United States Court of Appeals
For the First Circuit

No. 14-1557

MAINE MEDICAL CENTER,

Plaintiff, Appellant,

v.

SYLVIA M. BURWELL, Secretary,
U.S. Department of Health and Human Services,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MAINE

[Hon. John A. Woodcock, Jr., U.S. District Judge]

Before

Lynch, Chief Judge,
Torruella and Kayatta, Circuit Judges.

William H. Stiles, with whom Benjamin E. Ford and Verrill Dana, LLP were on brief, for appellant.

Jeffrey Clair, Attorney, U.S. Department of Justice, Civil Division, with whom Thomas E. Delahanty, II, United States Attorney, Jill L. Steinberg, Special Assistant United States Attorney, Assistant Regional Counsel, District of Maine, John Osborn, Assistant United States Attorney, William B. Schultz, General Counsel, U.S. Department of Health and Human Services, and Nancy S. Nemon, Chief Counsel, Region I, U.S. Department of Health and Human Services, were on brief, for appellee.

January 5, 2015

LYNCH, Chief Judge. Maine Medical Center ("Maine Medical") challenges a district court ruling upholding the decision of the Secretary for the Department of Health and Human Services ("HHS") denying Maine Medical's claim for partial federal reimbursement of "bad debt" for two fiscal years. Maine Med. Ctr. v. Sebelius, No. 2:13-CV-00118-JAW, 2014 WL 1234173, at *1 (D. Me. Mar. 25, 2014). A "bad debt" is an amount considered uncollectible arising from covered medical services that may be eligible for federal reimbursement under certain conditions. 42 C.F.R. § 413.89. The bad debt at issue arose from services that Maine Medical provided to Medicare/Medicaid "dual-eligible" patients during fiscal years 2002 and 2003. The Secretary had required a particular form of proof, a state-issued remittance advice ("RA"), which Maine Medical had not acquired from Maine's Medicaid program, MaineCare. The parties dispute both the difficulty of obtaining such proof and the adequacy of the alternative documentation the hospital offered.

Two legal issues are presented on appeal. The first concerns the appropriate level of deference to afford the decision of the Secretary as to the adequacy of Maine Medical's proof in this case. The second concerns whether, under the appropriate standard, the Secretary's decision denying reimbursement was arbitrary and capricious, an abuse of discretion, otherwise contrary to the law, or unsupported by substantial evidence.

See Visiting Nurse Ass'n Gregoria Auffant, Inc. v. Thompson, 447 F.3d 68, 72 (1st Cir. 2006) (citing 5 U.S.C. § 706(2)).

After careful consideration of the record, we affirm the Secretary's decision. It is not arbitrary and capricious for the Secretary to demand that Maine Medical provide documentation from the State, including documentation confirming the identity of Medicaid-eligible beneficiaries and qualified Medicare beneficiaries, the amount that is the State's to pay, and the State's refusal to pay. Nor is it arbitrary and capricious, on the facts of this case, to deny Maine Medical's reimbursement claims that were unsupported by such documentation. The consequence of this decision is that Maine Medical may need to absorb roughly $3 million of bad debt; it will not receive reimbursement from the Secretary unless it succeeds in obtaining the RAs. Whether Maine Medical has any recourse against the State of Maine is not before us.

I.

Maine Medical, a non-profit hospital in Portland, Maine, provides medical services to both Medicare and Medicaid recipients. Some of these patients are "dual-eligible," that is, indigent patients who are covered by both Medicare, a federal health insurance program, and the state-administered Medicaid insurance

program, MaineCare.[1] Medicare and MaineCare share responsibility for paying the so-called "crossover claims" for services provided to these dual-eligible patients, with Medicare the primary payer and MaineCare the secondary payer responsible for covering coinsurance and copayments.

Any amount remaining that is both unpaid by MaineCare and for which MaineCare is not liable is generally considered a "bad debt," an "amount[] considered to be uncollectible" for covered services. 42 C.F.R. § 413.89(b)(1), (e), & (h);[2] see Provider Reimbursement Manual ("PRM") § 322. Medicare partially reimburses bad debt, from dual-eligible and non-dual-eligible[3] patients alike, provided that reimbursement claims are adequately documented and are supported by evidence demonstrating that the medical provider

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[1] Medicare is a national health insurance program for the elderly and disabled that uses federal funding to, among other things, reimburse providers for reasonable costs of services. 42 U.S.C. §§ 1395 et seq.; see also South Shore Hosp., Inc. v. Thompson, 308 F.3d 91, 95 (1st Cir. 2002) (describing the statutory scheme); Grossmont Hosp. Corp. v. Sebelius, 903 F. Supp. 2d 39, 43 (D.D.C. 2012) (same).

Medicaid is a "cooperative federal-state program that finances medical care for the poor, regardless of age." Grossmont, 903 F. Supp. 2d at 43-44 (citing 42 U.S.C. §§ 1396 et seq.). States can both elect to participate in Medicaid or not, and decide the nature of coverage, subject to approval by the Centers for Medicaid and Medicare Services (CMS). See id.

[2] 42 C.F.R. § 413.89 was formerly designated as 42 C.F.R. § 413.80. See 69 Fed. Reg. 49,254 (Aug. 11, 2004). The relevant text remains unchanged.

[3] Non-dual-eligible patients are Medicare patients who are not eligible for Medicaid.

made "reasonable collection efforts" but that the amount is "actually uncollectible."[4] 42 C.F.R. § 413.89(e) (stating regulatory requirements for allowable bad debt); see also id. § 413.89(a) & (h) (governing reimbursement of bad debt).

A. Collection Process

HHS has long interpreted "reasonable collection efforts" to require billing those responsible for payment. See, e.g., Cmty. Hosp. of the Monterey Peninsula v. Thompson (Monterey), 323 F.3d 782, 796, 798 (9th Cir. 2003) (discussing the policy's history and enforcement); see also PRM §§ 310, 312, 322 (explaining the requisite collection efforts).[5] Where patients are also eligible for Medicaid, the Secretary has historically required medical providers to submit proof that it billed the relevant Medicaid program but was denied payment. See Monterey, 323 F.3d at 796. This proof usually takes the form of an RA issued by the Medicaid

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[4] Bad debts from certain sources are reimbursable to ensure the costs of treating Medicare beneficiaries are not shifted to non-Medicare beneficiaries. 42 U.S.C. § 1395x(v)(1)(A) (prohibiting cost-shifting); 42 C.F.R. § 413.89(d) (same).

[5] PRM § 310 explains that a provider's "reasonable collection efforts" to obtain deductible and coinsurance amounts "must be similar" to efforts to collect from non-Medicare patients, including "the issuance of a bill . . . to the party responsible" and "other actions such as subsequent billings."

PRM § 312 waives the PRM § 310 procedures for indigent patients for whom "no source other than the patient would be legally responsible for the . . . bill."

PRM § 322 explains that amounts the state Medicaid program "is not obligated to pay can be included as bad debt . . . provided that the requirements of § 312 or, if applicable, § 310 are met."

program, reflecting the patient's eligibility, and payment (or nonpayment). See, e.g., PRM-II § 1102.3L (Rev. 4) (assuming that satisfaction of the Billing Requirement will be demonstrated through RAs). These two requirements -- which we denominate the "Billing Requirement" and the "RA Requirement" -- try to ensure that the claimed amounts are in fact bad debt not covered by the relevant Medicaid program.

Some version of this "must-bill policy" has generally been enforced.[6] From 1995 to 2003, however, the Secretary's manual permitted providers to substantiate crossover bad debt by submitting alternative documentation "[i]n lieu of billing." See PRM-II § 1102.3L (Rev. 4). In March 2003, the Ninth Circuit held that this waiver of the Billing Requirement marked a change in bad debt reimbursement policy, violating the Congressional moratorium on such changes, and so could not be enforced. See Monterey, 323 F.3d at 798-99 & n.9. In response, the Secretary removed the offending language from the PRM, effective October 1, 2003. See

[6] It is not clear that the consistently enforced version of the "must-bill policy" includes both the Billing Requirement and the RA Requirement. Cf. Grossmont, 903 F. Supp. 2d at 49, 52 (recognizing the "must-bill policy" as requiring billing, and discussing a distinct "'mandatory State determination' policy"). The now-repealed language of PRM-II § 1102.3L suggests that HHS assumed that billing the state Medicaid program would generate a Medicaid RA, such that satisfaction of the Billing Requirement entailed satisfaction of the RA Requirement. See PRM-II § 1102.3L (Rev. 4) ("Evidence of [crossover] bad debt . . . may include a copy of the Medicaid [RA] . . . . However, it may not be necessary for a provider to actually bill the Medicaid program . . . ."). To avoid ambiguity, we refer to the two requirements separately.

Change Request 2796 at *1, 3. It is not clear that the Secretary ever permitted broad use of this alternative document billing provision. Compare Transcript of Proceedings at 142-43, Maine Med. Ctr., PRRB Dec. No. 2013-D3 (Nov. 29, 2011) (Nos. 06-1318, 07-1386) ("[T]his Intermediary never followed the instructions . . . . [T]hey always required Medicaid [RAs]."), and Monterey, 323 F.3d at 796-99 (suggesting not), with Cove Assocs. Joint Venture v. Sebelius, 848 F. Supp. 2d 13, 28-29 (D.D.C. 2012) (providing an example of a case where alternative documentation had been permitted). Regardless, the Secretary provided a grace period, issuing a memorandum instructing the Intermediaries that process claims to "hold harmless" providers who had relied on the provision in settling claims before January 1, 2004. See JSM-370. That memorandum, known as JSM-370, articulated both the Billing Requirement and the RA Requirement. See id. ("[I]n those instances where the state owes none or only a portion . . . , the unpaid liability for the bad debt is not reimbursable . . . until the provider bills the State, and the State refuses payment (with a State Remittance Advice)."). Maine Medical did not rely on this grace period for the alternative documentation.

B. Maine's Process

The Centers for Medicaid and Medicare Services (CMS), acting on behalf of the Secretary, processes crossover claims from Maine pursuant to a trading partner agreement with MaineCare. See

Grossmont Hosp. Corp. v. Sebelius, 903 F. Supp. 2d 39, 43-45 (D.D.C. 2012) (citing 42 U.S.C. §§ 1395h, 1395u). Under the agreement, medical providers like Maine Medical submit crossover claims to an Intermediary, a private-sector contractor that processes the claims for CMS. The Intermediary (1) pays the Medicare portion as primary payer, and (2) identifies and aggregates crossover claims, which (3) it submits -- i.e., "bills" -- to MaineCare on a weekly basis. Ordinarily, MaineCare then processes these billed claims, issuing RAs that confirm receipt of the billed claims and identify MaineCare's obligations for each claim. Providers use these RAs to substantiate their bad debt reimbursement claims for amounts exceeding MaineCare's obligations.

For FY 2002 and FY 2003, the cost years at issue, Maine Medical submitted its crossover claims to the Intermediary. The Intermediary then submitted these claims to MaineCare, pursuant to the trading partner agreement.[7] But from November 15, 2001 to August 21, 2003, MaineCare failed to process these crossover claims and to issue RAs for them due to an "anomaly of unknown origin" in MaineCare's claim management system ("MMIS"). Maine Med. Ctr., 2014 WL 1234173 at *4. Maine Medical does not appear to have

[7] The parties do not meaningfully dispute that Maine Medical submitted these crossover claims to the Intermediary, or that the Intermediary submitted these claims to MaineCare, pursuant to the trading partner agreement. We would reach the same outcome in any event: if Maine Medical failed to submit its claims to the Intermediary, then there would be absolutely no evidence that it made "reasonable collection efforts."

sought the missing RAs from MaineCare or taken other steps to rectify the problem during this period of over twenty months.

The MMIS program continued to encounter technical difficulties, and by the end of 2004 was unable to process any claims for anyone. In November 2004, the Maine Hospital Association, of which Maine Medical is a member, urged the Maine Department of Health and Human Services ("Maine DHHS") to adopt regulations requiring the issuance of RAs within sixty days after the close of the hospital fiscal year. But Maine DHHS denied the request as outside the scope of the rulemaking because it concerned reports that "d[id] not affect Medicaid reimbursement." MMIS was taken offline in January 2005, and replaced by a new system, MeCMS. The new system still encountered difficulties, which Maine is working to resolve.[8]

Despite these problems, Maine Medical does not appear to have taken any individual action to acquire the missing RAs until early 2005, three years after the problem began in November 2001

[8] Evidence in the record suggests that Maine is working both to resolve the technological glitch and to arrive at settlements with providers. For example, MaineCare has again authorized Maine Medical's CPA in this case, Roland Mercier, on behalf of other clients, to work with MaineCare Eligibility files and "to perform claim level detail to MaineCare eligibility verification for Maine Providers who cannot verify MaineCare eligibility prior to September 1, 2010." Maine DHHS granted the authorization because Maine DHHS had "recently received data requests from Maine Providers regarding verification of MaineCare Eligibility" but did "not have the time or resources to dedicate to respond to these individual claim level detail data requests."

and over a year after the relevant cost years concluded in September 2003. At that time, Maine Medical's CPA, Roland Mercier, "request[ed] assistance [from MaineCare] . . . for th[e] discrepancy in crossover processing for [Maine Medical]." According to Mercier, MaineCare's response suggested that between the uncertainty of the cause and ongoing difficulties with the MeCMS, "it was apparent that this older problem could not be remediated [sic] with the new environment." Instead, Mercier sought and received permission from MaineCare officials to work with the Muskie Institute, a "quasi-state agency that assists MaineCare with certain functions and has MaineCare eligibility data," to develop alternative documentation.

Mercier submitted the bad debt logs and alternative documentation to the Intermediary in July 2005. But the CMS Central Office rejected Mercier's alternative methodology for compiling crossover bad debts, citing the Congressional moratorium on CMS's bad debt policy. When informing Mercier of this decision, the Intermediary lamented that "[i]t is unfortunate that [Mercier] did not present his methodology to our office prior to us being in the field for [Maine Medical's] audit, so that an earlier decision could have been obtained from CMS and communicated to [Maine Medical]."

Mercier again pressed the Intermediary in early 2006, and the Intermediary again iterated its position that RAs would be

required and that bad debt reimbursement claims for FY 2002 and FY 2003 would be rejected without them. It added that Mercier's claim that "the State cannot produce these [RAs] contradicts" what state representatives had told them. The Intermediary then denied Maine Medical's reimbursement claims for crossover bad debt from FY 2002 and FY 2003, totaling $2,859,083, because the bad debt reimbursement claims were not substantiated by the requisite RAs denying payment.

A week later, on March 22, 2006, Mercier finally contacted MaineCare to request the missing RAs for FY 2002 and FY 2003. But MaineCare declined to issue them. The claims had never been processed in MaineCare's system, and so MaineCare could not "at this point verify that [the claims] were ever received as claimed by the Medicare intermediary." Similarly, because the claims were never processed, an RA was never issued "and in addition, obviously cannot now be generated" two to four years after the fact. "[I]n an effort to resolve [the] issue" between Maine Medical and Medicare auditors, the Director of Maine DHHS emphasized that he was "completely confident in the analysis of [the Muskie Institute] . . . and believe[d] it to be the best available solution to this problem." In suggesting this solution, Maine DHHS did not deny or otherwise specify MaineCare's liability for the claims, or confirm that, had they been processed, MaineCare would have denied them completely.

The Muskie Institute had used MaineCare's eligibility data to verify MaineCare eligibility for patients on crossover listings from FY 2002 and FY 2003. But the alternative documentation produced omitted two important types of information ordinarily present on RAs. First, the alternative documentation failed to distinguish between crossover claims for Qualified Medicare Beneficiaries ("QMB") and crossover claims for non-Qualified Medicare Beneficiaries ("non-QMB").[9] Second, the documentation did not include a claim-by-claim analysis of MaineCare's obligations because the Muskie Institute assumed that MaineCare's payment would have been $0 under a MaineCare regulation eliminating payment for all crossover claims that had been in effect during the relevant period.[10] But the parties vigorously dispute whether MaineCare would have, or lawfully could have, denied all reimbursement for Maine Medical's FY 2002 and FY 2003 crossover claims. In particular, the Secretary argues that states cannot escape at least some liability for QMB crossover claims.

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[9] To the best of our understanding, the verification of Medicaid eligibility for all crossover claims, QMB and non-QMB alike, is important to providers because dual-eligible patients are presumed indigent under PRM § 312, relieving the provider of the need to bill the patient for the outstanding debt. The distinction between QMB and non-QMB patients is important, however, because while the state could eliminate payment for non-QMB crossover claims, it cannot escape at least some liability for QMB crossover claims.

[10] MaineCare adopted this regulation on July 1, 1999, and it continued through 2006. According to Maine Medical, MaineCare consistently applied this policy to crossover claims.

See 42 U.S.C. § 1396a(a)(10)(E)(i) (requiring state plans to provide for Medicare cost-sharing for QMBs); see also PRM § 322 (stating that amounts the state is statutorily obligated to pay are "not allowable as bad debts"). Yet the alternative documentation did not identify any of these QMB crossover claims, or calculate the extent of the resulting obligation.

C. Procedural History

Despite these shortcomings, Maine Medical used this alternative documentation to appeal the Intermediary's decision denying reimbursement to the Medicare Provider Reimbursement Review Board ("PRRB"). The PRRB ruled in favor of Maine Medical, finding that there is not an "absolute requirement" to bill state Medicaid programs and obtain a Medicaid RA before claiming crossover bad debt. The PRRB reasoned that neither the regulation (42 C.F.R. § 413.89(e)) nor the relevant manual provisions (PRM §§ 308, 310, 312, and 322) contain a Billing Requirement, but rather require only "that a provider make reasonable collection efforts and apply sound business judgment to determine that the debt was actually uncollectible when claimed." The PRRB relied in part on another manual provision, PRM-II § 1102.3L, which expressly permitted alternative documentation in lieu of billing and which was in effect during the relevant cost years. It accorded JSM-370's articulation of the RA Requirement "little weight" because it

neither "set policy, nor convey[ed] new instructions or clarification of existing requirements to intermediaries."

The CMS Administrator, on the Secretary's behalf, reversed, reasoning that the PRRB had been incorrect to discount JSM-370, because it restated HHS's "longstanding" must-bill policy including the RA Requirement. The decision then proceeded to make what we interpret to be two findings.

First, it appeared to have applied a per se RA Requirement (regardless of circumstances), finding that "the failure to produce the Medicaid [RAs] represents a failure on the part of [Maine Medical] to meet the necessary criteria for Medicare payment . . . ." The Secretary also said: "[R]egardless of any omissions by the State to provide the Medicaid [RAs], [Maine Medical] was required to bill for and produce the [RA] before including crossover bad debt claims on its cost reports."

Second, it found that Maine Medical's attempt to provide alternative documentation did not demonstrate, in any event, that the regulatory requirements of 42 C.F.R. § 413.89(e) had been met. The alternative documentation assumed that MaineCare liability would have been zero. But this was based on Chapter III, Section 45 from the Maine Medicaid Manual that purported to "eliminate" payments for crossover claims. The difficulty is that Section 1905(p)(3) of the Social Security Act imposes cost-sharing on states for Qualified Medicare Beneficiaries. See 42 U.S.C.

§ 1396a(a)(10)(E)(i). While a state may effectively limit liability by capping Medicaid rates below Medicare rates, it may not decline payment altogether.[11] The Administrator explained why this makes obtaining a determination from the state necessary:

> [T]he State maintains the most current and accurate information to determine if the beneficiary is dually eligible at the time of service, and the State's liability for any unpaid deductible and coinsurance amounts through the State's issuance of a [RA] after being billed by the provider. Regardless of a State's pronouncements, only through billing and receiving a State Medicaid [RA] can a provider demonstrate that a State is or is not liable for any portion thereof.

Because the State is required to "process the bills or claims," providers may not "write-off a Medicare bad debt as worthless

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[11] PRM § 322, Medicare Bad Debts under State Welfare Programs, explains that:

> Where the State is obligated either by statute or under the terms of its plan to pay all, or any part, of the Medicare deductible or coinsurance amounts, those amounts are not allowable as bad debts under Medicare. Any portion of such deductible or coinsurance amounts that the State is not obligated to pay can be included as a bad debt under Medicare, provided that the requirements of § 312 or, if applicable, § 310 are met.
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> In some instances, the State has an obligation to pay, but either does not pay anything or pays only part of the deductible or coinsurance because of a State payment "ceiling." For example, assume that a State pays a maximum of $42.50 per day for SNF services and the provider's cost is $60.00 a day. The coinsurance is $32.50 a day so that Medicare pays $27.50 ($60.00 less $32.50). In this case, the State limits its payment towards the coinsurance to $15.00 ($42.50 less $27.50). In these situations, any portion of the deductible or coinsurance that the State does not pay that remains unpaid by the patient, can be included as a bad debt under Medicare . . . .

without first billing and receiving the [RA] from the State," even in cases where the "provider has calculated that the State has no liability." As the Administrator explained, this is consistent with the regulation in 42 C.F.R. § 413.89(f) governing "the timing of when a bad debt can be claimed consistent with the general Medicare documentation requirements." Section 413.89(f) provides that "amounts uncollectible from specific beneficiaries are to be charged off as bad debts in the accounting period in which the accounts are deemed to be worthless." That is, a provider may not claim a bad debt until the account has been deemed worthless, and, because the state has the final word on whether it will pay, a provider cannot deem an account's crossover claims worthless until it has affirmatively been denied payment from the state.[12]

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[12] The Secretary's decision explained that "[t]he basic effect of [42 C.F.R. § 413.89 and the PRM § 314] is to bar providers from reporting bad debts on an accrual accounting basis." Palms of Pasadena Hosp. v. Sullivan, 932 F.2d 982, 983-84 (D.C. Cir. 1991) (citing 42 C.F.R. § 413.80). Instead, 42 C.F.R. § 413.89 requires that Medicare bad debts be treated "on a cash basis." Id.

"Accrual" accounting recognizes revenue "when earned, regardless of when collected," and expenses "when incurred, regardless of when paid." Id. at 983 (citations omitted). Similarly, accrual accounting estimates bad debt "[w]hen an account receivable is created," regardless of when payment is denied, "in light of experience." Id. By contrast, "cash-based" accounting only recognizes bad debts "in the accounting period when the particular account receivable actually becomes worthless." Id. at 984.

Because 42 C.F.R. § 413.89 requires that providers treat Medicare bad debt on a cash basis, providers may only report (and receive reimbursement for) Medicare bad debts in the accounting period in which the account "actually becomes worthless." Palms of Pasadena Hosp., 932 F.2d at 983-84 (rejecting bad debt reimbursement claim based on "an estimate of the receivables [the

The district court affirmed, according substantial deference to what it characterized as "the Secretary's interpretation -- through the PRM and must-bill policy -- of her own regulations." Maine Med. Ctr., 2014 WL 1234173 at *1, 14. The district court upheld the application of a "bright-line rule," as it was appropriate to keep the burden "on the potential recipient" rather than on the federal government "to demonstrate it does not owe reimbursement." Id. at *20.

II.

Our review of the district court's judgment on the record is de novo, "applying the same standards to the Secretary's final action that the district court was bound to apply." Doe v. Leavitt, 552 F.3d 75, 78 (1st Cir. 2009). We may reverse and set aside agency actions, findings, or conclusions only "if they are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' or 'unsupported by substantial evidence.'" Visiting Nurse, 447 F.3d at 72 (quoting 5 U.S.C. § 706(2)). In so doing, we are not wed to the district court's reasoning and may affirm "on any ground made manifest by the record," see Doe, 552 F.3d at 78, but we are limited to the "rationale advanced by the agency in the administrative proceeding," Citizens Awareness Network, Inc. v. United States, 391 F.3d 338, 349 (1st Cir. 2004) (citing SEC v. Chenery Corp., 318 U.S. 80, 95 (1943)).

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provider] ultimately would not collect").

The parties agree on these standards, but dispute the appropriate level of deference to accord this application of the Secretary's must-bill policy, and the RA Requirement in particular.

The first question, one of the appropriate deferential framework, depends on the characterization of the Secretary's decision. Maine Medical disputes in this appeal the district court's characterization of the Secretary's decision as applying the Secretary's direct interpretation of the relevant regulations. Maine Medical insists instead that the RA Requirement interprets the interpretative rules (articulated in the PRM) that themselves interpret the regulations. Maine Medical now also argues that the RA Requirement interprets JSM-370, a memorandum that itself interprets the PRM, adding a further layer of interpretation. Maine Medical argues that because the decision is appropriately characterized as the latter, considerably less deference is owed; otherwise agencies would be able to insulate themselves from judicial review by promulgating vague regulations and vague interpretations of those regulations. See, e.g., Elgin Nursing & Rehab. Ctr. v. U.S. Dep't of Health & Human Servs., 718 F.3d 488, 493-94 (5th Cir. 2013) (holding that agency's "interpretation of its manual interpreting its [published] interpretative regulation" was not entitled to deference, citing concerns about ensuring fair notice and preventing agencies from insulating themselves against review).

Whatever its merits, this argument has been waived. Maine Medical not only failed to raise this theory before the district court, but itself characterized the challenged RA Requirement as "the Secretary's interpretation of her own regulations." Pl.'s Mot. J. Admin. R. at *12, Maine Med. Ctr. v. Sebelius, No. 2:13-CV-00118-JAW, 2014 WL 1234173 (D. Me. Mar. 25, 2014), ECF No. 13 (emphasis added). See Rockwood v. SKF USA, Inc., 687 F.3d 1, 9 (1st Cir. 2012) ("[A]rguments not raised in the district court cannot be raised for the first time on appeal." (citations and internal quotation marks omitted)). We proceed to treat the Secretary's decision as applying an interpretation of the regulations in 42 C.F.R. § 413.89.[13]

Similarly, Maine Medical waived any argument that Skidmore deference applies under our precedent in Visiting Nurse Ass'n Gregoria Auffant, Inc. v. Thompson, 447 F.3d 68, 73 (1st Cir. 2006), rather than Seminole Rock substantial deference. In arguing before the district court, Maine Medical only cited cases applying Seminole Rock substantial deference (and exceptions thereto), like Thomas Jefferson University v. Shalala, 512 U.S. 504 (1994). As a result, we apply the substantial deference framework to the whole of the Secretary's decision.

[13] Indeed, this outcome may be appropriate in this case for a different reason. Even if the RA Requirement is not a direct interpretation of the regulations, the Secretary directly interpreted the C.F.R. regulations in concluding that the alternative documentation was inadequate. See Parts I & III.

Accordingly, we afford substantial deference to the application of the must-bill policy unless it is a "plainly erroneous" interpretation or "inconsistent with" the regulation's language. South Shore Hosp., Inc. v. Thompson, 308 F.3d 91, 97 (1st Cir. 2002) (quoting Thomas Jefferson, 512 U.S. at 512). On its face, the must-bill policy is neither a plainly erroneous interpretation nor inconsistent with the regulations. Neither portion of the must-bill policy, the Billing Requirement and the RA Requirement, contradicts the four "[c]riteria for allowable bad debt" under 42 C.F.R. § 413.89(e): (1) that the debt is "related to covered services and derived from deductible and coinsurance amounts," (2) that the provider made "reasonable collection efforts," (3) that the debt was "actually uncollectible when claimed as worthless," and (4) that "[s]ound business judgment established that there was no likelihood of recovery at any time in the future." 42 C.F.R. § 413.89(e); see also, e.g., Monterey, 323 F.3d at 790 n.7; Grossmont, 903 F. Supp. 2d at 52. Rather, the Billing Requirement is a natural interpretation of these regulations, and the RA Requirement provides a standardized way to document that it has been met. Cf., e.g., Grossmont, 903 F. Supp. 2d at 52 ("[T]he Secretary reasonably believes that permitting individual States to rely on their own protocols for bad debt reimbursement -- whether with respect to billing or supporting documentation -- could wreak administrative havoc on the Medicare

system."). Indeed, the Secretary is authorized by statute to require a provider to "furnish[] such information as the Secretary may request." 42 U.S.C. § 1395g(a).

While we find that a general RA requirement appears entitled to deference (subject to one concern, below), we agree with Maine Medical that a per se RA Requirement would not be. The Secretary has made exceptions and accepted alternative documentation from the State where circumstances warranted the exception. See Grossmont, 903 F. Supp. 2d at 45-46, 48. A per se RA Requirement is also inconsistent with the regulatory language that requires "reasonable collection efforts" and the exercise of "[s]ound business judgment" to determine that there is "no likelihood of [future] recovery." 42 C.F.R. § 413.89(e)(2) & (4) (emphasis added); see also Cove, 848 F. Supp. 2d at 28 (recognizing the possibility that a provider might be denied Medicaid RAs despite reasonable collection efforts). And the now-repealed PRM-II § 1102.3L demonstrates that RAs are not the sine qua non of proof. But while the enforcement of a per se RA Requirement would not be entitled to deference, it is not inconsistent with the regulations to require a particular type of documentation, except under certain circumstances, to demonstrate that the Billing Requirement has been met. Cf. Grossmont, 903 F. Supp. 2d at 52.

That said, there may be another hurdle less readily overcome: While in our view the Billing Requirement and a general

RA Requirement (which is not a per se rule but admits limited exceptions) are consistent with the statute and regulations, see 42 U.S.C. § 1395hh(a)(1); 42 C.F.R. § 413.89(e), the Secretary has not consistently adhered to this interpretation. See South Shore, 308 F.3d at 102 (citing Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993); INS v. Cardoza-Fonseca, 480 U.S. 421, 446 n.30 (1987)) ("[I]f, over time, an agency interprets a regulation erratically, that inconsistency may warrant a court in declining to defer to the agency in a particular situation."). During the cost years in question, the since-repealed PRM-II § 1102.3L expressly waived the Billing Requirement and, with it, the RA Requirement. See PRM-II § 1102.3L (Rev. 4) (repealed September 2003). "In lieu of billing," the Secretary would accept alternative documentation of:

- Medicaid eligibility at the time services were rendered (via valid Medicaid eligibility number), and
- Non-payment that would have occurred if the crossover claim had actually been filed with Medicaid.

Id. The payment calculation would then be audited "based on the state's Medicaid plan in effect on the date that services were furnished." Id. Maine Medical argues that this inconsistency entails that the Secretary's decision -- denying alternative documentation it previously would have found adequate -- is entitled to less deference, even within the substantial deference framework applicable to agency interpretations of their own

regulations. Cf. South Shore, 308 F.3d at 102 (citing Good Samaritan, 508 U.S. at 417).

The extent to which inconsistency in interpretation undermines Seminole Rock deference remains uncertain, but it is well-established in this circuit that agencies are afforded "a substantial measure of freedom to refine, reformulate, and even reverse their precedents in the light of new insights and changed circumstances." See South Shore, 308 F.3d at 102 (citation and internal quotation marks omitted); M.C. Stephenson & M. Pogoriler, Seminole Rock's Domain, 79 Geo. Wash. L. Rev. 1449, 1472-81 (2011) (collecting cases) (discussing ambiguity in the doctrine regarding the significance of inconsistency). The repeal of this provision occurred under unusual circumstances: the Ninth Circuit found that the since-repealed PRM-II § 1102.3L itself marked a change in the Secretary's bad-debt-reimbursement policy away from the must-bill policy we are now asked to affirm. See Monterey, 323 F.3d at 797-99. But Congress had imposed a moratorium on changes in bad-debt-reimbursement policies. See id. at n.9 (noting that "the Secretary lacked authority" to effect a change). Following this decision, the Secretary reinstated the pre-1995 language of PRM-II § 1102.3L, repealing the billing waiver. See JSM-370. This suggests that the Secretary did not alter her policy without reason.[14]

[14] Monterey also addressed this inconsistency between the PRM-II § 1102.3L and the Secretary's application of the must-bill policy, deferring to the latter. 323 F.3d at 798-99. However,

The concerns that such a radical shift in policy might create are also not evident here. Maine Medical concedes that it did not rely on PRM-II § 1102.3L when responding to the lack of RAs. Cf. Cove, 848 F. Supp. 2d at 30 (remanding for determination "of whether Plaintiffs were justified in relying on CMS' prior failure to enforce the must-bill policy" (emphasis added)). And Maine Medical also does not suggest that the grace period, created by the Secretary to "hold harmless" those who acted in reliance on the alternative documentation scheme before January 2004, should apply. See JSM-370. That is, on the facts of this case, the policy shift does not implicate concerns about reliance interests or inconsistent treatment.

In light of these circumstances, we reject Maine Medical's argument that the Secretary's inconsistency undermines the deference owed to the Secretary's determination that the regulations demand satisfaction of the Billing and general RA Requirements, subject to limited exceptions. Because such exceptions to this policy appear to be made on a case-by-case basis, there remains only the question of whether the Secretary's

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there are two significant differences between Monterey and this case. First, Monterey involved the Secretary's rejection of a scheme that would avoid billing altogether, not the state's denial of RAs due to a technical glitch by the state. See id. Second, PRM-II § 1102.3L was not in existence during the relevant cost years in Monterey, but was in existence during the cost years here. See id.

determination that this was not such an exceptional case was arbitrary and capricious.

III.

We find that the rejection of Maine Medical's alternative documentation was not arbitrary and capricious, and affirm on that basis. Although the Secretary's decision relied heavily on Maine Medical's failure to provide RAs, the Secretary also found that Maine Medical failed to demonstrate satisfaction of the statutory and regulatory requirements. In particular, the Secretary found that Maine Medical's documentation failed to show that at least two of the four required bad debt criteria had been met, namely, that "[t]he debt was actually uncollectible when claimed as worthless," 42 C.F.R. § 413.89(e)(3), and that Maine Medical had made "reasonable collection efforts," 42 C.F.R. § 413.89(e)(2).[15]

The Secretary found that Maine Medical failed to satisfy the regulatory requirement that the debt be "actually uncollectible when claimed as worthless" because it lacked adequate documentation that MaineCare was not liable for any portion of the claimed debt. 42 C.F.R. § 413.89(e)(3); see also PRM § 322 (explaining that amounts the state is obligated to pay by statute are not allowable as bad debts). Rather, Maine Medical -- together with the Muskie

[15] Because all four criteria must be met to claim a bad debt, we need not reach the Secretary's finding that Maine Medical failed to demonstrate that "[s]ound business judgment established that there was no likelihood of recovery at any time in the future." 42 C.F.R. § 413.89(e)(4).

Institute -- assumed that MaineCare's liability would be zero based on a provision in the Maine Medicaid Manual purporting to "eliminate[]" payment for crossover claims. The Secretary rejected this inference. By statute, states may only limit their cost-sharing liability for QMB crossover claims to the Medicaid rate. See 42 U.S.C. § 1396a(a)(10)(E)(i). The state has the "most current and accurate information . . . to determine the State's cost sharing liability," and thus remains the final authority on the state's liability. We observe that Maine Medical neither secured express denial of liability -- even in the letter from the state authorizing cooperation with the Muskie Institute -- nor performed its own claim-by-claim analysis to either identify QMB crossover claims for which MaineCare was statutorily liable or to determine the extent of the resulting obligation based on MaineCare's rate for the services provided. It simply assumed that the state would not pay.

The Secretary found that this first failure also violated the regulatory requirement in 42 C.F.R. § 413.89(f) that accounts may only be "charged off as bad debts in the accounting period in which the accounts are deemed to be worthless." "The basic effect of these provisions is to bar providers from reporting bad debts on an accrual accounting basis." Palms of Pasedena Hosp. v. Sullivan, 932 F.2d 982, 983-84 (D.C. Cir. 1991). The Secretary thus found that Maine Medical's assumption that MaineCare would not pay was

essentially an attempt to report these bad debts on an accrual accounting basis, anticipating that the accounts would become unrecoverable rather than having confirmation that the accounts had actually become unrecoverable. Because there is no state-issued determination contemporaneous with the cost-reporting periods of FY 2002 and FY 2003, the debts did not "become worthless" during those periods.

With respect to the second bad debt criterion, the Secretary was skeptical that Maine Medical had demonstrated that it had made "reasonable collection efforts" as required by 42 C.F.R. § 413.89(e)(2). Although the Secretary's decision does not expressly discuss the time gap between the first missing RAs in late 2001 and the request for assistance in early 2005, the Secretary did discuss Maine Medical's failure to "maintain verifiable and supporting documents to justify their requests for payment." The Secretary's repeated insistence that Maine Medical "bill" MaineCare or "submit[] claims" to the state indicates that Maine Medical had an obligation to seek the documentation confirming MaineCare's denial of payment, and so too to promptly inquire when such documentation was not forthcoming. This obligation also stems from the record-keeping requirements of 42 C.F.R. § 413.20, which the Secretary interprets as requiring providers "to keep 'contemporaneous' records and documentation throughout the cost year and to then make available those records

to the intermediary." See 42 C.F.R. § 413.20(a) ("The principles of cost reimbursement require that providers maintain sufficient financial records . . . for proper determination of costs payable under the program." (emphasis added)). But Maine Medical failed to acknowledge or seek the missing RAs until several years later, in violation of § 413.20's record-keeping requirements. This violation of § 413.20 suggests that Maine Medical failed to make reasonable collection efforts under § 413.89.

Finally, we reject Maine Medical's argument based on dicta in Cove, 848 F. Supp. 2d at 28, that the Secretary's refusal to make an exception and accept the alternative documentation is arbitrary and capricious under the circumstances. This is not a case, alluded to in Cove, where Maine Medical has "establish[ed] that they have submitted the correct forms and made the right applications," but the Secretary has "not accept[ed] an alternative form of documentation or . . . require[d] that the states comply with her regulations." Cove, 848 F. Supp. 2d at 28 (suggesting such a decision would be arbitrary and capricious). Although Maine Medical initially submitted the correct forms to the Intermediary, it failed to address the missing RAs in a timely manner. This is not a case where MaineCare has flatly refused to issue the RAs; it is a case where a technical glitch impeded the issuance of RAs, and the provider waited years before seeking to address the issue. As

the Secretary had been aware, Maine Medical was the only hospital to encounter this problem.[16]

What happened here is unfortunate: MaineCare's computer dysfunctions deprived Maine Medical of the RAs it could have expected to receive in ordinary course; Maine Medical did not notice the absence of these RAs right away; and the Secretary (who needs to have a system that can reliably process millions of transactions from a large number of providers in 50 states) concluded that Maine Medical's efforts to address the problem were not enough to justify reimbursement in the absence of RAs. In affirming that conclusion, we do not ourselves determine that Maine Medical acted unreasonably. Rather, we merely sustain the Secretary's determination that Maine Medical's efforts did not justify an exception to the RA Requirement because we cannot say that determination was arbitrary and capricious.

We affirm. No costs are awarded.

[16] It is not apparent from the record whether other hospitals successfully produced RAs because they followed up on the error within an adequate time or because the technical issue did not affect the processing of their claims in FY 2002 and FY 2003.