UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SELECT SPECIALTY HOSPITAL-DENVER, INC., *et al.*, Plaintiffs, v. ALEX M. AZAR II, *Secretary, U.S. Department of Health and Human Services*, Defendant.	Civil Action No. 10-cv-1356 (BAH) Chief Judge Beryl A. Howell

MEMORANDUM OPINION

The plaintiffs in this consolidated case are seventy-five long-term care hospitals ("LTCHs") located in twenty-six states seeking a total of $20,325,174 in reimbursements from the Department of Health and Human Services ("HHS"), in connection with the plaintiffs' provision of inpatient care, over the period of 2005 through 2010, for patients eligible for both Medicare and Medicaid ("dual-eligible patients"), who generally are indigent. Prior to 2007, the Centers for Medicare and Medicaid Services ("CMS") had reimbursed LTCHs for their dual-eligible patients' unpaid co-insurance and deductible obligations ("bad debt") without requiring the LTCHs to bill state Medicaid programs for a formal determination of how much of that bad debt would be covered by state Medicaid programs. Billing state Medicaid programs was regarded as unnecessary, because the states were not liable for Medicare bad debts incurred at LTCHs.

In 2007, however, CMS abruptly began denying LTCHs reimbursement for dual-eligible patients' bad debts unless the LTCHs had both billed their state Medicaid programs *and* received a specific document from those state Medicaid programs called a State Remittance Advice ("RA")—to prove that the state Medicaid programs were, in fact, not liable for any portion of the

bad debts. This requirement that LTCHs bill the state Medicaid program to confirm that the state will not pay the Medicare cost-sharing amounts on behalf of a dual-eligible patient is known as CMS's "must-bill policy."

At the time of CMS's change in the must-bill policy, no means were available to satisfy CMS's new requirements because the LTCHs were not enrolled in their respective state Medicaid programs, and states would neither process bills nor issue RAs to non-participating providers. Moreover, when the LTCHs attempted to enroll in their respective state Medicaid programs, some states rejected the LTCHs as unrecognized provider types under their state Medicaid programs. When the LTCHs were eventually able to enroll successfully in their state Medicaid programs, obtaining the requisite RAs remained impossible because states would not process claims for prior fiscal years.

The plaintiffs claim, *inter alia*, that CMS could not change the requirements for Medicare bad debt reimbursement, at least as to non-participating Medicaid providers, without conducting notice-and-comment rulemaking, as required by the Medicare Act, 42 U.S.C. § 1395hh(a)(2). Complaint ¶¶ 120–124 ("S1-Compl."), *Select Specialty Hosp.-Denver, Inc. v. Azar* (*Select I*), Civ. No. 10-1356 (filed Aug. 12, 2010), ECF No. 1; Complaint ¶¶ 129–134 ("S2-Compl."), *Select Specialty Hosp.-Birmingham v. Azar* (*Select II*), Civ. No. 17-235 (filed Feb. 2, 2017), ECF No. 1; Complaint ¶ 66(*l*) ("H-Compl."), *Select Specialty Hosp.-Tulsa/Midtown, LLC v. Azar* (*Hillcrest*), Civ. No. 18-584 (filed Mar. 15, 2018), ECF No. 1. The D.C. Circuit's holding in *Allina Health Servs. v. Price* (*Allina II*), 863 F.3d 937 (D.C. Cir. 2017), *aff'd*, *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019), confirms that the plaintiffs are correct. Thus, for the reasons set forth below, the plaintiffs' Motion for Summary Judgment ("Pls.' Mot."), ECF No.

66, is granted, and HHS's Cross-Motion for Summary Judgment ("Def.'s Mot."), ECF No. 67, is denied.

I. BACKGROUND

Summarized below are the relevant statutory and regulatory provisions, including CMS's "must-bill" policy and the changes made to this policy leading to the plaintiffs' claims, followed by the factual and procedural history of this case.

A. Statutory and Regulatory Background

1. *The Medicare Act and Reimbursement Generally*

"Medicare is a federally funded medical insurance program for the elderly and disabled" that was "[e]stablished as part of the Social Security Act, 42 U.S.C. § 1395 *et seq.*" *Fischer v. United States*, 529 U.S. 667, 671 (2000). Inpatient hospital care, which is at issue in this lawsuit, is generally covered under Part A of the Medicare Act. 42 U.S.C. §§ 1395c–1395i-5. CMS, "formerly the Health Care Financing Administration (HCFA), administers the Medicare program on behalf of the Secretary" of HHS, *St. Luke's Hosp. v. Sebelius*, 611 F.3d 900, 901 n.1 (D.C. Cir. 2010), and is headed by the CMS Administrator, *Forsyth Mem'l Hosp. v. Sebelius*, 639 F.3d 534, 535 (D.C. Cir. 2011).

The Secretary is required by statute to delegate most of "[t]he administration of [Part A] . . . through contracts with [M]edicare administrative contractors." 42 U.S.C. § 1395h(a). These contractors, known as "Intermediaries," are responsible for, *inter alia*, "[d]etermining . . . the amount of the payments required . . . to be made to providers of services, suppliers and individuals;" for making those payments; and for providing communication, education, and technical assistance to health care providers treating Medicare patients. *Id*. § 1395kk-1(a)(4). In order to receive payment from the Medicare program, through the Intermediaries, health care providers such as the plaintiffs must submit "cost reports . . . on an annual basis." 42 C.F.R.

§ 413.20(b). After receiving and reviewing these cost reports, Intermediaries "must within a reasonable period of time . . . furnish the provider . . . a written notice reflecting the contractor's final determination of the total amount of reimbursement due the provider." *Id.* § 405.1803(a). These notices, which "[e]xplain the [Intermediary's] determination of total program reimbursement due the provider," *id.* § 405.1803(a)(1)(i), are known as notices of program reimbursements ("NPRs").

When dissatisfied with an NPR, a provider may seek review of, and a hearing regarding, the Intermediary's decision before the Provider Reimbursement Review Board ("PRRB"), so long as certain jurisdictional requirements, which are not at issue here, are met. 42 U.S.C. § 1395oo(a). "A decision of the Board shall be final unless the Secretary, on his own motion, . . . reverses, affirms, or modifies the Board's decision." *Id.* § 1395oo(f)(1). The Secretary has delegated responsibility for hearing appeals from PRRB decisions to the CMS Administrator. *See* 42 C.F.R. § 405.1875; *Mercy Home Health v. Leavitt*, 436 F.3d 370, 374 (3d Cir. 2006). A dissatisfied provider may file a civil action challenging the PRRB or the Administrator's final decision in the "District Court of the United States for the judicial district in which the greatest number of providers participating in both the group appeal and the civil action are located or in" this District. 42 C.F.R. § 405.1877(e)(2).[1]

2. *The Cost-Shifting Prohibition and Bad Debt Reimbursement*

The Medicare Act requires that the Secretary, in promulgating rules concerning provider reimbursement for reasonable costs, must (1) "take into account both direct and indirect costs of

[1] The parties agree that jurisdiction and venue properly lie in this District pursuant to 42 U.S.C. § 1395oo(f) given that the seventy-five plaintiffs are distributed across twenty-six states. Pls' Mem. Supp. Mot. Summ. J. ("Pls.' Mem.) at 30, ECF No. 66; Def.'s Answer ¶¶ 9–11 ("S2-Answer"), *Select II*, Civ. No. 17-235 (filed June 13, 2017), ECF No. 11; Def.'s Answer ("H-Answer") ¶¶ 8–10, 41, 66, *Hillcrest*, Civ. No. 18-584 (filed July 5, 2018), ECF No. 12.

providers of services," and (2) employ "methods of determining costs" for "efficiently delivering covered services to [covered] individuals" that ensure such costs are "not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs." 42 U.S.C. § 1395x(v)(1)(A).[2] The purpose of this cost-shifting prohibition is to ensure that neither providers nor non-Medicare-covered patients end up paying the costs for services rendered to Medicare beneficiaries. Although the costs incurred for most of the care provided to Medicare patients are borne by the federal government, individual Medicare patients are "often responsible for both deductible and coinsurance payments for hospital care." *Hennepin Cnty. Med. Ctr. v. Shalala* (*Hennepin Cnty.*), 81 F.3d 743, 745 (8th Cir. 1996). If Medicare patients fail to pay the deductible or coinsurance amounts they owe for hospital care, Medicare allows for reimbursement to the provider of these "bad debts" so long as certain criteria are met. 42 C.F.R. § 413.89(e).

"Bad debts" in the Medicare context are defined as "amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services." 42 C.F.R. § 413.89(b)(1). Such debts are "attributable to the deductibles and coinsurance amounts" billed to Medicare patients. *Id*. § 413.89(a). Pursuant to the cost-shifting prohibition, Medicare reimburses providers for these bad debts, ensuring that the costs are not "borne by individuals not so covered." 42 U.S.C. § 1395x(v)(1)(A). Ordinarily, Medicare will reimburse providers for bad debts they can prove are "allowable." 42 C.F.R. § 413.89(d). Under

[2] 42 U.S.C. § 1395x(v)(1)(A) provides, in pertinent part: "Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this title) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this title will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive."

long-standing regulations, four criteria in effect since 1966, determine whether a bad debt is "allowable" and thus eligible for reimbursement:

> (1) The debt must be related to covered services and derived from deductible and coinsurance amounts;
> (2) The provider must be able to establish that reasonable collection efforts were made;
> (3) The debt was actually uncollectible when claimed as worthless; and
> (4) Sound business judgment established that there was no likelihood of recovery at any time in the future.

Id. § 413.89(e); *see* 31 Fed. Reg. 14808, 14813 (Nov. 22, 1966); *see also* 20 C.F.R. § 405.420 (1967); 42 C.F.R. § 413.80 (1986).

The second requirement, that the provider make "reasonable collection efforts," is principally at issue here. CMS has set out the requirements constituting a reasonable collection effort in its Provider Reimbursement Manual, Part I ("PRM-I") § 310. With respect to dual-eligible patients, CMS allows providers to presume the beneficiary is indigent and the debt uncollectible, and therefore providers need not engage in the collection practices described in PRM-I § 310. *See* PRM-I § 312 ("Providers can deem Medicare beneficiaries indigent or medically indigent when such individuals have also been determined eligible for Medicaid as either categorically needy individuals or medically needy individuals, respectively."). In order to rely on a patient's status as a Medicaid beneficiary to establish indigence and satisfy the reasonable collection efforts requirement, however, the provider "must determine that no source other than the patient would be legally responsible for the patient's medical bill; e.g., title XIX, local welfare agency and guardian." *Id.* Accordingly, the PRM requires providers to determine that Medicaid is not "legally responsible" for a dual-eligible patient's medical bills before seeking reimbursement from Medicare.

3. *The Must-Bill Policy and the Remittance Advice Requirement*

To demonstrate that "no source other than the patient would be legally responsible" for a dual-eligible patient's medical bills, PRM-I § 312, CMS currently requires providers to bill their respective state Medicaid programs *and* obtain an RA demonstrating that Medicaid is not responsible for any part of the debt. The Secretary refers to this two-pronged policy as simply the "must-bill policy," *see* Def.'s Mem. Supp. Cross-Mot. Summ. J. & Opp'n Pls.' Mot. Summ. J. ("Def.'s Mem.") at 28–29, ECF No. 67-1, but the policy has two components: (1) the requirement that providers bill state Medicaid programs for dual-eligible bad debts, and (2) the requirement that RAs are the only acceptable form of documentation to demonstrate that the state Medicaid program is not responsible for the bad debt ("the RA requirement"), each of which came into existence at a separate time.

The first requirement, that providers generally must bill state Medicaid programs, "has been consistently articulated in the final decisions of the Secretary" since at least 1983. *Cove Assocs. Joint Venture v. Sebelius*, 848 F. Supp. 2d 13, 28 (D.D.C. 2012) (citing *Hoag Mem. Hosp. Presbyterian Provider v. Blue Cross*, Admin. Dec. No. 2002-D28, 2002 WL 31548714 (Aug. 2, 2002); *Hosp. de Area de Carolina*, Admin. Dec. No. 93–D23 (Apr. 26, 1993); *St. Joseph Hosp.*, PRRB Dec. No. 84–D109 (Apr. 16, 1984); *Concourse Nursing Home*, PRRB Dec. No. 83–D152 (Sept. 27, 1983)); *see also Community Hosp. of Monterey Peninsula v. Thompson* (*CHMP*), 323 F.3d 783, 799 (9th Cir. 2003); *GCI Health Ctrs., Inc. v. Thompson* (*GCI*), 209 F. Supp. 2d 63, 67–75 (D.D.C. 2002); *Cal. Hosp. 90–91 Outpatient Crossover Bad Debts Grp. v. Blue Cross of Cal.*, PRRB 2000-D80, 2000 WL 1460668 (Sept. 6, 2000).[3] Nevertheless, the

[3] The Secretary cites a provision from CMS's 1985 Medicare Intermediary Manual as evidence that the must-bill policy has existed at least since then. *See* Def.'s Mem. at 28–29 (citing Def.'s Mem., Ex. B, "Medicare Intermediary Manual Part 4–Audit Procedures" at 7, ECF No. 67-3 ("If the State has been billed, but did not pay the amount due, determine if there is a written notice of rejection in the patient's file. Review the rejection notice and if it is found to be acceptable, allow the bad debt for Medicare purposes.")). The plaintiffs urge that the Medicare Intermediary Manual cannot be considered, as the Manual is not found in the Administrative Record. Pls.' Reply Supp. Mot. Summ. J. & Opp'n Def. Cross-Mot. Summ. J. ("Pls.' Reply") at 8–9, ECF No. 70 (citing *Mercy Gen.*

must-bill policy for reimbursement to LTCHs of bad debts for dual-eligible patients was not applied to any of the plaintiffs, none of which were state-Medicaid-participating providers, for their claimed reimbursements, "until the Intermediaries issued the first NPRs at issue," in 2007, for fiscal year 2005. *See* Pls.' Mem. at 12 (citing S1-AR[4] at 549, S2-AR at 1297, H-AR at 541–43).

Regarding the second requirement, CMS did not impose an "absolute requirement that the Providers obtain a Medicaid remittance advice (RA)," S1-AR at 56 (*Select Specialty '05 Medicare Dual Eligible Bad Debts Grp.* v. *Wisc. Physicians Serv.*, PRRB 2010-D25 (Apr. 13, 2010) ("2010 PRRB Decision") at 10), until 2004 with the issuance by CMS of Joint Signature Memorandum 370 ("JSM-370"). A JSM "is not issued to the general public," S1-AR at 55 (2010 PRRB Decision at 9 n.20), and is "not an appropriate vehicle to set policy," *id.* (2010 PRRB Decision at 9); rather, a JSM is "used by CMS to communicate internally with [CMS] contractors," *id.* (2010 PRRB Decision at 9 n.20). JSM-370 instructed Medicare Intermediaries that "in those instances where the state owes none or only a portion of the dual-eligible patient's deductible or co-pay, the unpaid liability for the bad debt is not reimbursable to the provider by

Hosp. v. Azar, 344 F. Supp. 3d 321, 348-49 (D.D.C. 2018) (noting that the same manual provision would not be considered because it was not on the Administrative Record in that case)). Irrespective of whether the Manual provision is considered or not, the Manual only supports the proposition that the must-bill policy existed in some form before 1987 when Congress imposed the notice-and-comment rulemaking requirement of 42 U.S.C. § 1395hh(a)(2), but does not address plaintiffs' assertions that as non-Medicaid-participating providers they were exempt from the must-bill policy and that CMS had no RA requirement. The Manual provision cited by the defendant stating that "[i]f the State has been billed, but did not pay the amount due, determine if there is a written notice of rejection in the patient's file," suggests that although *some* form of written notice was required, CMS did not at that time have a requirement that the sole acceptable documentation reflecting that the state Medicaid program had no obligation to pay the bad debt was an RA.

[4] Four Administrative Records have been filed in this consolidated case. The AR from the first-filed case, 10-cv-1356, is referred to as the *Select I* Administrative Record ("S1-AR"). *See* Joint Appendix ("JA"), Appendix from *Select I* AR (1 of 2), ECF No. 73-1; JA, Appendix from *Select I* AR (2 of 2), ECF No. 73-2. The first-filed case also includes a Supplemental AR ("S1S-AR") with documents from after the case was remanded to CMS. *See* JA, Appendix from *Select I* AR Supplement, ECF No. 73-3. The AR from the second-filed case, 17-cv-235, is referred to as the *Select II* Administrative Record ("S2-AR"). *See* JA, Appendix from *Select II* AR (1 of 3), ECF No. 73-4; JA, Appendix from *Select II* AR (2 of 3), ECF No. 73-5; JA from *Select II* AR (3 of 3), ECF No. 73-6. Finally, the AR from the third-filed case, 18-cv-584, is referred to as the *Hillcrest* Administrative Record ("H-AR"). *See* JA, Appendix from *Hillcrest* AR, ECF No. 73-7.

Medicare until the provider bills the State, and the State refuses payment (*with a State Remittance advice*)." S2-AR at 163 (emphasis added). The Secretary cites nothing in the record articulating an absolute RA requirement before the issuance of JSM-370, and none of the cited provisions in reimbursement instruction manuals, or PRMs, for providers make any mention of "remittance advices." *See generally* PRM-I §§ 310, 312, 322; *see also Mercy Gen. Hosp. v. Azar*, 344 F. Supp. 3d 321, 351 (D.D.C. 2018) ("[T]he Court concludes that the Administrator's finding that a remittance advice requirement existed prior to [August 1, 1987] is not supported by substantial evidence.").

B. Procedural Background

1. *The Parties*

As noted, the plaintiffs in this consolidated case are seventy-five LTCHs located in twenty-six different states, spanning three plaintiff groups.[5] The "*Select I* Plaintiffs" are five LTCHs located in Arkansas, Colorado, Delaware, Florida, and Louisiana. S1-AR at 674. The "*Select II* Plaintiffs" are seventy-three LTCHs located in twenty-six states, including those states in which *Select I* plaintiffs are located. *See* S2-AR at 64–83.[6] During the relevant time periods, 2005–2010, hospitals in both groups were operated by subsidiaries of the same parent company, Select Medical Corporation ("Select"). Answer ¶¶ 11–15 ("S1-Answer"), *Select I*, Civ. No. 10-1356, ECF No. 14; S2-Answer ¶ 62. The "*Hillcrest* Plaintiff" is a single LTCH located in Tulsa,

[5] Select Specialty Hospital-Denver, Select Specialty Hospital-Fort Smith, Select Specialty Hospital-Jefferson Parish, and Select Specialty Hospital-Wilmington are members of both the *Select I* and the *Select II* plaintiff groups, seeking reimbursement for different fiscal years in each of the two complaints, *see* S1-Compl. ¶¶ 11–14; S2-Compl., Ex. D, List of Hospitals in Group ("S2-Compl. Ex. D"), *Select II*, Civ. No. 17-235, ECF No. 1-4. Similarly, Select Specialty Hospital-Tulsa/Midtown is a member of the *Select II* group and is the lone *Hillcrest* plaintiff, seeking reimbursement for different fiscal years, *see* H-Compl. ¶ 12; S2-Compl. Ex. D.

[6] The states in which the Select II Plaintiffs are located are Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Nebraska, New Jersey, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, West Virginia, and Wisconsin. S2-AR 64–83.

Oklahoma. Pls.' Mem. at 9; H-Compl. ¶ 12; H-Answer ¶ 12. Each plaintiff participates in Medicare and provides care to Medicare beneficiaries. S1-AR at 639; S2-AR at 456; H-AR at 555–57, 565–67.

When CMS began applying the RA requirement to the plaintiffs in 2007, none of the plaintiffs participated in their respective state Medicaid programs. Pls.' Mem. at 9 (citing S1-AR at 640 (Aff. of Wade Snyder (Mar. 6, 2018) ¶ 5 ("Snyder Aff.") ("At the time the services resulting in the bad debt at issue in this appeal were provided, the Providers were non-Medicaid participating. Therefore, they were not able to submit claims to, and obtain reimbursement from, or claims denials in the form of remittance advices ("RAs") from such Medicaid programs.")); S2-AR at 457 (Stipulations ¶ 5 ("The Providers did not participate in their respective state Medicaid programs during their fiscal year 2006 through 2010 cost reporting periods.")); H-AR at 269 (Transcript, PRRB Hearing at 47 (Nov. 13, 2015) (provider's counsel confirming that the *Hillcrest* plaintiff did not participate in the state Medicaid program during the relevant period).[7] Indeed, during the relevant years, 2005–2010, at least some of the states would not allow plaintiffs to enroll in the state Medicaid program, *see* S2-AR at 44, 61-62, 457 (Stipulations ¶ 6 ("At the relevant times, the laws, regulations, and practices of certain states in which these Providers offer services did not permit LTCHs to enroll as Medicaid providers.")), 585–86; H-AR at 174-75, as evidenced by both formal rejection letters and informal correspondence with state Medicaid programs, *see* S2-AR at 230, 282, 320, 328, 1594.

[7] HHS claims that "at least some plaintiff providers appear to have been enrolled in their state Medicaid programs during the period at issue," referencing only the Tennessee Medicaid program. Def.'s Mem. at 25 (citing S2-AR at 360). In response, the plaintiffs state that "[t]his is incorrect," Pls.' Reply at 14, and that the Tennessee plaintiffs "only enrolled after CMS changed its interpretation of the must-bill policy," *id.* (citing S2-AR at 213, 350, 397-402, 410-11). The plaintiffs have provided record evidence of the Tennessee providers' 2007 Medicaid enrollment applications and acceptances, S2-AR at 350 *et seq.*, and evidence that the Tennessee Medicaid program "issued retroactive effective dates," Pls.' Reply at 14 (citing S2-AR at 354–62), but the retroactivity was "largely meaningless" because Tennessee Medicaid "had a one year timely billing requirement for Medicaid claims," *id.*

2. *The Reimbursement Requests*

In July and August 2007, the *Select I* Plaintiffs' Intermediary, Wisconsin Physicians Service Corporation ("WPS") (formerly known as "Mutual of Omaha"), denied *Select I* Plaintiffs' reimbursement requests for dual-eligible patients' bad debts in fiscal year 2005, totaling $438,693. S1-AR at 674. The *Select II* Plaintiffs' Intermediaries, WPS and Novitas Solutions, Inc. ("Novitas"), began denying such requests in June 2007, and eventually denied various such requests for fiscal years 2006–2010, totaling $19,317,678 worth of dual-eligible bad debts. S2-AR at 457 (Stipulations ¶ 9). The *Hillcrest* Plaintiff had dual-eligible bad debts reimbursement requests denied for the first time by Intermediary WPS in December 2008, and was ultimately denied $568,803 in reimbursements for dual-eligible bad debts for fiscal years 2007 and 2008. H-AR at 555–57, 565–67; H-Answer ¶¶ 6.

The Intermediaries processing the plaintiffs' dual-eligible bad debts reimbursement requests consistently cited the must-bill policy and the plaintiffs' lack of RAs as reasons for the denials. *See* S1-AR at 677–742; S2-AR at 6249, 6309, 6323; H-AR at 541–43, 555–57, 1087–89. The plaintiffs claim that they "were first made aware that the must-bill policy would begin to be applied to their dual eligible bad debts when Mutual of Omaha communicated with them by email before finalizing adjustments to the *Select I* Plaintiffs' FY 2005 cost reports," in April 2007. Pls.' Mem. at 11 (citing S1-AR at 548–49; S2-AR at 1297; H-AR at 541–43). The *Hillcrest* Plaintiff received a similar email in November 2008, signaling that fiscal year 2007 reimbursements would be denied. *See* H-AR at 548.

Prior to April 2007 for *Select I* and *Select II* Plaintiffs, and to November 2008 for the *Hillcrest* Plaintiff, the CMS Intermediaries had not applied the must-bill policy and the concomitant RA requirement to the plaintiffs. The *Hillcrest* Plaintiff included a pre-2007 Adjustment Report in the record to indicate that no deductions were made for failure to comply

with the must-bill policy before that time. *See* H-AR at 185–226; *see also* H-AR at 548 (Email from Don O'Neal, Audit Supervisor, WPS, to Kevin Vaughn, Vice President of Reimbursement, Ardent Health Services (Nov. 14, 2008) (indicating that "prior to March of 2007, we may have treated this situation differently in that we would have allowed the Medicare bad debt")). The *Select I* and *Select II* Plaintiffs point to statements by Select's Director of Reimbursement, Wade Snyder, at a hearing before the PRRB in which he indicated that the Intermediaries did not apply the must-bill policy to the plaintiffs prior to 2007, *see* S1-AR at 256–57 (Transcript, *Select Specialty 2005 Medicare Dual Eligible Bad Debts Group*, Case No. 08-0251G (PRRB Dec. 3, 2008) at 132–33 (explaining that before April 2007 the intermediaries allowed bad debt reimbursements without billing Medicaid "as long as [the hospitals] could provide evidence that those dual-eligible patients were indeed Medicaid beneficiaries")); S2-AR at 1243–44 (same); *see also* S1-AR at 641 (Snyder Aff. ¶ 10 ("The Intermediary has communicated to Select that proof of indigence for the dual eligible patients *is no longer sufficient* to support that reasonable collection efforts were exhausted and that the bad debt was uncollectible and could be written off despite that the Providers were non-Medicaid participating." (emphasis added)).

Moreover, contemporaneous correspondence confirms that CMS's application of the must-bill and RA requirements to the plaintiffs beginning in 2007 was a change in policy. *See* S1-AR at 549 (Email from Kristi Rohrich, Audit Supervisor, Mutual of Omaha, to Wade Snyder, Director, Reimbursement, Select Medical Corporation (Apr. 5, 2007) ("*From this point forward*, all providers, Medicaid certified or not, MUST bill the State and obtain a valid RA showing denied or partial payment before we allow the bad debt on the cost report." (emphasis added)); S2-AR at 1297 (same); H-AR at 543 (Email from Don O'Neal, Audit Supervisor, Wisconsin Physicians Service, to Kevin Vaughn, Vice President of Reimbursement, Ardent Health Services

(Nov. 14, 2008) ("My understanding is that prior to March of 2007, we may have treated this situation differently in that we would have allowed the Medicare bad debt."), 677 (Email from Kenyetta Smith, Medicare Audit and Reimbursement, Mutual of Omaha, to Lee Ann Burney, Reimbursement Manager, Ardent Health Services (Feb. 14, 2007) (explaining that the Hillcrest Intermediary's bad debt adjustment denying reimbursement had been removed, therefore allowing reimbursement, after receiving copies of patients' bills).

The plaintiffs also point to CMS's instructions for completing the Provider Cost Report Reimbursement Questionnaire ("HCFA-339"). These instructions explicitly stated that billing state Medicaid programs "'may not be necessary . . . where the provider can establish that Medicaid is not responsible for payment,'" Pls.' Mem. at 7 (quoting S1-AR at 512 (HCFA-339 at 2)); S2-AR at 1285 (same); H-AR at 552 (same), lending further support to the proposition that CMS previously did not apply the must-bill policy to all providers. HHS counters that the instructions cited by plaintiffs were changed, effective October 1, 2003, "to revert back to pre-1995 language, which requires providers to bill the individual states for dual-eligibles' co-pays and deductibles before claiming Medicare bad debt." Def.'s Mem. at 10 (quoting S2-AR at 1639 (JSM-370 at 2)); H-AR at 585 (same).[8] In other words, even if providers were not required for some period of years to bill state Medicaid programs, as of October 1, 2003, HHS contends the must-bill policy was restored with an obligation for providers to bill state Medicaid programs and obtain an RA for their dual-eligible patients' bad debt to be reimbursable by Medicare. This policy change in October 1, 2003 was clearly not understood by CMS's own Intermediary to apply universally to all providers, however, because shortly thereafter, on October 15, 2003, the CMS Intermediary issued a newsletter stating that "[i]f a provider can demonstrate that neither

[8] Nowhere in the record is a copy of the "pre-1995 language" or post-October 1, 2003 instruction language to compare to the instructions cited by the plaintiffs.

the [state Medicaid program] nor State or local law requires the welfare agency to pay the Medicare deductible or coinsurance amount, then the provider can be reimbursed for this amount without billing the welfare agency." S1-AR at 97 (Providers' PRRB Brief at 30 (quoting S1-AR at 401 (CMS's Oct. 15, 2003 Newsletter))).

In any event, as the PRRB made clear, "there is no legal requirement that a Medicare-certified hospital enroll in Medicaid as a condition of participation in Medicare or to obtain Medicare reimbursement," S1-AR at 54 (2010 PRRB Decision at 8), despite the fact that CMS's new, or revived, must-bill policy imposed such a legal requirement, by denying reimbursement for dual eligible bad debt claims of non-Medicaid participating providers that were unable to provide an RA.

3. *Post-Denial Attempts by Plaintiffs to Obtain RAs and to Enroll in Medicaid*

In response to the first Adjustment Reports denying reimbursement for dual-eligible bad debts due to the lack of RAs, the *Select I* and *II* Plaintiffs began submitting bills to state Medicaid programs in which they were not enrolled, in an attempt to obtain RAs.[9] The *Select I* Plaintiffs first submitted a batch of 402 claims in twenty states, followed by a second batch of 102 bills in six states after the instant litigation began. *See* Pls.' Mem. at 14–15; S1-AR at 133–

[9] HHS claims that the bills submitted, in at least some cases, were "'sample' bills" and that the plaintiffs did not actually attempt to bill state Medicaid. Def.'s Mem. at 25 ("[I]n at least the [*Select I*] and [*Select II*] lawsuits, Plaintiffs concede that the bills they submitted to certain states were merely 'sample' bills and therefore it is impossible to know whether real bills to the states would have been accepted." (citing S1-AR at 242, 259; S2-AR at 1229, 1234)). This dispute appears to arise from a misstatement by the *Select I* Plaintiffs' prior counsel at a hearing before another judge on this Court before the case was reassigned to the undersigned, leading to the erroneous conclusion that "the providers submitted 'sample' bills with fabricated claim numbers," *Cove Assocs.*, 848 F. Supp. 2d at 28, and the withholding of summary judgment for the plaintiffs, *see id.* ("If, at some point, Plaintiffs can establish that they have submitted the correct forms and made the right applications, it may in fact, in those circumstances, be arbitrary and capricious for the Secretary to not accept an alternative form of documentation or to require that the states comply with her regulations."). The *Select I* Plaintiffs' counsel subsequently clarified that the bills submitted were "actual" claims, acknowledged the misstatement, and pointed out that *Select I* Plaintiffs quickly corrected the mistake. Pls.' Reply. at 10 n.7 (citing S1S-AR at 19 n.18 (stating "legitimate claims for real patients and actual dates of service" were submitted to the state Medicaid programs)). Further, the record shows that the plaintiffs sent actual bills to state Medicaid offices in an effort to obtain RAs, *see* S2-AR at 538–39, 542, 547, 1099; and HHS has offered no response to the plaintiffs' explanation, thereby conceding this issue.

94; S2-AR at 1441–97. The *Select II* Plaintiffs submitted a total of eighty-three bills in twenty-three states where these plaintiffs' hospitals are located, *see* Pls.' Mem. at 16; S2-AR at 765–1104, and fifteen "claims for out-of-state dual eligible patients who were treated at a Plaintiff hospital during the FY 2008 cost reporting period," Pls.' Mem. at 16 (citing S2-AR at 688–92, 700–64). For both sets of *Select* Plaintiffs, the states denied the RA requests. *See* S2-AR at 1380, 1487, 1501–02. A common theme in the rejection letters sent to the plaintiffs from state Medicaid offices was that the plaintiff was not, or could not, be enrolled in Medicaid. *See* S2-AR at 1380, 1487, 1501–02.

In addition to submitting bills, a number of the plaintiffs attempted to enroll in Medicaid for the limited purpose of obtaining RAs, some before appealing the Intermediaries' decisions and others while the appeals were pending. For example, Alabama Medicaid sent a rejection letter, dated December 9, 2008, to a plaintiff hospital indicating that Alabama Medicaid does not enroll LTCHs. S2-AR at 215. Similarly, Delaware Medicaid sent a rejection letter, dated February 27, 2008, to a plaintiff hospital advising that Delaware does not enroll LTCHs. S2-AR at 230; *see also* S1-AR at 254. New Jersey Medicaid also denied a plaintiff hospital's enrollment application in a letter, dated January 16, 2008, citing N.J. Admin. Code § 8:33F-2.4(a) for the proposition that LTCHs cannot enroll in New Jersey Medicaid. S2-AR at 320. North Carolina Medicaid denied a plaintiff hospital's enrollment application in a letter, dated October 31, 2007, advising that LTCHs could not enroll. S1-AR at 536. Select Specialty Hospital-Gulf Coast tried to enroll in Mississippi Medicaid on November 11, 2008, S2-AR at 279–81, but received a rejection letter dated May 26, 2009 advising that LTCHs in Harrison County, where this hospital was located, could not enroll, S2-AR at 282 (citing Miss. Code Ann. § 41-7-191(6)). Select Specialty Hospital-Jackson, located in a different county, was eventually

able to enroll in Mississippi Medicaid, in November 2009, effective September 2008. S2-AR at 316.

Pennsylvania Medicaid denied an enrollment application of a plaintiff hospital in a letter, dated August 16, 2007. *See* S1-AR at 313; S2-AR at 328 (same). Select also attempted to enroll its hospitals in Pennsylvania as acute care hospitals, S2-AR at 385–92, and was once again rejected, because LTCHs could not enroll, S2-AR at 1594. The Pennsylvania hospitals were subsequently allowed to enroll in the state Medicaid program in 2012, S2-AR at 338–49, but after the period when the reimbursement claims at issue in this lawsuit arose. Similarly, the Arkansas plaintiffs attempted to enroll in Arkansas Medicaid, S2-AR at 217, and initially received a rejection letter, dated February 14, 2008, S2-AR at 218–19, citing various provisions of the Arkansas Code, including Ark. Code § 201.100(c) ("A hospital must be certified as an acute care/general hospital Title VIII (Medicare) provider."), but were later able to enroll, *see* S2-AR at 222-223.

In sum, the record contains ample evidence that plaintiffs were unable to enroll in Medicaid programs in at least seven states: Alabama, Arkansas, Delaware, Mississippi (Harrison County), New Jersey, North Carolina, and Pennsylvania during the relevant period because of their status as LTCHs. In the remaining nineteen states, in which the plaintiffs operate and the state Medicaid programs permitted enrollment of LTCHs, the plaintiffs applied for enrollment once they became aware of CMS's new policy requiring an RA for reimbursement of the dual-eligible patients' bad debts. *See* Pls.' Mem. at 37 (citing S2-AR at 209-416). The plaintiffs' effort to enroll in state Medicaid programs in order to comply with CMS's newly revealed requirement, however, did not produce the requisite RAs for earlier periods, leaving the plaintiffs holding the proverbial bag of unreimbursed bad debt. According to the plaintiffs, "[i]n many

states the Plaintiffs encountered lengthy delays from the state Medicaid programs when the Plaintiffs applied for Medicaid enrollment," Pls.' Mem. at 37–38, and even after Medicaid enrollment, "the Plaintiffs still had unpaid bad debts associated with claims with dates of service prior to the enrollment approval date," *id.* at 38; *see also* S2-AR at 457 (Stipulations ¶ 8: "In no state could the Providers in these appeals obtain Medicaid RAs for dates of service when the Providers were not enrolled in Medicaid.").

4. *Administrative Appeals*

Following the Intermediaries' denials of their respective reimbursement requests, each plaintiff appealed the Intermediaries' decisions to the PRRB. The *Select I* Plaintiffs appealed their Intermediary's reimbursement decisions on November 16, 2007. S1-AR at 849–51. The PRRB reversed the Intermediary's denials in full on April 13, 2010, finding:

> the Intermediary's application of the bad debt collections policy including the must-bill policy's absolute requirement that the Providers obtain a Medicaid remittance advice (RA) prior to claiming Medicare bad debts is unsupported by the applicable law, regulations and manual provisions, as it fails to recognize a non-Medicaid participating provider's inability to comply.

S1-AR at 56 (2010 PRRB Decision at 10). The *Select II* Plaintiffs appealed their Intermediaries' reimbursement denials in five different groups. S2-AR at 2914–21, 3976–83, 5091–96, 6099–6102, 6569–73. The PRRB consolidated these appeals and issued an opinion on September 27, 2016, reversing only reimbursement denials by the Intermediaries for the six state Medicaid plans in which the PRRB concluded the LTCHs could not enroll.[10] The PRRB affirmed denials for those states and years in which the plaintiffs could have enrolled in Medicaid despite being

[10] The *Select II* Plaintiffs maintain that they could not enroll in the Arkansas state Medicaid plan, *see* Pls.' Mem. at 23, 27 n.17, whereas the PRRB found that the LTCHs could have enrolled in Arkansas, *see* S2-AR at 59 (*Select Specialty Medicare Dual Eligible Bad Debts CIRP Grps.* v. *Novitas Solutions, Inc.*, PRRB 2016-D22 (Sept. 27, 2016) ("2016 PRRB Decision") at 9). Both these plaintiffs and the PRRB cite to the same exhibit, S2-AR at 210 (Provider Exhibit P-100), for their contrary conclusions. Provider Exhibit P-100 lists Arkansas among states to which the plaintiffs applied for Medicaid Enrollment on November 26, 2007, but were rejected on February 14, 2008, then subsequently admitted in 2010. S2-AR at 210. Thus, this exhibit confirms the plaintiffs' position.

LTCHs. S2-AR at 61–63. The *Hillcrest* Plaintiff also appealed its Intermediary's reimbursement decision, and the PRRB reversed the reimbursement denial in Oklahoma. H-AR at 56–67 (*Hillcrest Specialty Hosp.* v. *Novitas Solutions, Inc.*, PRRB 2018-D3 (Nov. 6, 2017)).

The CMS Administrator, to whom the Secretary has delegated his authority to hear appeals from the PRRB, *sua sponte* reversed the PRRB's decision in each case, insofar as the PRRB had reversed reimbursement denials, and reinstated the Intermediaries' decisions to deny the plaintiffs' dual-eligible bad debt reimbursements for noncompliance with the RA requirement. S1-AR at 2–19; S2-AR at 1–22; H-AR at 2–29.

5. *Proceedings before this Court*

The *Select I* Plaintiffs appealed the Administrator's decision to this Court on August 12, 2010. *See* S1-Compl. On March 26, 2012, the Court granted partial summary judgment to the plaintiffs because the Administrator's decision may have failed to take into account the plaintiffs' legitimate reliance on prior interpretation, and remanded the case to the Administrator "for reconsideration of the limited issue of whether Plaintiffs were justified in relying on CMS's prior failure to enforce the must-bill policy with respect to dual-eligible reimbursement claims from non-participating Medicaid providers." *Cove Assocs. Joint Venture*, 848 F. Supp. 2d at 30. Although the plaintiffs' motion for summary judgment on grounds that the Administrator's decision was arbitrary and capricious was denied, the Court noted that

> [i]f, at some point, Plaintiffs can establish that they have submitted the correct forms and made the right applications, it may in fact, in those circumstances, be arbitrary and capricious for the Secretary to not accept an alternative form of documentation or to require that the states comply with her regulations.

Id. at 28.

Four years later, on March 21, 2016, the Administrator affirmed its previous decision. S1S-AR at 3–9. The *Select I* Plaintiffs then moved to reopen their case in this Court, which

motion was granted on March 7, 2017.[11] The *Select II* Plaintiffs appealed the Administrator's decision in their case to this Court on February 2, 2017. *See* S2-Compl. at 56. The *Hillcrest* Plaintiff appealed the Administrator's decision to this Court on March 15, 2018. *See* H-Compl. at 22. The Court subsequently consolidated all three cases. *See* Minute Order (Jan. 10, 2019).

Now pending before the Court are the parties' cross-motions for summary judgment, *see* Pls.' Mot.; Def.'s Mot., which motions became ripe on May 28, 2019, one week before the Supreme Court affirmed the D.C. Circuit's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).[12]

II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 56, summary judgment may be granted when the court finds, based upon the pleadings, depositions, and affidavits and other factual materials in the record, "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a), (c); *see Tolan v. Cotton*, 572 U.S. 650, 656-57 (2014) (per curiam); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). "A genuine issue of material fact exists if the evidence, 'viewed in a light most favorable to the nonmoving party,' could support a reasonable jury's verdict for the non-moving party." *Muwekma Ohlone Tribe v. Salazar*, 708 F.3d 209, 215 (D.C. Cir. 2013) (quoting *McCready v. Nicholson*, 465 F.3d 1, 7 (D.C. Cir. 2006)).

In cases involving claims under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), such as this one, and cross-motions for summary judgment, "the district judge sits as an

[11] This case was reassigned to the undersigned Chief Judge on February 10, 2017. *See* Minute Entry (Feb. 10, 2017).

[12] The parties have not sought to supplement their briefing in the intervening months since the Supreme Court's decision in *Allina Health Services*. Since *Allina Health Services* affirmed the D.C. Circuit's decision in *Allina II*, which the parties addressed in their briefing, the parties presumably believe no further briefing is necessary.

appellate tribunal. The 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (collecting cases). Accordingly, the court need not, and ought not, engage in lengthy fact finding, since "[g]enerally speaking, district courts reviewing agency action under the APA's arbitrary and capricious standard do not resolve factual issues, but operate instead as appellate courts resolving legal questions." *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996); *see also Lacson v. U.S. Dep't of Homeland Sec.*, 726 F.3d 170, 171 (D.C. Cir. 2013) (noting, in APA case, that "determining the facts is generally the agency's responsibility, not ours"); *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) ("Under the APA . . . the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." (internal quotation marks omitted)). Judicial review is limited to the administrative record, since "[i]t is black-letter administrative law that in an [Administrative Procedure Act] case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision." *CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014) (internal quotation marks omitted; second alteration in original); *see* 5 U.S.C. § 706 ("[T]he Court shall review the whole record or those parts of it cited by a party . . . ."); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) (noting when applying arbitrary and capricious standard under the APA, "[t]he focal point for judicial review should be the administrative record already in existence . . . ." (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973))).

III. DISCUSSION

The plaintiffs are entitled to summary judgment on their claim that CMS was required, under the Medicare Act, 42 U.S.C. § 1395hh(a)(2), to conduct notice-and-comment rulemaking

before subjecting the plaintiffs, as non-Medicaid-participating providers, to the must-bill policy and the RA requirement.

The Supreme Court's recent decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), controls the outcome of this case and requires that CMS have conducted notice-and-comment rulemaking before applying the must-bill policy and the RA requirement to these LTCHs. "[T]he Medicare Act requires notice-and-comment rulemaking for any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services.'" *Allina II*, 863 F.3d at 943 (quoting 42 U.S.C. § 1395hh(a)(2)). Of these four elements, the parties dispute whether CMS's application of the must-bill policy and, in particular, the policy's RA requirement, to the plaintiffs constitutes a change in a "substantive legal standard" within the meaning of the statute. *See* Def.'s Mem. at 38 ("[N]o substantive legal standard was established or changed here.").

The phrase "substantive legal standard" "appears in § 1395hh(a)(2) and apparently nowhere else in the U.S. Code." *Allina Health Servs.*, 139 S. Ct. at 1814. Relying on the dictionary definition of "substantive law," the D.C. Circuit defined the term as "at a minimum includ[ing] a standard that 'creates, defines, and regulates the rights, duties, and powers of parties.'" *Allina II*, 863 F.3d at 943 (quoting BLACK'S LAW DICTIONARY (10th ed. 2014)); *see also Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 354 (D.C. Cir. 2017) (quoting *Allina II*, 863 F.3d at 943).

The Supreme Court affirmed the Circuit's holding in *Allina II* that the Medicare Act does not include the APA's interpretive-rule exception to the notice-and-comment requirement. *See Allina Health Servs.*, 139 S. Ct. at 1814. As a result, in some circumstances CMS would not be obligated to conduct notice-and-comment rulemaking under the APA but is nonetheless required

to do so under the Medicare Act. In so holding, the Supreme Court rejected the government's argument that the counterpart to a "substantive legal standard" under the Medicare Act would be an "interpretative legal standard," tracking the respective meanings under the APA of a "substantive rule," which must be promulgated using the notice-and-comment procedure, and an "interpretative rule," which may be promulgated without notice-and-comment. *Id.* at 1811. The Supreme Court found significant the fact that the term "substantive rule" had become a term of art by the 1980s when the Medicare Act provision was enacted, but that Congress chose to use a different term, noting that the term adopted in the statute "appears to carry a more expansive scope than that borne by the term 'substantive rule' under the APA." *Id.* at 1813.

Notably, however, in addition to rejecting the government's theory that a substantive legal standard is functionally equivalent to a substantive rule under the APA, the Supreme Court also declined to endorse "in every particular" the definition of "substantive legal standard" that the D.C. Circuit expressed, preferring instead to "await other cases" before resolving additional "questions about the statute's meaning." *Id.* at 1814. The Circuit's definition—which the Supreme Court thus neither fully endorsed nor rejected—grounded the definition of "substantive legal standard" in the dictionary definition of "substantive law;" dictionaries define this term in contrast to "procedural law." *See* BLACK'S LAW DICTIONARY (11th ed. 2019) ("Substantive law [is] [t]he part of the law that creates, defines, and regulates the rights, duties, and powers of parties. Cf. PROCEDURAL LAW."); *see also id.* ("[W]e may say that the substantive law defines the remedy and the right, while the law of procedure defines the modes and conditions of the application of the one to the other.") (quoting John Salmond, *Jurisprudence* 476 (Glanville L. Williams ed., 10th ed. 1947)). Notwithstanding the Supreme Court's hesitation in endorsing the

D.C. Circuit's definition of "substantive legal standard," this Court, being bound by the law of this Circuit, must apply the Circuit's definition.

A comparison of the only two cases decided in this Circuit to analyze the term illustrates why a substantive legal standard is at issue in this case. In *Allina II*, CMS had changed the formula used to calculate payments to disproportionate share hospitals ("DSH"), i.e., hospitals which treat a higher percentage of low-income patients, which had the effect of lowering payments to such hospitals. CMS's formula "define[d] the scope of hospitals' legal rights to payment for treating low-income patients." *Allina II*, 863 F.3d at 943. Therefore, by changing the formula, the Circuit concluded, CMS had made a change to a substantive legal standard within the meaning of the Medicare Act.

By contrast, in *Clarian Health West, LLC v. Hargan*, 878 F.3d 346 (D.C. Cir. 2017), the Circuit held that CMS's statement of the circumstances under which CMS Intermediaries were required to report hospitals to CMS for the reconciliation of certain prospective payments the hospitals had received, called "outlier payments," with the hospitals' actual costs, was not a substantive legal standard under § 1395hh(a)(2) because the instructions "merely set forth an enforcement policy that determines when [the Intermediaries] will report hospitals for reconciliation." *Id.* at 355–56. In the Circuit's view, these instructions merely "reflect[ed] the agency's policy about how best to deploy its contractors' limited resources." *Id.* at 355. The instructions did not alter "whether an outlier payment is warranted or the amount of an outlier payment," *id.* at 354, because ultimately, duly-enacted regulations "subjected all outlier payments to reconciliation and set forth the formula for calculating payments during the reconciliation process," *id.* at 355.

At first blush, the instant case may appear akin to *Clarian*. CMS's insistence that plaintiffs obtain a certain document—an RA—and submit that document to the Intermediaries as a prerequisite to reimbursement for dual-eligible patients' bad debt, sounds like an administrative or procedural requirement, merely specifying the type of filing necessary to effectuate entitlement to a sum of money, a sum which the new requirement does not change. That is, in contrast to *Allina II*, CMS has not attempted to change the amount owed to providers. Moreover, the mere fact that failure to comply with the RA requirement could result in the plaintiffs receiving no bad debt reimbursements at all, *cf.* Pls.' Mem. at 64 ("The Plaintiffs' legal entitlement to bad debt payments was abruptly denied."), does not alone remove the RA requirement from the realm of procedural rather than substantive law, as failure to comply with procedural requirements can of course also carry severe consequences, including complete loss of an otherwise valid claim.

Yet, closer analysis confirms that this case falls squarely within the holding of *Allina II*. When CMS instructed Intermediaries to apply the must-bill policy and RA requirement to all providers, the plaintiffs were non-participants in state Medicaid programs and could not comply. Further, the plaintiffs in many instances were not permitted to enroll in state Medicaid programs or, if permitted to enroll, were out-of-time to submit the dual-eligible patients' bad debts. To bill state Medicaid programs and obtain RAs, providers must now necessarily participate in state Medicaid programs, "even though [Medicaid participation] is not a condition of participation or payment for purposes of Medicare reimbursement." Pls.' Mem. at 34; *see also* S1-AR at 54 (2010 PRRB Decision at 8). To participate in state Medicaid programs, providers must enter into legal contracts with states. *See Spectrum Health Continuing Care Grp. v. Anna Marie Bowling Irrecoverable Trust*, 410 F.3d 304, 313 (6th Cir. 2005) ("A health-care provider is not

required to participate in the Medicaid program, but rather voluntarily contracts with the state to provide services to Medicaid-eligible patients in return for reimbursement from the state at the specified rates.").

As a result of CMS's implementation of the must-bill policy to the plaintiffs, compounded by the RA requirement, CMS changed not just the steps that existing LTCHs must take, vis-à-vis CMS, to be reimbursed, but also changed whether such entities must form contracts with third parties, the state Medicaid programs. Deeming CMS's imposition of this new obligation a mere change in procedure, as opposed to a change in substantive law, would be out of place. This new requirement of providing an RA, even if superficially appearing to be merely procedural, had significant substantive consequences for the contractual obligations that LTCHs had to undertake. The RA requirement has essentially changed the eligibility criteria for reimbursement under the Medicare Act for dual-eligible patients, by requiring provider participation in the state Medicaid program. This change makes the RA requirement "substantive."

Remarkably, HHS asserts that "Plaintiffs need not participate in Medicaid to comply with the must-bill policy," Def.'s Mem. at 24; *see also* Def.'s Reply at 4 ("Plaintiffs are not required to participate in Medicaid in order to receive Medicare reimbursement . . . ."), a seemingly broad proposition, but one that HHS's own briefing later indicates means only that providers need not 'fully' participate in Medicaid, because states "are 'required to permit the provider to enroll for the limited purpose of obtaining adjudication of the [Qualified Medicare Beneficiary] cost-sharing amount,'" Def.'s Mem. at 24 (quoting S1-AR at 1098–1101 (CMS Informational Bulletin (June 7, 2013)). In its reply, HHS more explicitly admits that "[i]n order for the state to return an RA, it would have to be able to identify the provider, which a state could determine

only if the provider was actually enrolled in Medicaid at least for the limited purposes of obtaining RAs from the state." Def.'s Reply at 9 (emphasis added). Tellingly, HHS cites to nothing in the record dated prior to 2013 that articulates to the state Medicaid programs an obligation to enroll providers for the limited purpose of issuing RAs. *See* Def.'s Mem. at 24 (citing CMS Informational Bulletin (June 7, 2013)). The plaintiffs contend that CMS is misrepresenting the level of Medicaid participation required and point out that "states refuse to allow the Plaintiffs to bill if they are not enrolled as full-fledged Medicaid providers." Pls.' Mem. at 40. Irrespective of whether best characterized as 'full' or 'limited,' CMS changed a substantive legal standard by newly requiring LTCHs to assume some form of Medicaid participation.

Whatever reasons CMS offers for imposing the must-bill policy and RA requirement on non-Medicaid-participating LTCHs, the agency has not argued that these requirements are compelled by the Medicare Act itself. Rather, CMS is filling a "gap" as to how best to administer the Medicare program. As the Supreme Court has made clear, however, CMS "can't evade its notice-and-comment obligation under § 1395hh(a)(2)," just because the agency is changing a "'gap'-filing policy." *Allina Health Servs.*, 139 S. Ct. at 1817. Thus, when CMS imposed the RA requirement, it changed a "substantive legal standard"—state Medicaid participation—that the LTCHs had to satisfy for reimbursement to occur, and CMS was required to conduct notice-and-comment rulemaking pursuant to § 1395hh(a)(2).[13]

[13] HHS argues that § 1395hh(a)(2)'s rulemaking requirement is inapplicable in the instant case because the provision was enacted in 1987, whereas the "must-bill policy challenged by the Plaintiffs as articulated by the Secretary in several PRM provisions . . . became effective in 1968." Def.'s Mem. at 37–38. Under this reasoning, "for 42 U.S.C. § 1395hh(a)(2) to apply to the policy, it must be applied retroactively," *id.* at 38, which is "'disfavored in the law,'" *id.* (quoting *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988)). Though unsupported by the record, even if true, HHS's efforts to date the challenged policy back to 1968 would nonetheless be inapposite because the plaintiffs "are not challenging the must-bill policy generally; Plaintiffs challenge the agency's change in interpretation or enforcement of the must-bill policy to non-Medicaid participating providers that

IV. CONCLUSION

CMS created a bureaucratic nightmare by requiring a certain type of paperwork that the plaintiffs simply could not provide without sufficient advanced notice, and by obstinately continuing to deny reimbursement claims rather than working to find a reasonable solution in conjunction with the state Medicaid programs. For many of the plaintiffs, this has already been a twelve-year journey to obtain reimbursement for dual-eligible patients' bad debts. Indeed, this whole affair is likely just the sort of scenario Congress sought to avoid by enacting the notice-and-comment requirement of § 1395hh(a)(2), ensuring that all parties would receive sufficient advanced notice of meaningful changes to reimbursement requirements. At any rate, without satisfying the notice-and-comment obligation of § 1395hh(a)(2), CMS could not, and indeed cannot, impose the must-bill policy and RA requirement on the plaintiffs for the period when they were non-Medicaid-participating providers. On remand, the Administrator is directed promptly to reconsider whether, absent the must-bill and RA requirements, the plaintiffs are entitled to bad debt reimbursement.

An Order consistent with this Memorandum Opinion will be filed contemporaneously.

Date: August 22, 2019

BERYL A. HOWELL
Chief Judge

was applied to them beginning in April 2007," including the RA requirement. Pls.' Reply at 31. Accordingly, HHS's no-retroactivity argument is unpersuasive.