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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

IN HOME HEALTH, LLC,

Plaintiff-Appellant,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the United States Department of Health & Human Services,

Defendant-Appellee.

No. 25-3542

Appeal from the United States District Court for the Northern District of Ohio at Toledo.
No. 3:24-cv-00281—Jack Zouhary, District Judge.

Argued: April 30, 2026

Decided and Filed: July 27, 2026

Before: READLER, DAVIS, and BLOOMEKATZ, Circuit Judges.

COUNSEL

ARGUED: Joseph S. Diedrich, HUSCH BLACKWELL LLP, Washington, D.C., for Appellant. Brendan F. Barker, UNITED STATES ATTORNEY'S OFFICE, Cleveland, Ohio, for Appellee. **ON BRIEF:** Joseph S. Diedrich, HUSCH BLACKWELL LLP, Washington, D.C., Shawn J. Anderson, HUSCH BLACKWELL LLP, Milwaukee, Wisconsin, for Appellant. Brendan F. Barker, UNITED STATES ATTORNEY'S OFFICE, Cleveland, Ohio, for Appellee. William A. Dombi, Jason E. Bring, ARNALL GOLDEN GREGORY LLP, Washington, D.C., for Amici Curiae.

OPINION

BLOOMEKATZ, Circuit Judge. Every year millions of Americans enter hospice. Medicare pays for hospice when a beneficiary is "terminally ill," which means the patient has a life expectancy of six months or less. But it is hard to predict with certainty when someone will die. Doctors decide if someone qualifies for hospice in the first instance, examining whether a patient's clinical profile satisfies the medical standard governing terminal illness. Down the line, when a healthcare provider seeks Medicare reimbursement, administrators review the doctor's determination. So what happens when an administrator concludes that the doctor was wrong in their prognosis? The Medicare statute answers with a safe harbor: A provider is not on the hook so long as the doctor's application of the standard for assessing terminal illness was reasonable. This case is primarily about when and how hospice providers qualify for that safe harbor.

When making that assessment in this case, the ALJ concluded that the safe harbor did not apply because In Home Health knew about the operative Medicare notice on hospice standards. This was a mistake. Instead, the ALJ should have asked whether the provider adopted a reasonable interpretation of the operative Medicare notice as applied to relevant claims. Accordingly, we vacate and remand to the district court with instructions to return the case to the ALJ to apply the safe harbor under the proper statutory standard in the first instance.

BACKGROUND

I. Hospice Regulatory Scheme

Hospice is a specialized form of medical care that millions of Americans rely on every year. Rather than trying to cure or slow the progression of terminal disease, hospice focuses on comfort: managing pain, controlling symptoms, and supporting the patient's emotional and spiritual well-being for whatever time they have left to live. Hospice also supports a patient's family members and caregivers both during the patient's illness and through bereavement. Given the broad service offerings, hospice care teams include not just doctors and nurses, but also social workers, bereavement counselors, spiritual care providers, and trained volunteers.

Nat'l Hospice & Palliative Care Org., *NHPCO Facts and Figures*, 2 (Sep. 10, 2024), https://perma.cc/JY8V-84V7. Because of these services, hospice "greatly improve[s] the quality of care of patients and their families near the end of life." Amy S. Kelley et al., *Hospice Enrollment Saves Money for Medicare and Improves Quality Across a Number of Different Lengths-of-Stay*, 32 Health Affairs 552, 552 (2013).

Recognizing the advantages of hospice, Congress expanded Medicare to cover it in 1982. *See* Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 122, 96 Stat. 324, 356–63. Medicare is a federal health insurance program primarily for Americans ages 65 and older. 42 U.S.C. § 1395c. Medicare covers hospice services that are "reasonable and necessary for the palliation or management of terminal illness." *Id.* § 1395y(a)(1)(C). An individual is "terminally ill" if they have a life expectancy of six months or less, assuming their illness runs its normal course. *Id.* §§ 1395f(a)(7), 1395x(dd)(3)(A). That said, "[p]redicting life expectancy is not an exact science," 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010), so some individuals placed in hospice may live months, even years longer than six months. Accordingly, Medicare does not cap the amount of time an individual can spend in hospice. 42 U.S.C. § 1395d(d)(1). Instead, so long as an individual has a prognosis of six months or less and continues to have that prognosis even if they live longer than six months, the statutory scheme allows them to remain in hospice.

Still, Medicare has imposed extensive reporting requirements to ensure that hospice remains a short-term, end-of-life form of healthcare. The law requires hospices to keep detailed medical records that document a patient's condition. These requirements begin when an individual enrolls in hospice. At that point, a hospice physician must certify in writing that, based on their clinical judgment, the individual is terminally ill. *Id.* § 1395f(a)(7). That certification "must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less." 42 C.F.R. § 418.22(b)(3). Moreover, "[c]linical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record." *Id.* § 418.22(b)(2). The initial certification covers a 90-day period, then the hospice physician must recertify that the patient's terminal condition continues to engender a life expectancy of six months or less. 42 U.S.C. § 1395f(a)(7)(A)(i), (ii); 42 C.F.R. § 418.22(a)(1). The second certification likewise lasts for

90 days. 42 U.S.C. § 1395f(a)(7)(A)(ii); 42 C.F.R. § 418.21(a)(2). Then, after the second certification period ends, the hospice physician must recertify every 60 days, provided the patient's condition continues to support a six-month prognosis. 42 C.F.R. §§ 418.21(a)(3), 418.22(a)(1).

These documentation requirements supply the evidentiary foundation for the administrative process through which Medicare pays—and when necessary, recoups—hospice reimbursements. Medicare is administered by the Centers for Medicare and Medicaid Services (CMS), part of the Department of Health and Human Services. CMS contracts with private insurance companies, who together with local peer review organizations (collectively "contractors") review, approve, and pay Medicare claims that healthcare providers submit. 42 U.S.C. § 1395h(a). Medicare coverage turns on whether a particular item or service is "reasonable and necessary." *Id.* § 1395y(a)(1)(C). When making these determinations, contractors rely on Local Coverage Determinations (LCDs), which provide notice of how the contractor will determine whether an item or service satisfies the "reasonable and necessary" standard. *Id.* § 1395ff(f)(2). LCD 33393, the LCD relevant here, sets forth clinical diagnoses, statuses, signs, symptoms, and characteristics that demonstrate a patient is terminally ill. CMS, *Hospice – Determining Terminal Status LCD 33393*, https://perma.cc/NJ4W-BSYM. If a contractor concludes that a patient is terminally ill, as defined by the LCD, Medicare pays the hospice a predetermined fee for each day of care it provided. 42 U.S.C. § 1395ddd.

Even after reimbursement, contractors can initiate a post-payment review that evaluates whether the item or service satisfies the reasonable and necessary standard. *See id.* §§ 1395ddd, 1395g(a), 1395y(a)(1)(C). If, upon second review, the Medicare contractor concludes the services were not reasonable and necessary, meaning that Medicare paid a provider when it should not have, then the contractor can seek to recoup that payment. *Id.* § 1395ddd(f).

When Medicare seeks to recoup payment, it's not surprising that providers may disagree with the contractor's determination. But they are not without recourse. There is a four-part administrative appeal process that providers can undertake to challenge an unfavorable outcome of a post-payment review. The process consists of: (1) requesting a redetermination of the decision by the Medicare contractor that sought to recoup the overpayment; (2) requesting a

reconsideration of the Medicare contractor's redetermination by a different contractor (known as a "Qualified Independent Contractor"); (3) requesting a de novo hearing before an administrative law judge (ALJ); and (4) appealing any adverse ALJ decision to the Medicare Appeals Council of the Health and Human Services Departmental Appeals Board. 42 C.F.R. § 405.904(a)(2), (b). If the Council either affirms the coverage denial or does not render a decision within a 90-day timeframe, a provider can appeal the overpayment determination in federal district court. 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1132.

Even if a provider does not successfully prove that the item or service satisfied Medicare's statutory standard during these proceedings, it is not necessarily financially liable. The Medicare statute contains a safe harbor. *See Banks v. Sec'y, Dep't of Health & Hum. Servs.*, 38 F.4th 86, 91 (11th Cir. 2022). Under 42 U.S.C. § 1395pp, a provider need not reimburse an overpayment if it "did not know, and could not reasonably have been expected to know, that payment would not be made" for the services at issue. 42 U.S.C. § 1395pp(a)(2). "A sort of good faith affirmative defense," this provision reflects Congress's "recognition of the complexity of the Medicare maze." *Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) (Gorsuch, J.). It safeguards providers that deliver healthcare services that they reasonably believed Medicare would cover.

II. Procedural History of In Home Health's Claims

In Home Health is a Medicare-certified provider of hospice services. In 2020, a Medicare contractor informed In Home that it did not meet Medicare coverage requirements for 252 of 374 claims reviewed for nine of In Home's patients, amounting to almost $1 million in overpayments to In Home that it would need to pay back.

In Home appealed the contractor's determination. First, it sought redetermination by the contractor. Then, after receiving an unfavorable redetermination decision, In Home sought reconsideration before a Qualified Independent Contractor. The Qualified Independent Contractor reviewed the underlying medical records and then, applying LCD 33393, reversed the prior contractor's coverage determinations for 79 of the disputed claims while upholding the denial of coverage for the remaining 173 claims.

In Home then sought review by an ALJ of 155 of those 173 denied claims that related to five different patients. Dr. Thomas DeGregory, the Medical Director of In Home, testified during a hearing before the ALJ. Although he treated only one of the five patients, Dr. DeGregory maintained that they were all terminally ill as defined by LCD 33393 and so Medicare should have covered their hospice services.

The ALJ issued a decision that was partially favorable to In Home. Applying LCD 33393, the ALJ determined that Medicare covered 52 claims that the previous contractors had deemed uncovered. But he also upheld the previous denials of 104 claims for four patients.[1] The ALJ further concluded that for those 104 claims, In Home could not benefit from the safe harbor contained in 42 U.S.C. § 1395pp because In Home should have had "knowledge of the billing and practice information contained in the appropriate CMS notices . . . as well as the standards for sufficient documentation of services." AR Vol. 1 at 73. Thus, the ALJ concluded that In Home was financially liable for the 104 denied claims.

In Home sought review of the ALJ's decision regarding the 104 denied claims by the Medicare Appeals Council. Because the Council did not issue a decision within 90 days, In Home sought review in federal district court. The district court affirmed the ALJ's decision as to both the scope of Medicare coverage and the safe harbor.

Overall, out of the 252[2] claims for which the contractor originally sought recoupment, In Home prevailed in reversing 131 claims (79 before the Qualified Independent Contractor, 52 before the ALJ) and continues to dispute the denial of 104 claims. Pressing its challenge to those denials, In Home timely appealed.

ANALYSIS

This case presents two issues. *First*, whether substantial evidence supported the ALJ's conclusion that Medicare did not cover certain services that In Home provided to patients. We

[1]Although In Home appealed 155 claims to the ALJ, the total number of claims it discussed (52 claims reversed, 104 affirmed) amounts to 156 since the ALJ split one claim by partially affirming and partially reversing the Qualified Independent Contractor.

[2]In Home did not appeal the Qualified Independent Contractor's determination with respect to all 173 claims it denied.

agree with the government that substantial evidence supported the ALJ's decision given its thorough, reasoned assessment of the record. *Second*, whether the ALJ properly applied the Medicare statute's safe harbor when he determined that In Home is financially liable for the disputed services. Here, we conclude that the ALJ failed to apply the correct standard because the decision did not consider whether a provider could reasonably have determined that the denied claims satisfied LCD 33393.

I. Coverage Determination

We begin our analysis by explaining the standard that the ALJ applied, LCD 33393, to determine whether the patients at issue were "terminally ill" and therefore entitled to Medicare coverage for hospice. Then we evaluate whether substantial evidence supports the ALJ's decision that the patients did not meet that standard.

We review de novo the district court's conclusion that substantial evidence supported the ALJ's coverage determination. *Jordan v. Comm'r of Soc. Sec.*, 548 F.3d 417, 422 (6th Cir. 2008). Where, as here, the Medicare Appeals Council did not review the ALJ's decision, we treat the ALJ's decision as final. *Calvin v. Chater*, 73 F.3d 87, 90 (6th Cir. 1996). And we must affirm that underlying decision unless we determine that substantial evidence did not support it. *Waters v. Becerra*, 80 F.4th 782, 787 (6th Cir. 2023); 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). Substantial evidence "falls somewhere between more than a scintilla but less than a preponderance." *Waters*, 80 F.4th at 787 (citing *Cohen v. Sec'y of Dep't of Health & Hum. Servs.*, 964 F.2d 524, 528 (6th Cir. 1992)). It "does not mean a large or considerable amount of evidence, but rather 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Pierce v. Underwood*, 487 U.S. 552, 565 (1988) (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)). Reviewing for substantial evidence precludes us from reweighing conflicting evidence, making credibility determinations, or substituting our judgment for the ALJ's reasoned determination. *Jordan*, 548 F.3d at 422.

A. Regulatory Standard

To determine whether Medicare covered the claims at issue, the ALJ relied on LCD 33393, which sets forth clinical diagnoses, statuses, signs, symptoms, and characteristics that

support a terminal prognosis. The LCD contains three parts: Part I lists signs and symptoms of decline; Part II lists "[n]on-disease specific baseline guidelines," such as whether a patient depends on assistance for two or more activities of daily living; and Part III lists disease-specific considerations that an ALJ should take into account when determining whether a patient is eligible for hospice services. CMS, *LCD 33393*. A patient can qualify for hospice by either satisfying Part I of the LCD or by satisfying Parts II and III.

In Home argues that the remaining claims qualify under Part I of LCD 33393, so we focus on that pathway for demonstrating terminal illness. Once a patient has entered hospice—meaning a doctor has certified they have a life expectancy of six months or less—Part I of LCD 33393 says that a measurable decline in their clinical status supports a continued terminal prognosis. Part I instructs physicians to assess, among other things, whether the patient exhibits weight loss (at least 10% of total body weight in six months), worsening infections such as pneumonia or sepsis, increasing dependence on help with basic daily tasks, worsening lab results or vital signs, or more frequent ER visits. Doctors use various scales such as the Karnofsky Performance Status (KPS), Palliative Performance Score (PPS), and Functional Assessment Staging Tool (FAST) to measure changes in these metrics. While Part I of the LCD states that these scales and other daily living indicators inform whether a patient is "terminally ill," it does not specify how much these metrics must change, or over what period, for that change to signify terminal illness.

B. Application

We now turn to whether substantial evidence supports the ALJ's decision that these various claims did not satisfy LCD 33393. We conclude that it does. After setting out the applicable law, the ALJ examined the relevant data from the administrative record and provided an explanation of his decision that included a rational connection between the record facts and the coverage determination. For each patient and claims period at issue, the ALJ worked through face-to-face encounter notes, recertification evaluations, nursing visit notes, and interdisciplinary team care plans. The ALJ tracked individual clinical datapoints across time to assess whether they showed a pattern of decline. Where the record contained conflicting data (for instance,

where a certification evaluation and a nursing note reported vastly different weights for similar dates), the ALJ acknowledged the discrepancy and reached a reasoned conclusion.

An example from the record illustrates the ALJ's reasoned analysis. Beneficiary 1 was admitted to hospice in September 2015 with a terminal diagnosis of senile brain degeneration with related dementia and Alzheimer's disease. The ALJ found that her FAST score fluctuated, and that her KPS score, while declining at first, remained stable at 30%. Notwithstanding that decline, the ALJ concluded that Beneficiary 1 did not satisfy LCD 33393's requirements because her weight loss, while present, did not approach the 10% threshold set out in LCD 33393.

It might be reasonable to apply LCD 33393 to these facts and come to a different conclusion, as we discuss in greater detail in the next section. Nonetheless, substantial evidence supports the ALJ's coverage determinations because "a reasonable mind might accept as adequate" the ALJ's application of LCD 33393 to the underlying medical record. *Pierce*, 487 U.S. at 565 (quoting *Consol. Edison Co.*, 305 U.S. at 229).

In Home responds with two primary arguments, but we do not find either persuasive. *First*, In Home contends that the ALJ improperly treated LCD 33393 as the controlling legal standard and that even if the beneficiaries were not eligible for hospice under LCD 33393, they still could have been "terminally ill" and thus eligible for the hospice benefit.

In Home is correct that LCDs do not "establish or change a substantive legal standard." *Agendia, Inc. v. Becerra*, 4 F.4th 896, 900 (9th Cir. 2021) (citation modified) (quoting 42 U.S.C. § 1395hh(a)(2)). Indeed, the substantive legal standard "would remain unaltered" even if LCDs "ceased to exist." *Id.* Thus, LCD 33393 is just "one path to eligibility" for hospice coverage if a hospice can "otherwise demonstrate . . . that the patient has a terminal prognosis." *United States v. Vista Hospice Care, Inc.*, No. 07-cv-604-M, 2016 WL 3449833, at *4 (N.D. Tex. June 20, 2016) (citation modified); *see also* 42 U.S.C. § 1395x(dd)(3)(A). It is true that Medicare regulations require the ALJ to give "substantial deference" to the LCD when analyzing medical records, but it need not be determinative. 42 C.F.R. § 405.1062(a). And In Home has not explained what alternative standard for assessing a patient's terminality the ALJ should have used. Nor did it propose a different method for assessing terminality to the ALJ. Rather, even

Dr. DeGregory, In Home's own employee and expert, based his testimony before the ALJ on whether the disputed patients were terminally ill as defined by LCD 33393. Thus, the ALJ did not improperly rely on LCD 33393.

Second, In Home claims that substantial evidence does not support the ALJ's determination because the ALJ ignored significant evidence that ran contrary to his opinion, including the physician certifications and Dr. DeGregory's testimony. Consequently, In Home says, the ALJ "played doctor" by making his own independent medical findings that contradicted the medical professionals' assessments. Appellant Br. at 45.

We disagree. The ALJ analyzed whether the objective medical evidence was consistent with a prognosis of six months or less under the benchmarks set forth in LCD 33393. And substantial evidence could support the ALJ's decision even though Dr. DeGregory and a certifying physician said otherwise. As a preliminary matter, the ALJ did not ignore Dr. DeGregory's testimony. Indeed, the ALJ relied on Dr. Gregory's testimony to reverse the contractor's denial and conclude that Beneficiary 3 was terminally ill. But the ALJ does not serve as a mere rubber stamp for medical testimony. The relevant regulations require objective medical evidence to corroborate the physician's certification, *see* 42 C.F.R. § 418.22(b)(2), and a "signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit under Medicare." 70 Fed. Reg. 70532, 70534–35 (Nov. 22, 2005). Here, the ALJ independently reviewed the objective medical evidence and concluded it did not support the physician certifications or Dr. DeGregory's assessment for some claims. True, that mirrors, in some respect, how In Home's providers assessed the patients' terminality. But that exercise was also necessary to the ALJ's review of those underlying assessments. And since those medical professionals did not have "unchecked authority to certify patients as hospice eligible," *United States v. Care Alternatives*, 81 F.4th 361, 371 (3d Cir. 2023), the ALJ did not err by departing from their opinions.

Therefore, we agree with the district court that substantial evidence supported the ALJ's determination that Medicare did not cover the disputed claims.

II. Safe Harbor

We next review de novo whether the ALJ properly applied the safe harbor. *See Cardew v. Comm'r of Soc. Sec.*, 896 F.3d 742, 746 (6th Cir. 2018). Even though substantial evidence supported the ALJ's denial of coverage for some of In Home's claims, In Home is not necessarily required to reimburse Medicare for those services. Rather, In Home's financial liability turns on whether it qualifies for the Medicare statute's safe harbor. Because we have not previously addressed the safe harbor's governing legal standard, we explain that standard here, especially as it relates to hospice services. The ALJ did not have the benefit of this explanation. Accordingly, we vacate and remand to the district court with instructions to return the case to the agency for the ALJ to apply the safe harbor under this standard in the first instance.

A. Legal Standard

The Medicare statute's safe harbor requires Medicare, in certain circumstances, to pay for items or services it does not technically cover. Congress, of course, does not want hospices or other medical providers to abuse the system by furnishing unnecessary care. "Medicare fraud has long plagued the American healthcare system." *United States v. Daneshvar*, 925 F.3d 766, 792 (6th Cir. 2019). But not all denied claims result from bad faith or fraud. Sometimes it may not be clear whether Medicare covers a specific service, and a provider acting in good faith may reasonably, yet wrongly, conclude that Medicare will cover a patient's care. To avoid discouraging legitimate care, Medicare will reimburse a provider, even after an unfavorable coverage determination, if it "did not know, and could not reasonably have been expected to know" that the disputed items or services were "not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. §§ 1395pp(a)(2), 1395y(a)(1)(A). This safe harbor operates as a cost-shifting mechanism, limiting a provider's liability when it acted reasonably and in good faith. *See Caring Hearts*, 824 F.3d at 970. And Congress explicitly applied this safe harbor to hospice care, limiting liability when a hospice provider "could not reasonably have been expected to know" that an "individual is not terminally ill." 42 U.S.C. § 1395pp(a)(2), (g).

The question here is how to determine when a provider meets that standard—that it neither knew, nor could reasonably have known that Medicare did not cover an item or service.

Beyond the statutory language, Medicare regulations provide some instruction. A provider "is considered to have known" that Medicare did not cover the disputed services if "[i]t is clear" that "services were excluded from coverage" based on (1) Medicare notices, including written guides or directives from private contractors, about those services; (2) Federal Register notices addressing the issue; or (3) the service's inconsistency with the local medical community's "acceptable standards of practice." 42 C.F.R. § 411.406(e). Under the regulation, then, the ALJ must assess the relevant notices and ask whether, given the facts of a particular claim, the provider was on clear notice that Medicare would not cover the claim. If so, the provider does not fall within the safe harbor.

This regulation helps explain the safe harbor, but it does not fully delineate its scope. The statute states that the safe harbor applies only if the provider did not know and "could not reasonably have been expected to know" that Medicare would not cover a claim. 42 U.S.C. § 1395pp(a)(2). The regulation identifies one circumstance that falls within that standard—when a provider is on clear notice that Medicare coverage does not extend to a claim. If there is clear notice, the provider cannot "reasonably" contend that the denial was unexpected. For instance, a provider cannot reasonably claim it was unaware that Medicare would not reimburse it for using a particular medical device to treat osteoarthritis when published Medicare decisions and guidance stated that Medicare would not cover the device for that use. *See Almy v. Sebelius*, 679 F.3d 297, 300 (4th Cir. 2012).

But the statute—which we must follow—turns on reasonableness, not on clear notice alone. Thus, even in the absence of "clear notice," the safe harbor still requires a provider to have *reasonably* interpreted the relevant notice or local standard of practice as it applies to its claims. An LCD's language, for instance, may make it unreasonable for a provider to think that Medicare will cover the claimed services for a particular patient, even if the LCD does not address that type of patient directly or "clear[ly]." 42 C.F.R. § 411.406(e). For instance, every patient who loses 10% of their bodyweight is not eligible for hospice even though that is one marker of "terminal illness" under LCD 33393—indeed, they might just be on a GLP-1. CMS, *LCD 33393*. It would be unreasonable for a provider to conclude under LCD 33393 that such a

patient is terminally ill and bill Medicare for hospice just because the notice does not address that circumstance explicitly.

Accordingly, in applying the safe harbor, an ALJ must consider whether a provider could reasonably have interpreted the relevant notices or local standards of practice as covering each denied claim. If the provider is on clear notice that Medicare would not cover the claim, it does not fall within the safe harbor. And even absent clear notice, a provider does not fall within the safe harbor if their interpretation of a relevant notice or local standard of practice is unreasonable. But if a provider reasonably—albeit incorrectly—interpreted the Medicare notices and standards as covering a patient's claim, then the safe harbor saves them from liability.

B. The ALJ's Decision

Until this opinion, we had not explained the scope of the safe harbor, and so the ALJ did not employ this standard when evaluating In Home's claims. Instead, the ALJ reasoned that "as a provider of services," In Home "[wa]s expected to have knowledge of the billing and practice information contained in the appropriate CMS notices, including manual issuances, bulletins, or other written guides or other directives from Medicare contractors, which would include . . . the standards for sufficient documentation of services." AR Vol. 1 at 157. He further stated that In Home should have also "ha[d] knowledge or experience of acceptable standards of practice, including billing practices, by the local medical community." *Id.* This approach, however, reads the safe harbor right out of the statute. By the ALJ's reasoning, all providers are imputed with knowledge of the relevant notices and standards, and that knowledge alone is sufficient to say they should have known Medicare excluded their claims. So no provider could ever qualify for the safe harbor irrespective of how vague or ambiguous the Medicare notice and standards are as applied to their claims nor how reasonable the providers' view that Medicare would cover them.

The ALJ's analysis is particularly problematic in this context because it treats In Home's awareness of LCD 33393 as a bright-line rule with only one reasonable interpretation for these patients. All parties agree that LCD 33393 is the only relevant notice for these claims. And, in essence, the ALJ treated the LCD as "clear" notice that Medicare would deny these claims. 42 C.F.R. § 411.406(e). But LCD 33393 is a multi-factor, fact intensive standard. As a result,

and as this proceeding's history illustrates, LCD 33393 allows for multiple reasonable applications in some instances. Put differently, a provider might know that LCD 33393 exists, apply it in good faith, yet reasonably disagree with another provider as to how it maps on to a particular patient. The ALJ, therefore, should have instead asked whether In Home adopted a reasonable interpretation of the LCD as applied to these four patients' denied claims.

To understand how there may be multiple reasonable interpretations of how LCD 33393 applies to a given patient, consider Part I, which, as mentioned above, requires a "decline" in certain health-related benchmarks. A hospice provider could reasonably interpret that language to mean that if a patient stabilizes at a certain point, they are no longer eligible for hospice services. The LCD seems to confirm as much when it notes that doctors should consider discharging a patient if they "improve[] and/or stabilize[] sufficiently over time while in hospice." CMS, *LCD 33393*. But the LCD contains very little guidance of what indicators would suggest that a patient has improved or stabilized "sufficiently" to warrant discharge from hospice. *Id.* More confusing still is that the same paragraph goes on to note that patients who stabilize or improve while in hospice remain eligible for those services so long as providers "have a reasonable expectation of continued decline for a life expectancy of less than six months." *Id.* Here again, there is no specific metric that tells a doctor how to determine whether a patient has satisfied that standard. It is no surprise that the LCD does not contain precise metrics; as explained, "predicting life expectancy is not an exact science." 75 Fed. Reg. at 70488. But that flexibility means that the ALJ should have considered whether In Home reasonably interpreted LCD 33393 as covering the disputed claims.

There are also examples from the ALJ's opinion that highlight how there could be multiple reasonable ways to apply LCD 33393 to a given patient. Consider the LCD's guidance stating that a decline in ability to conduct daily activities, as measured by KPS or PPS scores, due to a progression of disease is evidence supporting a terminal prognosis. It does not specify when that decline must occur relative to the certification period at issue—whether it requires active, ongoing deterioration, or whether a prior decline that has left the patient stabilized at a lower functional level qualifies. The ALJ relied on a 10% decline in KPS score to justify reversing the Qualified Independent Contractor and approving coverage for Beneficiary 3.

But Beneficiary 1 exhibited the same decline in KPS, and the ALJ did not even contemplate that In Home could have reasonably, in good faith, believed that Beneficiary 1 had a terminal prognosis. Perhaps, for reasons not apparent to us, despite having the same decline in KPS as Beneficiary 3, it was nonetheless unreasonable for In Home to believe Beneficiary 1's hospice care would be covered for the disputed period. But it is that type of analysis that the ALJ must undertake.

Consider too that the ALJ reversed the Qualified Independent Contractor and approved coverage for Beneficiary 3 for another disputed period. The ALJ reasoned that even though Beneficiary 3's weight had fluctuated, other clinical indicators—requiring assistance with all daily tasks of living, a recurring infection, sleeping up to 22 hours a day, inability to follow simple commands, trace edema, and nonsensical speech—justified approving coverage given the benchmarks set forth in Part I of LCD 33393. But the ALJ took a different approach with Beneficiary 2. Even though Beneficiary 2 lost a higher percentage of her bodyweight (albeit, before the service period at issue) than Beneficiary 3, the ALJ rejected In Home's claims related to Beneficiary 2 after concluding that she was stable and so did not exhibit the symptoms of decline required by Part I of LCD 33393. But Beneficiary 2 exhibited many of the same traits as Beneficiary 3—requiring help with all daily tasks of living, sleeping 18–20 hours a day, and nonsensical speech. We wonder why, given these factors which were arguably dispositive in the ALJ's analysis of Beneficiary 3, it was not reasonable for In Home to have determined Beneficiary 2 was also terminally ill, as defined by LCD 33393.

Given the LCD's indeterminacy, the ALJ should not have just asked whether In Home knew the LCD existed. Rather, the proper inquiry was whether in good faith, In Home could reasonably have believed that the patients were terminally ill as defined by LCD 33393. The government does not point us to anything in any of the patients' records that should have alerted In Home, contemporaneously, that it was unreasonable for it to determine that the patients were terminally ill as defined by the LCD. And if such evidence exists, the ALJ did not cite it as a basis for his conclusion. *See Waters*, 80 F.4th at 787 (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)). So we remand to allow the ALJ to conduct the reasonableness inquiry in the first instance.

CONCLUSION

We vacate and remand to the district court with instructions to return the case to the ALJ to apply the safe harbor to each of the disputed coverage periods using the legal standard set out in this opinion.