

May 31, 2016

Elisabeth A. Shumaker
Clerk of Court

PUBLISH

UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

CARING HEARTS PERSONAL
HOME SERVICES, INC.,

Plaintiff - Appellant,

v.

No. 14-3243

SYLVIA MATHEWS BURWELL,
Secretary of the United States
Department of Health and Human
Services,

Defendant - Appellee.

**Appeal from the United States District Court
for the District of Kansas
(D.C. No. 2:12-CV-02700-CM-KMH)**

Donald M. McLean, Kansas City, Kansas, for Plaintiff-Appellant.

Melissa D. Hart, Special Assistant United States Attorney, United States Department of Health & Human Services, Baltimore, Maryland (Barry R. Grissom, United States Attorney, and Jackie A. Rapstine, Assistant United States Attorney, and William B. Schultz, General Counsel, Janice L. Hoffman, Associate General Counsel, and Susan Maxson Lyons, Deputy Associate General, United States Department of Health and Human Services, Topeka, Kansas, with her on the brief), for Defendant-Appellee.

Before **LUCERO**, **HARTZ**, and **GORSUCH**, Circuit Judges.

GORSUCH, Circuit Judge.

Executive agencies today are permitted not only to enforce legislation but to revise and reshape it through the exercise of so-called “delegated” legislative authority. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 865-66 (1984). The number of formal rules these agencies have issued thanks to their delegated legislative authority has grown so exuberantly it’s hard to keep up. The Code of Federal Regulations now clocks in at over 175,000 pages. And no one seems sure how many more hundreds of thousands (or maybe millions) of pages of less formal or “sub-regulatory” policy manuals, directives, and the like might be found floating around these days. For some, all this delegated legislative activity by the executive branch raises interesting questions about the separation of powers. *See, e.g., Dep’t of Transp. v. Ass’n of Am. R.Rs.*, 135 S. Ct. 1225, 1240-42 (2015) (Thomas, J., concurring in the judgment); *id.* at 1237 (Alito, J., concurring); *see also De Niz Robles v. Lynch*, 803 F.3d 1165, 1171 & n.5 (10th Cir. 2015). For others, it raises troubling questions about due process and fair notice — questions like whether and how people can be fairly expected to keep pace with and conform their conduct to all this churning and changing “law.” *See, e.g., The Federalist No. 62*, at 381 (James Madison) (Clinton Rossiter ed., 1961) (“It will be of little avail to the people, that the laws are made by men of their own choice, if the laws be so voluminous that they cannot be read, or so incoherent that they cannot be understood; . . . or undergo such incessant changes

that no man, who knows what the law is to-day, can guess what it will be to-morrow.”). But what if the problem is even worse than that? What happens if we reach the point where even these legislating agencies don’t know what their own “law” is?

That’s the problem we confront in this case. And perhaps it comes as little surprise that it arises in the Medicare context. Medicare is, to say the least, a complicated program. The Centers for Medicare & Medicaid Services (CMS) estimates that it issues literally thousands of new or revised guidance documents (not pages) every single year, guidance providers must follow exactly if they wish to provide health care services to the elderly and disabled under Medicare’s umbrella. Currently, about 37,000 separate guidance documents can be found on CMS’s website — and even that doesn’t purport to be a complete inventory. *See* Jessica Mantel, *Procedural Safeguards for Agency Guidance: A Source of Legitimacy for the Administrative State*, 61 Admin. L. Rev. 343, 353 (2009).

But how did CMS wind up confused about its own law? It began this way. Caring Hearts provides physical therapy and skilled nursing services to “homebound” Medicare patients. 42 U.S.C. § 1395f(a). Of course, any Medicare provider may only charge the government for services that are “reasonable and necessary.” *Id.* § 1395y(a)(1)(A). But Congress hasn’t exactly been clear about who qualifies as homebound or what services qualify as reasonable and necessary. So CMS has developed its own rules on both subjects — rules the agency has

(repeatedly) revised and expanded over time. In a recent audit, CMS purported to find that Caring Hearts provided services to at least a handful of patients who didn't qualify as "homebound" or for whom the services rendered weren't "reasonable and necessary." As a result, CMS ordered Caring Hearts to repay the government over \$800,000.

The trouble is, in reaching its conclusions CMS applied the wrong law. As we'll see, the agency didn't apply the regulations in force in 2008 when Caring Hearts provided the services in dispute. Instead, it applied considerably more onerous regulations the agency adopted only years later. Regulations that Caring Hearts couldn't have known about at the time it provided its services. Regulations that even CMS concedes bore only prospective effect. *See* 42 U.S.C. § 1395hh(e)(1)(A). And as we'll see, Caring Hearts can make out a pretty good case that its services were entirely consistent with the law as it was at the time they were rendered. So this isn't (and never was) a case about willful Medicare fraud. Instead, it's a case about an agency struggling to keep up with the furious pace of its own rulemaking.

So what to do? Caring Hearts says we can find a way out through 42 U.S.C. § 1395pp. In seeming recognition of the complexity of the Medicare maze, Congress there indicated that providers who didn't know and couldn't have reasonably been expected to know that their services weren't permissible when rendered generally don't have to repay the amounts they received from CMS. A

sort of good faith affirmative defense, if you will. Of course, in administrative proceedings CMS rejected Caring Hearts's application for relief under § 1395pp. But in doing so, the agency held that the firm knew or should've known its conduct was unlawful only in light of regulations that were then but figments of the rulemakers' imagination, still years away from adoption. And Caring Hearts submits this means we should vacate the agency's decision, just as we would any other that rests on a mistake about applicable law.

With this we agree. For surely one thing no agency can do is apply the wrong law to citizens who come before it, especially when the right law would appear to support the citizen and not the agency. *See, e.g., Lax v. Astrue*, 489 F.3d 1080, 1084 (10th Cir. 2007) ("We review the [agency] decision to determine whether the factual findings are supported by substantial evidence in the record and whether the correct legal standards were applied."); *Sandoval v. Aetna Life & Cas. Ins. Co.*, 967 F.2d 377, 380 n.4 (10th Cir. 1992) ("In our view, both lack of substantial evidence and a mistake of law would be indicia of arbitrary and capricious actions and thus may be subsumed under the arbitrary and capricious label."); *cf. Danti v. Lewis*, 312 F.2d 345, 349 (D.C. Cir. 1962) (holding a decision "arbitrary and capricious" where it was based on a failure to comply with a resolution "which did not exist when [the application] was filed, when in fact

the application was sufficient to establish eligibility under [the] standards at the time it was received”).¹

Take first the cases where CMS says Caring Hearts provided care to individuals who weren't homebound. Here's a typical example, involving a patient known in our record as L.Sm. At the time Caring Hearts provided L.Sm. with home health services he was 85 years old, weighed 352 pounds, and suffered from diabetes, high blood pressure, and a host of other ailments. By all accounts he could not easily walk 20 feet and, while he sometimes used a walker or cane, he more or less “lived” in a wheelchair. Despite these documented facts, CMS adopted the ALJ's judgment that L.Sm. wasn't homebound and Caring Hearts could not have reasonably thought otherwise. In support of its conclusion the agency reasoned that “the evidence does not establish . . . that leaving his home would require considerable and taxing effort.” ALJ Op. at 46 (App. Vol. 2 at 338). And it's surely true that CMS's *current* regulations state that for a patient to qualify as homebound he must “normal[ly]” be unable “to leave home” even

¹ You might wonder if there's a more direct route to the same destination. For if an agency's refusal to recognize an affirmative defense to a penalty is unlawful because the agency relied on the wrong law, you might ask whether the agency's decision to issue the penalty in the first instance was also impermissible for exactly the same reason. But while this argument might occur to you, it is not one Caring Hearts presents. And whether a more direct road lies unused before us doesn't much matter if the more circuitous one the petitioner walks leads to the same place. Neither given the efficacy of the path we consider here do we have to consider the various other paths toward reversal Caring Hearts offers in this appeal.

with a wheelchair and any attempt to leave home must also “require a considerable and taxing effort.” Medicare Benefit Policy Manual (MBPM), Pub. No. 100-02, Ch. 7, § 30.1.1 (Rev. 208, May 11, 2015). For purposes of this appeal, too, we spot CMS the possibility (without in any way deciding) that L.Sm. would fail to qualify as homebound within the meaning of this narrow definition because (again for argument’s sake only) we accept the possibility that he was often able to leave home in his wheelchair without “considerable and taxing effort.”

The trouble is that CMS’s current regulations defining who qualifies as homebound look little like the regulations in effect when Caring Hearts provided care to L.Sm. in 2008. Back then, CMS’s regulations indicated that, “[g]enerally speaking, a patient will be considered homebound if they [sic] have a condition due to an illness or injury that restricts their ability to leave the place of residence except with the aid of: supportive devices such as crutches, canes, wheelchairs, and walkers” MBPM, Ch. 7, § 30.1.1 (Rev. 1, Oct. 1, 2003). So rather than asking whether a patient could leave home *with* a supportive device, the regulations back then seemed to ask whether a patient could leave home *without* one. And it seems pretty clear from the record before us that L.Sm. qualified as homebound under this more generous definition. After all, no one disputes that L.Sm. was unable to leave his house without some kind of “supportive device,” for he “lived” in his wheelchair and struggled to walk even 20 feet. Indeed, it

seems CMS issued its current regulations narrowing the class of persons who qualify as homebound specifically to preclude relief in future cases exactly like this one. *See* Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Change Request 8444 (Oct. 18, 2013) (explaining the new regulations were expressly designed to “clarif[y] the definition” of what it means to be homebound and remove “vague terms” like “generally speaking” in an effort to “promote . . . clearer [one might add, stricter] enforcement”).

Of course, CMS’s regulations don’t exist in a vacuum. There’s also the statute they purport to interpret. And CMS suggests that, whatever its relevant regulations said at the time, the statute’s plain terms also and independently alerted Caring Hearts to the impropriety of its care for patients like L.Sm. The relevant statutory language provides that

an individual shall be considered to be “confined to his home” if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home”, the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

42 U.S.C. § 1395f(a).

But even looking to this language we don’t see how CMS could have rationally concluded that Caring Hearts knew or should have known individuals

like L.Sm. didn't qualify as homebound in 2008. To be sure, CMS points us to the second sentence and argues that, to establish a patient is homebound, a provider must prove both (1) that a patient "normal[ly]" cannot leave home even with a supportive device and (2) that "leaving home requires a considerable and taxing effort." Just as its current regulations require. The trouble is, without the added gloss of CMS's current regulations, this reading of the statute is far from obvious or obviously correct. Indeed, there exists another entirely plausible reading of the statute, one that seems entirely consistent with CMS's own earlier regulations on the subject and one that Caring Hearts says (without dispute) it held when those regulations controlled and it issued its services. Under this reading it is the first sentence that does the real work — providing that someone like L.Sm. "shall be considered" homebound because he has a condition that restricts his ability to leave home "except with" (but for) a wheelchair or some other form of assistance. Under this reading, the second sentence adds only hortatory guidance about the sorts of people who will generally qualify as homebound under the first sentence, but it doesn't narrow the universe of people encompassed by the first sentence.

More than a few clues seem to support the reasonableness of Caring Hearts's reading. Not least of course the fact that CMS itself seemed to take this very view at the time. But even beyond that, there's a good deal of textual evidence in the statute itself. Consider the verbs in the two sentences. The first

sentence says a person “shall be” considered homebound if he or she cannot leave without supportive assistance. Meanwhile, the second sentence says that certain additional clues “should be” present, suggesting that the second sentence provides useful but not necessarily dispositive tests for homebound status. Next consider the fact that the first sentence suggests individuals shall be homebound *either* because they need to use supportive devices to leave *or* because leaving is medically contraindicated (because of, say, the risk of infection). In this way the statute again seems to contemplate the possibility that some persons will be considered homebound even if they don’t use supportive devices and can leave the home without considerable or taxing effort. And consider, too, the statute’s use of the term “condition.” The first sentence says the patient must suffer from a “condition” that restricts his or her ability to leave home “except with” (but for) the use of a supportive device. Assuming (as we usually do) that Congress means the same thing when using the same word in adjoining sentences, *see, e.g., Atl. Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433 (1932), the second sentence’s use of the term “condition” may be best read as meaning that the patient’s condition normally renders him unable to leave home without considerable and taxing effort *but for* his supportive device.

The statutory sentences that follow these first two seem to provide yet further support for Caring Hearts’s (and CMS’s erstwhile) understanding of the law. They indicate that

[a]ny absence of an individual from the home attributable to the need to receive health care treatment, including regular absences . . . shall not disqualify an individual from being considered to be “confined to his home.” Any other absence of an individual from the home shall not so disqualify an individual if the absence is . . . of relatively short duration. [And] . . . any absence for the purpose of attending a religious service shall be deemed to be an absence of . . . short duration.

42 U.S.C. § 1395f(a). Notice that each of these sentences uses the more mandatory “shall” instead of the more hortatory “should,” suggesting that Congress well knew the difference when it chose in the second sentence alone to use the less emphatic verb. And notice how each of these sentences seems to undercut, too, the notion that a patient must “normally” be unable to leave the home even with the use of a supportive device. After all, the third and fifth sentences permit patients to leave every day for unlimited durations for certain purposes (health care and religious services). And the fourth permits an unlimited number of departures from the home for any purpose so long as the absences are of “relatively short duration.”

In saying as much as we do about the statute’s terms we take care to stress what we haven’t said. We are not asked to pass upon the question whether the statute unambiguously favors Caring Hearts and in that way forecloses CMS’s recent regulations in a *Chevron* step one proceeding. Neither are we asked to decide whether, if statutorily ambiguous, CMS’s recent regulations would qualify as reasonable interpretations of the statute in a *Chevron* step two proceeding. It may well be that our reasoning here would be relevant in deciding those

questions, but the question we face today is more pedestrian and so is our holding. Here we're only asked to pass on CMS's conclusion that Caring Hearts knew or reasonably should've known its services were wrongly rendered in light of the statute's plain terms. And given the many textual clues supporting Caring Hearts's reading of the law, along with CMS's own then-controlling interpretation, we just don't see how we might sustain the agency's decision.

In briefing before us CMS adds at this point one more point. The agency notes that in litigation long ago it advocated an interpretation of the homebound statute very similar to the one its regulations now adopt. *See Labossiere v. Sec'y of HHS*, No. 90-150, 1991 WL 531922, at *4-5 (D. Vt. July 24, 1991). But the CMS's order under review didn't cite *Labossiere* or suggest it placed Caring Hearts on notice of the impropriety of its understanding of the statute. And of course in administrative law the post-hoc rationalizations of counsel may not provide grounds for sustaining an agency decision, only those grounds cited in the agency's order may. *See SEC v. Chenery Corp.*, 318 U.S. 80, 94-95 (1943). Besides, there may be a good reason why CMS made no mention of the case in its order: under its own regulations its prior litigation positions are generally insufficient to put a provider on notice of what is and isn't compensable. *See* 42 C.F.R. § 411.406. Neither, for that matter, does it appear CMS's position in litigation always followed a straight course: as late as 2009 the agency seems to have endorsed an approach (in at least one case) closer to the one advocated by

Caring Hearts and found in the agency's prior regulations than the one the agency's regulations now pursue. *See Quality Home Health Servs., Inc.*, Medicare Appeals Council (Sept. 14, 2009).

That still leaves the second group of cases the agency addressed. Here CMS accepted or assumed that the patients Caring Hearts served were homebound but held that the firm couldn't show the physical therapy or skilled nursing services it provided were "reasonable and necessary." An illustrative patient here might be L.D. She was a 71-year-old woman with diabetes, degenerative joint disease, chronic obstructive pulmonary disease, and uncontrolled pain in her lower back, hips, and right leg. She experienced fatigue and weakness after walking 15 feet. By everyone's admission, doctors prescribed physical therapy to increase her strength and decrease her pain. And the record shows, too, that, thanks to the physical therapy, L.D. increased her ability to walk by 50 percent and experienced a decrease in her reported back pain from a 6 out of 10 to a 3 or 4 out of 10. Even so, CMS held, Caring Hearts couldn't show that its physical therapy services were reasonable and necessary because its documentation was insufficient. The company's "notes" didn't contain details of progress made by L.D. "at each visit" and didn't contain enough "quantitative" data. *See CMS Op.* at 26 (App. Vol. 2 at 249).

To support its conclusion that Caring Hearts knew or should've known its documentation was insufficient, CMS doesn't cite or rest on the relevant statutory

language as it did earlier on the homebound question. And it's understandable why. The relevant statute states simply that charges must be "reasonable and necessary," without offering providers any guidance as to what might and might not qualify, let alone indicating what sort of documentation might be demanded. *See* 42 U.S.C. § 1395y(a)(1)(A). Instead, to support its decision denying Caring Hearts relief when it comes to this class of cases, the agency relies only on regulations it issued under the statute's auspices as evidence the company should've known its paperwork wasn't enough. In particular, when it comes to physical therapy services the agency repeatedly cites and relies on 42 C.F.R. § 409.44(c)(2)(ii)(H)(4), though as its opinion progresses it seems to shorten its citations for convenience's sake, and by the time it reaches L.D. it speaks in seeming shorthand of § 409.44(c). *Compare* CMS Op. at 19-20 (App. Vol. 2 at 242-43), *with id.* at 22, 26-27 (App. Vol. 2 at 245, 249-50).

But here again the agency appears unfamiliar with its own regulations. Back in 2008 there wasn't any § 409.44(c)(2)(ii)(H)(4). In fact, there never was and still isn't. As best we can tell, the agency's opinion means to rely on and direct us to 42 C.F.R. § 409.44(c)(2)(i)(H)(4). But that provision was adopted in November 2010, well after the events in question, and thanks to still more regulatory activity it appears today not as (H)(4) but (F)(4). *See* 42 C.F.R. § 409.44 (2015). At any rate, as adopted in November 2010 the regulation surely did require physical therapy providers to supply "[d]ocumentation of objective

evidence or clinically supportable statements of expectation that the patient can continue to progress toward the treatment goals and is responding to therapy” Just the sort of thing the agency argues Caring Hearts failed to supply. But here once more even the agency doesn’t suggest this regulation bore retroactive effect. 75 Fed. Reg. 70372, 70461-63 (Nov. 17, 2010). And back in 2008, when Caring Hearts provided its services, § 409.44(c)(2)(i) entailed no subdivisions, let alone spun out 22 separate enumerated subparagraphs all the way to (H)(4) and beyond. Instead, back then § 409.44(c)(2)(i) consisted of just one paragraph that spoke not at all of documentation and said only this: “services must be considered under the accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary’s condition.” Rather than requiring extensive paperwork, then, the regulation focused on whether the provider’s physical therapy services were consistent with accepted contemporary standards of medical practice. And that’s a condition no one disputes Caring Hearts can satisfy: nowhere does CMS’s opinion suggest the doctors who prescribed the care in this case defied accepted medical standards.

Now we imagine CMS might reply along these lines. As we’ve seen, while the agency cites repeatedly to § 409.44(c)(ii) — really (i) — (H)(4), as its opinion progresses it refers instead to § 409.44(c) alone. And perhaps you might wonder whether this change in citation should be taken as directing us to some other subsection besides (H)(4), one that may have actually existed in 2008. But try as

we might we cannot see how that might be the case. Each time CMS cites § 409.44(c) it does so (only) in the context of complaining about Caring Hearts's documentation, the very subject of (H)(4). In this light, it really does seem CMS's citations get shorter out of convenience rather than to convey a difference of meaning. Certainly, too, if CMS citations do mean to refer to some other part of § 409.44(c) that existed in 2008, we're left guessing what part that might be and we may not, of course, affirm an agency by guess. *See Chenery*, 318 U.S. at 94-95. Neither does even CMS's brief in this court offer any such possibility. Much to the contrary and like the agency's order itself, the agency's briefing on appeal struggles to keep up with the right regulations, repeatedly citing and quoting and relying on the 2010 provisions and (H)(4) just as its order did. *See* Br. of Appellee at 37-38, 44, 49. In fact, CMS's brief even goes so far as to quote the 2010 language of (H)(4) with a mistaken parenthetical date reading "(2008)." *See id.* at 38.

The same story repeats itself when it comes to the skilled nursing services Caring Hearts supplied. Once more, the agency based its denial of coverage for most patients for want of sufficient documentation, stating that the skilled nursing "notes" did not show that the beneficiaries "required or received the type of services described by the regulations and applicable policy guidance." CMS Op. at 27 (App. Vol. 2 at 250). And once more, it is surely true that CMS's *current* regulations demand extensive documentation for every skilled nursing visit,

stating that “the home health record *must* document the rationale that demonstrates that there is a reasonable potential for a future complication or acute episode.” MBPM, Ch. 7, § 40.1.2.1 (Rev. 179, Jan. 14, 2014) (emphasis added); *see also id.* § 40.1.1. But once more, CMS does not suggest that these regulations bear retroactive effect. And, once more, back in 2008 when the services were provided the agency’s regulations were very different and far less demanding, requiring the provider to show merely that “the patient’s medical history *may* support the likelihood of a future complication or acute episode,” MBPM, Ch. 7, § 40.1.2.1 (Rev. 1, Oct. 1, 2003) (emphasis added), and that the skilled nursing services provided were “reasonably expected to be appropriate treatment,” *id.* § 40.1.1. So once again the focus was less on exacting documentation than on whether the services provided were consistent with prevailing medical practice. And once again the agency supplies little reason to think the services provided here were not at least that. *See* Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., Change Request 8458 (Jan. 14, 2014) (acknowledging that the agency’s new documentation requirements “introduce additional guidance in this area”).

At this point just one last wrinkle remains to unfold. In closing, CMS suggests that § 1395pp allows it to relieve a provider of liability only when the dispute concerns whether the provider’s services were “reasonable and necessary” or when “custodial care” is at issue. *See* Br. of Appellee at 58 (citing 42 U.S.C.

§ 1395pp(a)(1) and *id.* §§ 1395y(a)(1)(A), (9)). According to CMS, § 1395pp “clearly do[es] not” allow it to forgive a provider’s putative errors in determining whether a patient qualifies as homebound. *Id.*; *see also id.* at 13. So for at least those cases where the homebound question is at issue, CMS says, it simply cannot provide relief.

But here too it seems CMS is unfamiliar with its own law. For while § 1395pp begins by affording the agency a power to forgive mistakes relating to § 1395y(a)(1) (“reasonable and necessary”) and § 1395y(a)(9) (“custodial care”), the statute proceeds to afford the agency a parallel power for mistakes concerning matters “described in subsection (g) of this section.” 42 U.S.C. § 1395pp(a)(1). And that subsection expressly includes errors relating to whether “the individual . . . is or was not confined to his home.” *Id.* § 1395pp(g)(1)(A) (citing *id.* §§ 1395f(a)(2)(C) and 1395n(a)(2)(A)). Now maybe the agency’s confusion stems from the fact that the statute at one time *didn’t* allow CMS to address errors involving homebound status. But that was thirty years ago and it does seem curious that the agency in this case proves so sensitive to its past law when it doesn’t matter but not when it does. *See* Pub. L. No. 99-509, 100 Stat. 1991, 1991-92 (1986) (extending waiver of liability provisions to homebound denials).

This case has taken us to a strange world where the government itself — the very “expert” agency responsible for promulgating the “law” no less — seems unable to keep pace with its own frenetic lawmaking. A world Madison worried

about long ago, a world in which the laws are “so voluminous they cannot be read” and constitutional norms of due process, fair notice, and even the separation of powers seem very much at stake. But whatever else one might say about our visit to this place, one thing seems to us certain: an agency decision that loses track of its own controlling regulations and applies the wrong rules in order to penalize private citizens can never stand. Indeed, we would not be surprised if — should Caring Hearts bring an otherwise eligible application for costs and fees under the Equal Access to Justice Act, 28 U.S.C. § 2412(d) — CMS were to accept on remand that its positions in this case were not “substantially justified.” *See Gatson v. Bowen*, 854 F.2d 379, 380-81 (10th Cir. 1988); *Estate of Smith v. O’Halloran*, 930 F.2d 1496, 1501-02 (10th Cir. 1991). The district court’s order affirming the agency’s denial of relief under § 1395pp is vacated and this matter is remanded to the district court with instructions to return the case to the agency promptly for further proceedings consistent with this opinion.