AMERICAN HEALTH LAW ASSOCIATION

HEALTH LAW CONNECTIONS
February 2021

Going Retro: Retroactive Rulemaking Under the Medicare Statute and When Is a Rule Really Retroactive

Caroline L. Wolverton, Akin Gump Strauss Hauer & Feld LLP

John R. Jacob, Akin Gump Strauss Hauer & Feld LLP

In August 2020, the Centers for Medicare & Medicaid Services (CMS) issued a Notice of Proposed Rulemaking (NPRM) to address the calculation of the Medicare disproportionate share hospital (DSH) adjustment for certain years as a result of the Supreme Court's decision in *Azar v. Allina Health Services*.[1] The Supreme Court held in *Allina* that CMS' policy for treating Medicare Part C patient days in the calculation violated the Medicare statute because it was not issued through proper notice and comment rulemaking.[2] The August NPRM, which CMS said is necessary as a result of the Court's landmark *Allina* ruling, is notable for its proposal of a rule that operates retroactively.

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.

Without delving into the details of the DSH calculation mechanics, the proposed rule would apply the same policy and treatment of Medicare Part C patient days in the DSH adjustment calculations to cost reporting periods prior to fiscal year 2014 that the Supreme Court invalidated in *Allina*.[3] CMS asserts in the NPRM's preamble that the proposed retroactive operation falls within the Medicare statute's authorization for retroactive rulemaking, Section 1871(e)(1)(A) of the Social Security Act.[4]

This article examines Section 1871(e)(1)(A), focusing on its language, legislative history, how CMS has applied this statutory authority, and how it has been interpreted by the courts. We consider the principle that a rule's impact on prior facts is not always retroactive in effect and whether the August NPRM is correct in stating that a retroactive rule is necessary to calculate the DSH payments outstanding after *Allina*. At bottom, is "going retro" in this instance the proper path and what is necessary to protect the public interest?

Section 1871(e)(1)(A): When Can CMS Go Retro?

The Medicare statute authorizes retroactive rulemaking in narrow circumstances. Specifically, a substantive change in Medicare regulations and guidance may be applied retroactively only if the Secretary determines that retroactive application is "necessary to comply with statutory requirements" or that "failure to apply the change retroactively would be contrary to the public interest."[5] The statute is framed in the negative, specifying that a substantive change "shall not be applied" retroactively "unless" the Secretary makes one of the two specified determinations.[6]

The negative phrasing of Section 1871(e)(1)(A) reflects the strong presumption against retroactive rulemaking that the Supreme Court established in *Bowen v. Georgetown University Hospital*.[7] The presumption is grounded in the principle that "[e]lementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct accordingly; settled expectations should not be lightly disrupted."[8] *Bowen*, a "paradigmatic case of retroactivity,"[9] involved a rule that altered the calculation method for Medicare provider reimbursement payments, applied the new method to recalculate payments that had already been made to providers, and permitted the Secretary to make recoupments.[10] The Supreme Court invalidated the rule's retroactive operation and articulated the now well-established principle that a statute will not be construed to authorize retroactive rules unless Congress conveys that power "in express terms."[11]

Legislative History

In 2003, Congress amended the Medicare statute to authorize retroactivity expressly but, in keeping with the strong presumption against retroactive rules, limited the authorization to two narrow circumstances: where retroactivity is necessary to comply with a statute and where it is necessary to prevent something that would be contrary to the public interest.[12] An early version of the provision described the public interest prong

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.

as where retroactivity would have a "positive impact" on beneficiaries, providers, or suppliers.[13] A later version revised "positive impact" to "beneficial to the public interest."[14] The final version changed the standard to permit retroactivity where failure to apply a change retroactively would be contrary to the public interest.[15]

The legislative history does not explain the changes in the framing of the public interest standard or why Congress ultimately adopted a negatively framed standard. That said, the fact that the drafters went from sanctioning retroactivity when it would have a "positive impact" on beneficiaries, providers, or suppliers to sanctioning it where failure to apply a change retroactively would be "contrary to the public interest" certainly seems significant. The negative framing in the standard ultimately adopted suggests a congressional intent that the authorization for retroactive Medicare rules be narrow, which is consistent with the strong presumption against retroactivity that the Supreme Court established in *Bowen*.

Applications of Section 1871(e)(1)(A): What It Looks Like When CMS Goes Retro

The August NPRM cites three examples of the Secretary's exercise of Section 1871(e)(1)(A)'s retroactive rulemaking authority:

- The proposed fiscal year 2021 inpatient prospective payment system (IPPS) rulemaking included a proposal to codify what the agency described as longstanding Medicare bad debt policies and provided for retroactive operation to cost reporting periods prior to the effective date.[16] The Secretary asserted that clarification was appropriate in light of the expiration of the famous (to hospital finance pros and health care lawyers) "bad debt moratorium." Although not everyone might agree, CMS emphasized that the policies to be codified had existed in Medicare guidance for decades and were familiar to providers and beneficiaries. That proposed rule, therefore, purported to not affect prior transactions or impose additional duties or adverse consequences, and to not diminish rights of providers or beneficiaries. The NPRM stated that failure to apply the rule retroactively could result in confusion as some providers might believe that the codified bad debt policies did not apply to earlier cost reporting periods, which could lead them to resubmit cost reports the review of which would require expenditure of government resources and funds.[17]
- One year earlier, the fiscal year 2020 IPPS final rule made retroactive changes to the regulation governing low-volume hospital payment adjustments.[18] The 2018 Consolidated Appropriations Act directed the Secretary to apply the payment adjustment policy described in his 2018 regulation in making payment adjustments for fiscal years 2011 through 2017.[19] The preamble to the 2020 IPPS rule stated that to the extent the rule could be viewed as a retroactive rulemaking it was authorized under Section 1871(e)(1)(A)(i) as necessary to comply with the 2018 Consolidated Appropriations Act.
- Finally, in 2013, the Secretary revised the rule on use of predicate facts in provider reimbursement appeals and cost report reopenings to specify that factual findings made in one fiscal period must be timely appealed to be used as predicate facts for an appeal

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.

or reopening in a later fiscal period.[20] CMS characterized the rule as not retroactive on the ground that it only clarified longstanding agency policy and was procedural in nature. But the agency went on to state that if the rule were to be considered retroactive, it would pass muster under both prongs of Section 1871(e)(1)(A). CMS stated that retroactive application was necessary to comply with statutory provisions including the cap on residents for graduate medical education (GME) reimbursement, the 180-day period for filing appeals to the Provider Reimbursement Review Board, and the three-year limit on cost report reopening, as well as to protect public interests in finality of reimbursement determinations and consistency with Medicare's statutory scheme.

Section 1871(e)(1)(A) has not been the subject of much litigation, but two published cases have reviewed the Secretary's invocation of this statutory provision:

- In *St. Francis Medical Center v. Price*, hospitals challenged the 2013 predicate fact rule described immediately above as impermissibly retroactive.[21] The district court assumed without deciding that the rule was retroactive and then applied an arbitrary or capricious standard of review to CMS' asserted justifications for the retroactivity. The court concluded that CMS' reliance on statutory requirements and the public interest in finality of reimbursement determinations were sufficient justification under Section 1871(e)(1)(A).[22] On appeal, the D.C. Circuit invalidated the rule on other grounds and did not reach the question of whether it was impermissibly retroactive.[23]
- In *Medcenter One Systems v. Leavitt*, the district court invalidated a CMS rule retroactively disallowing hospitals' claimed reimbursements for residency training.[24] CMS had justified the retroactivity by pointing to a public interest in preventing hospitals from obtaining inflated reimbursements for resident training that had been paid in part by other parties. Like the district court in *St. Francis*, the court applied an arbitrary and capricious standard of review. It rejected the Secretary's asserted justification as unfounded where two hospitals shared the costs of residency training. The Eighth Circuit reversed on other grounds and did not address the lower court's retroactivity analysis.[25]
- Another case also worth mentioning is *H. Lee Moffitt Cancer Center and Research Institute Hospital v. Azar*.[26] While that case did not review the Secretary's invocation of Section 1871(e)(1)(A), it did address when the Secretary should have invoked his power to issue a retroactive rule under the section. The Secretary had implemented a rule adjusting certain outpatient payments for cancer hospitals as directed by the Affordable Care Act but did so a year later than the Act mandated. The court noted the Secretary's retroactive rulemaking authority under Section 1871(e)(1)(A) in holding that that the payment adjustments must be applied retroactively to comply with the effective date mandated by the Act.

Not All Throwbacks Are Retroactive

The Medicare statute does not explicitly define a retroactive rulemaking, but the text of Section 1871(e)(1)(A) directs its application only to retroactivity "of substantive changes."[27] The textual limitation comports with the principle that a rule operates retroactively only when it imposes "new legal consequences" for past conduct.[28]

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.

The Supreme Court made clear in *Landgraf v. USI Film Products* that a rule that operates on earlier facts is not necessarily retroactive.[29] A rule "is not made retroactive merely because it draws upon antecedent facts for its operation."[30] Only where a rule creates "new legal consequences" for prior actions is it retroactive.[31] Whether a rule imposes "new legal consequences" is guided by "familiar considerations of fair notice, reasonable reliance, and settled expectations."[32]

For example, in *Regions Hospital v. Shalala,* the Supreme Court held that a 1990 regulation directing re-audits of 1984 GME costs submitted for reimbursement was not impermissibly retroactive where it provided for the recalculated 1984 GME costs to be used in determining allowable GME costs in future cost reporting periods.[33] Congress, through the so-called GME amendment to the Medicare statute, had directed the Secretary to determine the average amount of reasonable GME costs during 1984 to use as the base period for calculating GME reimbursements for subsequent years. The Secretary stated that the re-audits were to ensure that erroneous reimbursements during 1984 were not incorporated into the base period.[34] Even though the rule drew on prior facts (i.e., the reasonable GME costs in 1984) it applied only prospectively.

Similarly, in *Caritas Medical Center v. Johnson*, a reimbursement calculation rule was deemed not impermissibly retroactive where it filled a gap by continuing the calculation method used in prior years.[35] The gap was the result of a delayed effective date for a statutorily prescribed change in calculation method. The court reasoned that by simply continuing the method to which hospitals were accustomed, the rule did not attach new legal consequences to prior facts or disturb settled expectations. It therefore was not impermissibly retroactive.

Must the Rule Addressing Treatment of Part C Days in the DSH Calculation Be Retroactive?

So this brings us to CMS' latest effort to "go retro." The preamble to the August NPRM states that retroactive rulemaking is necessary because without it CMS could not calculate DSH payments for the fiscal years outstanding as a result of *Allina* and such an outcome would be contrary to the public interest of providing additional payments to DSH hospitals.[36] The preamble also identifies a public interest in adopting a policy through notice and comment rulemaking. Each of these asserted justifications is susceptible to challenge, and if incorporated into a final rule they will surely be the subject of litigation.

For purposes of this article, it is notable that the proposed retroactive rule may not be the only, and is likely not the best, way that the outstanding DSH payments can be addressed. Another option is a rule codifying the agency's pre-2004 practice, which was to exclude Part C days from the Medicare fraction used to calculate the DSH payment. Significantly, that rule would not be retroactive because it would not subject hospitals to

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.

any new legal consequences and instead would continue the calculation method of which hospitals had fair notice and reasonably relied upon. Such a rule would be similar to the rules in *Regions Hospital* and *Caritas Medical Center* that were held to be not retroactive. It would simply draw upon antecedent facts (i.e., hospitals' cost reports for the prior fiscal years) for its operation (i.e., calculating DSH payments according to the same method that applied before the changes that *Allina* invalidated). As a result, looking at the dictates of Section 1871(e)(1)(A) it is not clear how retroactive rulemaking in this instance would be necessary to comply with statutory authority or how the failure to do so would be contrary to public interest.

Conclusion: Going Retro Should Be Saved for Special Occasions

Section 1871(e)(1)(A)'s provision for retroactive rulemaking in narrow circumstances is consistent with the strong presumption against retroactivity. That not all rules operating on antecedent facts are retroactive reinforces that principle. As the Supreme Court explained in *Bowen*, retroactive rulemaking is inconsistent with principles of fairness and notice and it disrupts settled expectations. Where Medicare program objectives can be achieved without resort to retroactive rulemaking, Section 1871(e)(1)(A) does not authorize CMS to go retro.

Endnotes

1 139 S. Ct. 1804 (2019).

2 *Id.*

3 CMS, *Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage*, 85 Fed. Reg. 47723 (Aug. 6, 2020).

4 42 U.S.C. § 1395hh(e)(1)(A).

5 *Id.*

6 Section 1871(e)(1)(A) provides:

A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.

furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

42 U.S.C. § 1395hh(e)(1)(A).

7 488 U.S. 204 (1988).

8 *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994).

9 *Id*. at 272.

10 Similar to the NPRM following the *Allina* Supreme Court ruling, in *Bowen* the Secretary's prior rule on the method for calculating the "wage index" had been struck down for failure to provide notice and opportunity to comment. The Secretary then issued the same rule through notice and comment and sought to apply it retroactively to an earlier period. The Supreme Court invalidated the rule as unauthorized. *Bowen*, 488 U.S. at 215.

11 *Id.* at 208.

12 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, § 903, 117 Stat. 2066 (2003).

13 H.R. Rep. No. 107-288, at 26 (2001).

14 H.R. Rep. No. 108-74, at 42 (2003).

15 H.R. Rep. No. 108-178 § 903 (2003).

16 85 Fed. Reg. 32460, 32867 (May 29, 2020).

17 The Secretary finalized the rule, including its retroactive provision, on September 18, 2020. 85 Fed. Reg. 58432, 59002.

18 84 Fed. Reg. 42044, 42349 (Aug. 16, 2019).

19 Consolidated Appropriations Act 2018, Pub. L. No. 115–141, 132 Stat. 384 (2018).

20 78 Fed. Reg. 74826, 75165 (Dec. 10, 2013). The regulation was a response to a court ruling that CMS' regulations permitted hospitals to appeal predicate facts used in

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.

reimbursement determinations in later fiscal year periods regardless of whether the predicate facts were timely appealed or reopened. *Kaiser Found. Hosps. v. Sebelius*, 708 F.3d 226 (D.C. Cir. 2013).

21 239 F. Supp. 3d 237 (D.D.C. 2017), *rev'd on other ground sub nom St. Francis Med. Ctr. v. Azar*, 894 F.3d 290 (D.C. Cir. 2018).

22 *Id.* at 245.

23 *St. Francis Med. Ctr. v. Azar*, 894 F.3d 290 (D.C. Cir. 2018).

24 666 F. Supp. 2d 1043, 1067–68 (D.N.D. 2009), *rev'd on other grounds*, 635 F.3d 348 (8th Cir. 2011).

25 635 F.3d 348 (8th Cir. 2011).

26 324 F. Supp. 3d 1 (D.D.C. 2018).

27 42 U.S.C. § 1395hh(e)(1)(A).

28 *Landgraf*, 511 U.S. at 269–70.

29 *Id.*

30 *Cox v. Hart*, 260 U.S. 427, 435 (1992).

31 *Landgraf*, 511 U.S. at 269–70.

32 *Id.* at 270.

33 522 U.S. 448 (1998).

34 *Id.* at 453–54.

35 603 F. Supp. 2d 81 (D.D.C. 2009).

36 85 Fed. Reg. 47723, 47724 (Aug. 6, 2020).

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.

About the Authors

Caroline L. Wolverton is a Senior Counsel in Akin Gump's litigation practice, where she focuses on government-facing litigation, including administrative and regulatory matters, counsel on rulemakings and other administrative procedures, and complex litigation matters including Medicare litigation. She is a former Senior Trial Counsel, Civil Division, Federal Programs Branch at the United States Department of Justice.

John R. Jacob is a Partner at Akin Gump and head of its health care and life sciences practice. He advises hospitals, device manufacturers and other health industry entities on numerous regulatory and policy issues, including those pertaining to Medicare and Medicaid regulatory and policy matters.

Copyright 2021, American Health Law Association, Washington, DC. Reprint permission granted.