclusion of care. That mandate states, in relevant part:

(2) a physician, . . . , certifies . . . that—

C) in the case of home health services, such services **are or were required** because the individual **is or was confined** to his home . . .”  
42 U.S.C. § 1395f(a)(2)(C) (emphasis added).  
See also, 42 U.S.C. § 1395n(a)(2)(A)

The use of past tense verbs “were required” and “was confined” combined with present tense verbs denote a clear standard that a physician certification can be well after services have stopped, in contrast to a standard that Respondent needs to support its action. Notably absent also is any semblance of the appellate court’s “valid excuse” requirement for obtaining the written certification at some point after the start of care.

The “prior to billing” timeliness requirement is actually based on when a plan of care is established, not the start of care. 42 C.F.R. § 424.22(c). A plan of care is not “established” until it is in writing, signed, and dated by the certifying physician, an action only required prior to billing services. 42 C.F.R. § 409.43(c)(3)(ii). Accordingly, a proper reading of the “as soon thereafter as possible” language in 42 C.F.R. § 424.22(c) for payment purposes is that certification must be obtained as soon as possible after a plan of treatment is in writing, signed, and dated by the certifying physician, not as soon as possible after the start of care. Respondent has not alleged any such violation.

This reading of 42 C.F.R. § 424.22(c) is wholly consistent with the longstanding policy issuances of the Centers for Medicare and Medicaid Services (CMS),

the arm of the U.S. Department of Health and Human Services responsible for administering the home health benefit. In CMS Pub. 100-01, Chapter 4, Section 30.1, CMS explains that home health services “[c]ertifications must be obtained at the time the plan of care is established or as soon thereafter as possible. The physician must sign and date the plan of care (POC) and the certification prior to the claim being submitted for payment.” <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c04.pdf>. This policy position clearly connects the deadline for a signed and dated certification with the deadline for the plan of care—prior to the billing date.

Medicare has maintained that timeliness standard even subsequent to the Court of Appeals’ original ruling in this case. In 2017, changes to its guidance regarding physician certification, Medicare had the opportunity to modify its certification timeliness standard and did not do so. Transmittal 704, Pub-100-08 Medicare Program Integrity, March 17, 2017 (Effective April 17, 2017). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R704PI.pdf>.

The clear connection of the certification and plan of care timeliness standards is highlighted in late 2016 guidance issued by Medicare as part of its intensive claim review project where all claims were subject to a comprehensive review prior to payment in targeted states. Medicare explained that a home health agency could utilize an old CMS form, CMS-485, which combined the formal written plan of care with the physician certification statement to achieve compliance. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Pre-Claim-Review-Initiatives/Down>

loads/Updated-Pre-Claim-Review-Frequently-Asked-Questions-10\_27\_16.pdf.<sup>4</sup>

Given that the plan of care needs to be signed and dated only prior to billing under 42 C.F.R. § 409.43(c)(3)(ii), using a Medicare approved form that permitted a combined physician certification and plan of care leads to the natural conclusion that certification is required only prior to billing. Again, Respondent has not alleged any violation of that standard.

Another clear indication that Medicare does not look to anything for purposes of payment other than a “prior to billing” standard is found in the Home Health Review Tool issued by Medicare for its contractor’s claim reviews. [https:// www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/Home-Health-Review-Tool-08-30-17.pptx](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/Home-Health-Review-Tool-08-30-17.pptx). Step 5 of that Tool process looks to whether a certification statement has all needed elements is present, but does not seek any review of the fact-dependent “as soon thereafter as possible” requirement un 42 C.F.R. § 424.22(c) prior to pronouncing that “All Requirements Are Met. Mark the case AFFIRMED or PAYABLE.”

Further, consistent with this guidance, Medicare published a Home Health Agency (HHA) and Physician Documentation: Review Decision Flowchart. [https:// www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Pre-Claim-Review-Initiatives/Downloads/Review-Decision-Flowchart.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Pre-Claim-Review-Initiatives/Downloads/Review-Decision-Flowchart.pdf). That flowchart includes Step

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<sup>4</sup> The CMS-485 is found at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Pre-Claim-Review-Initiatives/Downloads/FAQ-65-HH-Cert-and-Plan-of-Care-example.pdf>.

2B that considers “Is HHA information signed and dated by the physician?” Nowhere in that review flowchart does it require the Medicare contractor to determine if the certification was obtained at the start of care or as soon thereafter as possible. If the standard that Respondent alleges to be violated is material to payment, it would be expected that Medicare would include such in its claim review directions given to its contractors that are responsible for claim review and payment.

The guidance in the CMS manuals is supplemented in a number of ways by CMS, including guidance to HHAs from Medicare claim review contractors, e.g. “Plan of Care and Certification is required for home health services. The signature should be legible and dated prior to billing the end of episode claim.” <https://www.palmettogba.com/palmetto/providers.nsf/DocsCat/JM-Home-Health-and-Hospice~A4LNST6303>. This guidance clearly sets a timeliness standard as the point prior filing the final claim. Further, the contractor does not advise home health agencies that the requirement necessitates that they establish a reason for any delay in obtaining a physician certification. Instead, it indicates that both a plan of care and certification are categorically valid if they are signed prior to billing.

Also, not once has the HHS Office of Inspector General (OIG) questioned the use and application of a standard that permits home health agencies to obtain signed and dated physician certification prior to billing, e.g. “Medicare Compliance Review of Excellent Home Care Services, LLC,” <https://oig.hhs.gov/oas/reports/region2/21401005.asp>; “Medicare Compliance Review of Home Health VNA for 2011 and 2012.” <https://oig.hhs.gov/oas/reports/region1/11300518.asp> and “The

Physician's Role in Medicare Home Health 2001," <https://oig.hhs.gov/oei/reports/oei-02-00-00620.pdf>.

It would be highly unlikely that all of the audited claims had signed and dated certifications at the start of care or that the home health agencies fully presented explanations for any delays in certification as the appellate court interprets the "as soon thereafter as possible" provision. Consistent Medicare and industry practice has been to consider the certification timeliness requirement to be tied to the date of the billing. So long as the certification was obtained by that date, home health agencies considered their actions to be compliant. CMS never stated otherwise in its policies or its audits of claims.

To meet the requirement for pleading the materiality of the Petitioners' alleged non-compliance with 42 C.F.R. § 424.22(c) for purposes of payment, Respondent must plead that the "prior to billing" standard has been violated. Respondent failed to do so thereby warranting a grant of the writ of certiorari and a reversal of the Court of Appeals decision.

### **III. Relator Has Not Pled the Court of Appeals "Valid Excuse" Standard as Material to Payment of a Medicare Claim**

Respondent does not allege that Petitioners failed to have a "valid excuse" for not having a certification at the start of care because that standard did not exist until it was created by the Court of Appeals. That requirement, crafted outside the public notice and comment procedures of the Administrative Procedures Act, without the benefit of the expertise of the federal agency charged with administering the Medicare program, places the entire community of home health agencies nationwide at risk of untold numbers of

retroactive claim denials and exposes these companies to actions such as this under the False Claims Act. Such retroactive rulemaking is simply not permitted.

The appellate court-devised “valid excuse” standard may be a next generation standard of compliance in the event that Medicare chooses to adopt it someday. However, that day has not yet come.

The Court of Appeals for the Tenth Circuit dealt with a similar circumstance in *Caring Hearts Personal Home Services, Inc. v Burwell*, No. 14-3243, 2016 BL 171256 (May 31, 2016). In *Caring Hearts*, Medicare had rejected home health claims in a post-payment audit based on an application of the “homebound” requirement for benefit eligibility. However, Medicare’s post-payment rejection was based on an application of a revised interpretation of the homebound standard, one that was not issued until five years after the HHA had rendered the services at issue.

As can be expected, the Tenth Circuit concluded that Medicare cannot engage in retroactive rulemaking, citing 42 U.S.C. § 1395hh(e)(1)(A). Ultimately, the court did not rule on whether the HHA had met the eligibility standards applicable at the time of service as that claim was not before the court. Instead, the court vacated the District Court’s ruling affirming the denial of relief under 42 U.S.C. § 1395pp, a Medicare provision that permits waiver of recoveries of payments made when an HHA acts in good faith (knows or has reason to know standard) regarding a determination on a patient’s homebound status.

Here, we do not have the attempted retroactive application of a changed eligibility standard by the Medicare administration. Instead, we have the appellate court creating a new standard out of whole cloth,

the “valid excuse” standard. As such, if the Petitioner must meet that standard, it is necessary that Respondent plead that Petitioner has not complied with it and that such noncompliance is material as to whether Petitioners’ Medicare claims would be paid. Unsurprisingly, Respondent has failed to do so.

The complexity of defining and applying a “valid excuse” standard, particularly in the context of a False Claim Act prosecution, demonstrates why such should be left to CMS, not the courts, where the APA public notice and comment procedures can inform the decision-making.

To date, CMS has overtly avoided the creation of such a standard and has maintained a reasonable, clear, and definitive timeliness standard since the outset of the Medicare home health benefit—a signed and dated physician certification, as with the Plan of Care, is due no earlier than prior to billing. Such a bright-line standard for compliance is far better than the appellate court’s approach that would necessitate highly individualized analyses in over 6.6 million claims with a standard of review that is unmanageable and fraught with risk of subjectivity. It is that standard that has been material to a Medicare payment determination for decades. The Respondent does not allege a violation of that standard.

Nor has Respondent pled a violation of the appellate court’s “valid excuse” standard as material to Medicare payment. She would need to know the future to do so.

Nevertheless, this case, in its present posture, is about whether the Respondent has properly pled the materiality of the Petitioners’ actions relative to Medicare payment of its benefit payment claims. That means, Respondent must present a properly pled



allegation of materiality under the standards the appellate court ruled as applicable. No such allegations have been advanced by the Respondent thereby warranting a granting of the petitioned writ and a reversal of the appellate court's decision.

### CONCLUSION

For the foregoing reasons, NAHC respectfully requests that the Court grant the Petition for Writ of Certiorari and reverse the Court of Appeals decision.

Respectfully submitted,

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