[ORAL ARGUMENT NOT YET SCHEDULED]

No. 23-5310

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BATTLE CREEK HEALTH SYSTEM, *et al.*,

Plaintiffs-Appellees,

v.

XAVIER BECERRA, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of Columbia

BRIEF OF AMICI CURIAE AMERICAN HOSPITAL ASSOCIATION, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AND FEDERATION OF AMERICAN HOSPITALS IN SUPPORT OF PLAINTIFFS-APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), amici certify as follows:

A. Parties And Amici

Except for the following, all parties, intervenors, and amici appearing before the district court and in this Court are listed in the Brief for Appellant.

Amici Curiae: American Hospital Association, America's Essential Hospitals, Association of American Medical Colleges, and Federation of American Hospitals.

B. Rulings Under Review

Reference to the ruling at issue appears in the Brief for Appellant.

C. Related Cases

Amici are not aware of any related cases within the meaning of Circuit Rule 28(a)(1)(C).

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, amici disclose that:

The American Hospital Association has no parent company and no publicly held corporation owns 10% or more of its stock.

America's Essential Hospitals has no parent company and no publicly held corporation owns 10% or more of its stock.

The Association of American Medical Colleges has no parent company and no publicly held corporation owns 10% or more of its stock.

The Federation of American Hospitals has no parent company and no publicly held corporation owns 10% or more of its stock.

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GLOSSARY

Administrative Procedure Act ..... APA

Centers for Medicare & Medicaid Services ..... CMS

Disproportionate Share Hospital ..... DSH

Fiscal Year ..... FY

Provider Reimbursement Review Board ..... PRRB or Board

Secretary of Health and Human Services ..... Secretary

IDENTITY AND INTEREST OF AMICI CURIAE*

The American Hospital Association represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. Its members are committed to improving the health of the communities they serve, and to helping ensure that care is available and affordable for all Americans.

America's Essential Hospitals is dedicated to equitable, high-quality care for all people, including those who face social and financial barriers to care. Consistent with this safety-net mission, the association's more than 300 members provide a disproportionate share of the nation's uncompensated care, with three-quarters of their patients uninsured or covered by Medicare or Medicaid.

The Association of American Medical Colleges is a nonprofit association dedicated to improving the health of people everywhere through medical education, healthcare, medical research, and community collaborations. Its members include all 158 U.S. medical schools accredited by the Liaison

* No counsel for a party authored this brief in whole or in part, and no counsel or party contributed money intended to fund its preparation or submission. No person other than amici, their members, and their counsel contributed money intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

Committee on Medical Education, approximately 400 academic health systems and teaching hospitals, and more than 70 academic societies.

The Federation of American Hospitals is the national representative of more than 1,000 leading taxpaying hospitals and health systems throughout the United States. Its members provide patients in urban and rural communities with access to high-quality, affordable healthcare. Those members include teaching and non-teaching acute, inpatient-rehabilitation, behavioral-health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer-care, and ambulatory services.

Amici's member hospitals treat many patients enrolled in the Medicare program, 42 U.S.C. § 1395 *et seq.*, for which they are paid on a forward-looking basis under Medicare's prospective-payment system, *id.* § 1395ww(d). The amounts of these payments depend on many determinations made by the Centers for Medicare & Medicaid Services (CMS), on behalf of the Secretary of Health and Human Services, under Section 1395ww(d). Those determinations can significantly affect the Medicare payments amici's members receive.

Many hospitals are entitled to an increase in Medicare payments—the disproportionate-share-hospital (colloquially, "DSH") adjustment, 42 U.S.C. § 1395ww(d)(5)(F)—because they treat a relatively large share of lower-income patients, who typically cost more to treat. Whether a hospital is entitled to a DSH adjustment (and how much) turns on a complex formula that combines two fractions designed as proxies for a hospital's low-income population: the Medicare fraction, which measures the proportion of its patients entitled to Medicare Part A benefits who are entitled to supplemental-security-income benefits; and the Medicaid fraction, which measures the proportion of a hospital's patients who are eligible for Medicaid but not Medicare Part A. *Becerra* v. *Empire Health Foundation*, 597 U.S. 424, 429-430 (2022). The underlying dispute here concerns a 2009 CMS determination regarding how to calculate the Medicare fraction—namely, whether Medicare *Part C* enrollees count as patients entitled to *Part A*.

Like CMS's other determinations administering the prospective-payment system, its decisions interpreting the DSH formula can materially affect hospitals' Medicare payments. When an error by CMS causes

a hospital not to receive the full DSH payment it is owed, the hospital may face financial distress and be unable to serve patients adequately.

Given the stakes of CMS's determinations generally and DSH payments in particular, prompt review is essential. This case concerns whether providers may seek review of CMS determinations immediately, or instead must wait months or years to ask CMS to correct a mistake. Amici have a strong interest in the answer to that question.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are reproduced in an addendum to this brief. Add., *infra*, 1a-12a.

INTRODUCTION AND SUMMARY OF ARGUMENT

Medicare's prospective-payment system is a massive, complex machine with many moving parts. When Congress set that machine in motion—replacing Medicare's original, retrospective "cost reimbursement" regime—its "primary purpose * * * was to provide hospitals with predict[a]bility regarding payment amounts." *Washington Hospital Center* v. *Bowen*, 795 F.2d 139, 148 (D.C. Cir. 1986) (internal quotation marks omitted). To that end, Congress charged CMS with making myriad forward-looking determinations that govern future payments to give hospi-

tals "advance knowledge of the amount[s]" they will receive. *Ibid.*; see 42 U.S.C. § 1395ww(d).

For the same reason, Congress also augmented the then-exclusive avenue of review—which allowed hospitals only to challenge their total payment amounts after the fact—by permitting immediate review of any "final determination of the Secretary as to the amount of the payment under" Section 1395ww(d). 42 U.S.C. § 1395*oo*(a)(1)(A)(ii). Congress thereby deliberately "hasten[ed] the process of review so that a hospital will know at the earliest possible date exactly how much it will be paid." *Washington Hospital*, 795 F.2d at 148. Hospitals that disagree with final CMS determinations need not wait until their total payments are formally computed, reviewed, and settled by Medicare contractors months or years later to challenge CMS's position. They can seek review immediately.

The determination at issue here epitomizes the actions Congress intended to make immediately reviewable. Plaintiffs challenge CMS's June 2009 decision to count Medicare Part C enrollees toward hospitals' Part A populations in calculating the Medicare fractions for Fiscal Year (FY) 2007. That determination was "final" because it affected hospitals' right to payment and marked the end of CMS's decisional process, unless

and until it revisited the issue. And it was a determination "as to the amount of the payment" because it governed how hospitals' Medicare payments would be calculated—and undisputedly reduced the amounts many hospitals received.

The government's contrary position lacks any basis in the statute and would defeat Congress's fundamental design. The government does not dispute that CMS's 2009 Part C determination reduced many hospitals' DSH adjustments and thus their total Medicare payments. It asserts that the determination nevertheless was not "final" because CMS later modified its FY2007 calculations in other ways. That cramped view of finality flouts hornbook administrative-law principles and would enable CMS to insulate virtually any decision from review, thwarting Congress's aim of expanding timely access to administrative and judicial review.

The government also argues that CMS's Part C pronouncement was not a determination "as to the amount of the payment" because it supposedly did not resolve *every* remaining variable that would affect hospitals' payments. That arbitrary exception has no foothold in the statute's text, context, or purpose. The scope of that purported carveout is also unclear,

especially given the government's concessions that review *is* available of other CMS determinations that seem to flunk its own test.

The government's approach harms the hospitals that care for Medicare's tens of millions of enrollees. On its view, a hospital cannot challenge *any* CMS DSH-adjustment determination until its Medicare contractor officially computes the hospital's total payment for a given fiscal year. That process typically concludes years later, by which time a hospital wrongly deprived of its full DSH payment may have been forced to cut critical services, delay important investments, or even close. An incorrect CMS determination that takes away a hospital's DSH eligibility can also cause it to lose other key benefits, such as eligibility for discounts through the 340B Drug Pricing Program, on which many hospitals serving low-income patients depend.

Beyond the DSH context, the government's position appears to preclude immediate review of a vast yet unspecified array of CMS determinations that directly affect hospitals' Medicare payments. At minimum, its approach compounds the complexity of an already-byzantine administrative apparatus and needlessly increases uncertainty.

Congress did not intend any of this. It enacted a simple provision that broadly allows hospitals to seek immediate review of any final CMS determination that reduces the payment amounts they will receive—including the DSH adjustment. This Court should give effect to Congress's judgment and affirm.

ARGUMENT

I. CMS's June 2009 Part C Determination Is Reviewable

Section 1395*oo*(a)(1)(A)(ii) authorizes review of any "final determination of the Secretary as to the amount of the payment under" Section 1395ww(d), which governs the prospective-payment system. 42 U.S.C. § 1395*oo*(a)(1)(A)(ii). CMS's June 2009 determination to count Medicare Part C patients toward hospitals' Part A populations in the DSH formula fits that bill. It was "final" under familiar administrative-law principles. And it was a determination "as to the amount of the payment" because its purpose and effect was to prescribe how DSH adjustments are calculated—and it in fact reduced hospitals' DSH payments.

A. The Part C Determination Was "Final"

CMS's June 2009 action was "final," 42 U.S.C. § 1395*oo*(a)(1)(A)(ii), because it had direct legal consequences and represented the agency's

definitive position at that time. The calculations CMS published—and the Part C policy they embodied—were immediately reviewable. That CMS later made unrelated revisions did not retroactively render its action nonfinal.

1. The Part C Determination Had Direct Legal Effects And Was Definitive

The government acknowledges (Br. 34) that "final" in Section 1395*oo*(a)(1)(A)(ii) should be construed consistently with "final agency action" under the Administrative Procedure Act (APA), 5 U.S.C. § 704. An agency action is "final" under the APA if it "has direct and appreciable legal consequences" and "mark[s] the 'consummation' of the agency's decisionmaking process." *Bennett* v. *Spear*, 520 U.S. 154, 177-178 (1997) (citation omitted). CMS's June 2009 Part C policy checks both boxes.

The government does not dispute that CMS's policy has direct legal consequences. Gov't Br. 34, 37. For good reason: The "policy of counting Part C patients in the Medicare fraction" directly "affects a hospital's right to payment." *Azar* v. *Allina Health Services*, 587 U.S. 566, 573 (2019) (*Allina III*). CMS's determination "mean[t] that [hospitals] will * * * receive lower payments" due to lower DSH adjustments. *Allina Health Services* v. *Price*, 863 F.3d 937, 943 (D.C. Cir. 2017) (*Allina II*).

The Part C determination also reflected CMS's definitive position at that time. Neither the fractions nor the rules baked into them were provisional. The government cites nothing showing CMS's action was "tentative or interlocutory." *Bennett*, 520 U.S. at 178; see J.A. 32-43; Gov't Br. 35.

Indeed, as the government acknowledges (Br. 11), CMS's June 2009 Part C determination implemented a position that CMS had adopted—and had deemed "[f]inal"—five years earlier. 69 Fed. Reg. 48,916, 48,916, 49,099 (Aug. 11, 2004). CMS "issued a final rule in 2004 declaring that it would begin counting Part C patients" in the Medicare fraction. *Allina III*, 587 U.S. at 571. Although that aspect of the rule was vacated in 2012, *Allina Health Services* v. *Sebelius*, 904 F. Supp. 2d 75, 95 (D.D.C. 2012), aff'd in relevant part, 746 F.3d 1102 (D.C. Cir. 2014) (*Allina I*), it remained in effect in June 2009.

CMS's Part C policy has remained the agency's position ever since. Despite revising other parts of the FY2007 Medicare fractions, the Secretary never "reconsider[ed] or revise[d]," *Domestic Securities, Inc.* v. *SEC*, 333 F.3d 239, 246 (D.C. Cir. 2003), the Part C policy they reflect.

CMS has reiterated that position repeatedly. See *Allina II*, 863 F.3d at 939-940; Gov't Br. 12.

2. CMS's Later, Unrelated Revisions Are Irrelevant

The government argues (Br. 35-37) that the June 2009 Part C determination was nonfinal because CMS later revised other aspects of the Medicare fractions. The district court rightly rejected that contention, J.A. 111, because those revisions are irrelevant to finality. Later "revisions" to a final "publi[cation]" "do not negate [its] finality" nunc pro tunc. *National Ass'n of Home Builders* v. *Norton*, 415 F.3d 8, 14 (D.C. Cir. 2005). Otherwise, agencies could evade review through constant revision.

All that CMS's amendments to the Medicare fractions show is that CMS's publication, though final, was not set in stone. But final agency action remains "final" even though it is inherently "subject to change." *Appalachian Power Co.* v. *EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000). The "possibility" that an agency "may revise" a decision "is a common characteristic of agency action, and does not make an otherwise definitive decision nonfinal." *U.S. Army Corps of Engineers* v. *Hawkes Co.*, 578 U.S. 590, 598 (2016). Even a final rule is "*always* subject to displacement by a future rulemaking." *Natural Resources Defense Council* v. *Wheeler*,

955 F.3d 68, 80 (D.C. Cir. 2020). The Federal Register is full of amendments to final rules already in force.

The government's contrary contention (Br. 20) that the June 2009 publication was nonfinal because it was "subject to * * * revision" flouts settled precedent and would upend administrative law. That a particular kind of agency action is "especially susceptible to future alteration * * * does not alone defeat finality." *POET Biorefining, LLC* v. *EPA*, 970 F.3d 392, 405 (D.C. Cir. 2020). And "[i]f the possibility"—even "probability"—"of future revision in fact could make agency action non-final," "it would be hard to imagine when any" agency action "would *ever* be final." *General Electric Co.* v. *EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002) (emphasis added).

Indeed, under the government's "could have revised" theory (Br. 38), no publication of Medicare fractions could be final. It is not even clear that a "final" rule, such as the Part C rule CMS issued in June 2023, 88 Fed. Reg. 37,772 (June 9, 2023), would qualify. Those outcomes would be unrecognizable to the Congress that enacted Section 1395*oo*(a)(1)(A)(ii) and would thwart the provision's central purpose: to "haste[n] the process of review so that a hospital will know at the earliest

possible date exactly how much it will be paid." *Washington Hospital Center* v. *Bowen*, 795 F.2d 139, 148 (D.C. Cir. 1986).

3. The Government's Proposed-Rule Analogy Fails

The government tries (Br. 20, 37-38) to analogize CMS's June 2009 Part C determination to a "notice of proposed rulemaking," "any aspect" of which a final rule may change. But that analogy fails because the June 2009 fractions were not mere proposals. The government cites no statement by CMS that it was commencing a notice-and-comment process by which it would later determine final fractions. Nor do CMS's later actions suggest that the June 2009 publication set forth only a tentative, work-in-progress proposal for public input. See Plaintiffs' Br. 6 & n.5, 26-27 (explaining that subsequent CMS revision implemented a judicial decision requiring revisions to agency's methodology); J.A. 13 (Provider Reimbursement Review Board (PRRB or Board) describing later CMS actions as "updates" to June 2009 publication). A more apt analogy is to agency guidance and interpretive rules—which can be final upon issuance without further agency action, even though they are inherently subject to subsequent amendment. See, *e.g.*, *POET Biorefining*, 970 F.3d at 404-407.

The government's reliance (Br. 34) on *Southwest Airlines Co.* v. *United States Department of Transportation*, 832 F.3d 270 (D.C. Cir. 2016), fails for similar reasons. *Southwest Airlines* held that an agency letter was nonfinal because the agency "invested its time and resources in undertaking" a notice-and-comment process "that *w*[*ould*] *lead* to a final resolution of the matters addressed." *Id.* at 276 (emphasis added). And the agency did not "simply *say* it would give further consideration" but actually "instituted the process by which it could do so." *Ibid.* Nothing like that happened here.

Moreover, unlike in *Southwest Airlines*, CMS's later actions never revisited the "issues addressed" in the June 2009 publication that plaintiffs here "challeng[e]." 832 F.3d at 275. As the government recognizes (Br. 37), "the particular feature of the Medicare fraction[s] challenged by plaintiffs" is "the inclusion of Part C days." The government cites nothing showing that CMS in June 2009 left *that* issue open. Later adjustments that altered the FY2007 Medicare fractions in unrelated respects cannot plausibly render CMS's June 2009 Part C policy nonfinal.

B. The Part C Determination Was A Determination "As To The Amount Of The Payment"

The June 2009 Part C policy also was a "determination * * * as to the amount of the payment under [§ 1395ww(d)]." 42 U.S.C. § 1395*oo*(a)(1)(A)(ii). Statutory text, context, and purpose all point to the same straightforward understanding of that provision: It authorizes review of any final CMS determination concerning how payment amounts under Section 1395ww(d) are calculated. That broad category readily includes CMS's 2009 determination of how to calculate the DSH adjustment. The government's attempt to limit review to an arbitrary subset of CMS actions is legally unsupported and unavailing here in any event.

1. All Final CMS Determinations That Concern The Amount Of Payment Are Reviewable

Section 1395*oo*(a)(1)(A)(ii)'s text sweeps broadly, authorizing review of any determination "*as to* the amount of the payment." 42 U.S.C. § 1395*oo*(a)(1)(A)(ii) (emphasis added). "As to" is a capacious phrase that means "with respect to," "concerning," and the like. *New Oxford American Dictionary* 92 (3d ed. 2010); accord, *e.g.*, *Webster's New International Dictionary of the English Language* 158 (2d ed. 1960) ("About; as regards"). Instead of confining review to determinations "of" the payment

amount, Congress thus cast a much wider net covering all CMS determinations that *concern* "the amount of the payment under [§ 1395ww(d)]." 42 U.S.C. § 1395*oo*(a)(1)(A)(ii).

That broad language makes perfect sense in context. Congress enacted Section 1395*oo*(a)(1)(A)(ii) in 1983 together with Section 1395ww(d), which tasks the Secretary with making dozens of determinations concerning the "methods for calculating" payments. *Washington Hospital*, 795 F.2d at 142, 145 n.6. Those determinations mostly pertain to individual "components" that factor into the calculation of per-patient payments. *Cape Cod Hospital* v. *Sebelius*, 630 F.3d 203, 205-206 (D.C. Cir. 2011); see, *e.g.*, 42 U.S.C. § 1395ww(d)(3)(A)(iv)(II) ("[t]he Secretary shall determine a national adjusted [diagnosis-related-group] prospective payment rate" that is based on, *inter alia*, a "standardized amount" that "the Secretary shall compute"). Section 1395*oo*(a)(1)(A)(ii) naturally refers to those "determination[s]" that Section 1395ww(d) directs CMS to make, which affect payment amounts. Nothing in Section 1395*oo*(a)(1)(A)(ii) limits review to a narrower subset of determinations. In 1986, when Congress enacted the DSH provisions, it placed them in Section 1395ww(d),

thus making DSH determinations subject to review under Section 1395*oo*(a)(1)(A)(ii). Pub. L. No. 99-272, § 9105, 100 Stat. 82, 158 (1986).

Moreover, Congress separately excluded a handful of determinations under Section 1395ww(d) from "administrative or judicial review under section 1395*oo*." 42 U.S.C. § 1395ww(d)(7). Those express exceptions underscore the breadth of Section 1395*oo*(a)(1)(A)(ii)'s general rule and counsel against reading in additional, atextual limitations. See *United States* v. *Johnson*, 529 U.S. 53, 58 (2000). Some of those carve-outs concern only individual components of payment calculations, *e.g.*, 42 U.S.C. § 1395ww(d)(7)(B) ("the methodology for the classification of discharges within [diagnosis-related] groups")—and thus would be "wholly superfluous," *TRW Inc.* v. *Andrews*, 534 U.S. 19, 31 (2001) (citation omitted), if Section 1395*oo*(a)(1)(A)(ii) itself reached only determinations that completely resolve a hospital's ultimate payment amount.

This straightforward reading "effectuates" Congress's "primary purpose" in enacting Section 1395*oo*(a)(1)(A)(ii): "provid[ing] hospitals with 'predict[a]bility regarding payment amounts.'" *Washington Hospital*, 795 F.2d at 148 (citation omitted). Immediate review of final CMS determinations that affect the ultimate payment helps ensure that "a

hospital will know at the earliest possible date exactly how much it will be paid." *Ibid.* By contrast, deferring review until a Medicare contractor performs the ministerial task of calculating a hospital's payment—often *years* later—severely undermines that aim.

Precedent and practice are in accord. This Court has described Section 1395*oo*(a)(1)(A)(ii) as authorizing review of any final determination that "establish[es] *or alter*[*s*]" a payment amount under Section 1395ww(d). *Monmouth Medical Center* v. *Thompson*, 257 F.3d 807, 811 (D.C. Cir. 2001) (emphasis added). And as the government concedes, the Court has reviewed challenges to CMS's determinations about subsidiary "component[s]" of payments. Gov't Br. 33 (citing, *e.g.*, *Shands Jacksonville Medical Center, Inc.* v. *Azar*, 959 F.3d 1113 (D.C. Cir. 2020)). Other circuits' decisions are aligned. *Temple University Hospital, Inc.* v. *Secretary of HHS*, 2 F.4th 121, 126 (3d Cir. 2021) (construing Section 1395*oo*(a)(1)(A)(ii) to authorize review of CMS determinations regarding the "methods by which" Medicare "payments are calculated" (quoting *St. Francis Medical Center* v. *Shalala*, 32 F.3d 805, 812 (3d Cir. 1994))); *Doctors Hospital, Inc. of Plantation* v. *Bowen*, 811 F.2d 1448, 1452 (11th Cir.

1987) (holding, based on *Washington Hospital*, that "decisions that determine some of the elements of the formula" were reviewable).

Every interpretive tool thus shows that Section 1395*oo*(a)(1)(A)(ii) authorizes immediate review of any final CMS determination under Section 1395ww(d) regarding how Medicare payments are calculated. CMS's June 2009 Part C determination easily qualifies. "The inclusion of Part C days" in the Medicare fraction alters payment amounts—and generally "means that [hospitals] will * * * receive [a] lower" DSH adjustment. *Allina II*, 863 F.3d at 943. CMS's action was therefore a determination as to the amount of the payment.

2. The Government's Arbitrary Test Is Untenable

The government asserts that Section 1395*oo*(a)(1)(A)(ii) limits immediate review to a subset of CMS determinations: those that happen to resolve the "final remaining variable factor" for a given payment. Gov't Br. 19 (internal quotation marks omitted); see *id.* at 30. From this premise, it reasons (Br. 18) that *no* final CMS determination concerning the DSH adjustment is immediately reviewable because (it says) the other component of the DSH calculation—the Medicaid fraction—will always

"remai[n] outstanding" until a hospital's Medicare contractor computes a hospital's final payment. That is incorrect.

The government's premise (Br. 19) that Section 1395*oo*(a)(1)(A)(ii) covers only determinations that fix the "final remaining" variable for a particular payment has no basis in the statute. Nothing in clause (a)(1)(A)(ii) supports that arbitrary limitation. And it is incompatible with the broader statutory context and purpose. See pp. 16-18, *supra*.

Precedent does not support the government's premise either. It cites (Br. 28) *Monmouth*, which held that a "general policy against reopening" settled cost reports was not "a final determination 'as to the *amount of payment*.'" 257 F.3d at 811. But that *procedural* policy bears no resemblance to CMS's June 2009 *substantive* determination to count Part C patients. And *Monmouth* itself contemplated that Section 1395*oo*(a)(1)(A)(ii) would authorize review of a final determination that "alter[ed]" DSH adjustments. *Ibid.*

The government leans on *Washington Hospital*, but that decision—which *permitted* an appeal under Section 1395*oo*(a)(1)(A)(ii)—likewise lends it no support. *Washington Hospital*'s core holding rejected the government's extreme position that "amount of the payment" in that provi-

sion refers only to "the *total* amount" of payment calculated in a notice of program reimbursement. 795 F.2d at 147 (emphasis added). That position was wrong, this Court explained, because Section 1395*oo*(a)(1)(A)(i) already authorized appeals from the notice of program reimbursement, and clause (a)(1)(A)(ii) added in 1983 "contains no such reference to" those notices or to "total program reimbursement." *Id.* at 146-147. *Washington Hospital* thus made clear that clause (a)(1)(A)(ii) "refers to per-patient amounts rather than the overall figures contained in the [notice of program reimbursement]." *Id.* at 147. It is undisputed here that the DSH adjustment is a "per-patient" amount. Gov't Br. 28.

Washington Hospital further held that the decision at issue was a "final determination" as to a per-patient amount. 795 F.2d at 147. That conclusion was all but self-evident because the agency decision happened to resolve the "only variable factor" in the relevant per-patient amount; the other inputs were either "fixed by statute" or "fixed by the Secretary and * * * not subject to judicial review." *Ibid.* But in holding those circumstances sufficient to permit review under Section 1395*oo*(a)(1)(A)(ii), *Washington Hospital* did not purport to restrict review to final determi-

nations that occur only after *all* other determinations relevant to a per-patient amount are made.

Nor has this Court understood *Washington Hospital* to limit review in that way. *Monmouth* cited *Washington Hospital*'s "variable factor" language but stated the controlling test as whether a determination "establish[es] *or alter*[*s*]" the per-patient amount. 257 F.3d at 811 (citation omitted; emphasis added). A determination can "alter" a hospital's per-patient amount even if other components of the final payment calculation remain unresolved. And *Shands Jacksonville* presupposed that Section 1395*oo*(a)(1)(A)(ii) authorizes review of the individual components of the base per-patient calculation that CMS finalizes in its annual rulemakings. 959 F.3d at 1115-1116. That conclusion, which the government accepts (Br. 33), contradicts its position. That base calculation consists of at least five "components." *Cape Cod Hospital*, 630 F.3d at 205-206. On the government's view of *Washington Hospital*, those components should *not* be reviewable under Section 1395*oo*(a)(1)(A)(ii) because most are "subject to judicial review" by other means and so remain "variable" even when CMS issues its annual final rule. 795 F.2d at 147; see Gov't Br. 33; 42 U.S.C. § 1395ww(d)(7). Yet all agree they *are* reviewable.

That is only the beginning of the incongruities the government's position invites. Thanks to the government's theory, the PRRB has repeatedly rejected appeals of CMS's June 2023 Part C final rule, among others. See PRRB, *Notice of Dismissal of Part C Appeals Based on June 9, 2023 Final Rule*, Case No. 24-0317G (Apr. 26, 2024); see also, *e.g.*, PRRB, *Dismissal—Failure to File from an Appealable Determination*, Case No. 24-1531GC (Mar. 11, 2024) (dismissing challenges to "2024 [prospective-payment] Final Rule as it relates to the Secretary's policy to include * * * only certain § 1115 waiver days in the Medicaid fraction"). If even *final rules* fall outside Section 1395*oo*(a)(1)(A)(ii), it is a dead letter. Moreover, it usually takes "a clear statement of congressional intent to preclude" *any* "review" of agency action. *Knapp Medical Center* v. *Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017). Nothing in Section 1395*oo*(a)(1)(A)(ii)'s text comes close.

3. The Part C Determination Is Reviewable Under The Government's Own Test

The government's gerrymandered gloss on Section 1395*oo*(a)(1)(A)(ii) is unavailing in any event because CMS's June 2009 publication satisfies the government's own fix-the-final-variable test. The government asserts (Br. 30) that the DSH adjustment consists of "two variable inputs": the

Medicare and Medicaid fractions. It concedes (Br. 29) that the June 2009 publication "determin[ed]" the Medicare fraction for each hospital but claims that their Medicaid fractions remained unresolved.

But the June 2009 publication *also* determined each hospital's Medicaid fraction. Because "Part C days" are "counted in one fraction or the other," *Allina I*, 746 F.3d at 1108, CMS's decision to include Part C days in the Medicare fraction necessarily meant that those days were *excluded* from the Medicaid numerator. And all other information relevant to the Medicaid fractions was already reflected in the hospitals' "year-end cost report[s]" for FY2007, Gov't Br. 7, 29—which the hospitals were required to submit to CMS before June 2009, see 42 C.F.R. § 413.24(f)(2). The Medicaid fractions were therefore no more variable than the Medicare fractions once CMS published the latter.

The government asserts (Br. 18, 28-30) that the Medicaid fractions "remained outstanding" until Medicare contractors formally "compute[d]" them months or years later. But that made-to-order distinction does not work. The same is true of many other inputs affecting payments that the government either concedes or does not dispute pose no impediment to review. To take the government's own example, whether a hos-

pital receives an "additional payment" under Section 1395ww(d)(5)(A) turns on whether its "costs" for a cost-reporting period "exceed an outlier threshold set by the Secretary." Gov't Br. 26. The government asserts that challenges to "th[at] threshold" are reviewable because it is "the sole variable factor in this adjustment." *Ibid.* But whether a particular hospital *exceeds* that threshold also necessarily turns on the hospital's *costs*, which (like the Medicaid fraction) are not formally plugged into the calculation until its Medicare contractor computes its final payment.

Even in the DSH context, the Medicaid fraction is not the only DSH-related input that Medicare contractors compute. They must also calculate, for example, each hospital's "disproportionate share adjustment percentage" based on information reflected in the year-end cost reports—such as the type of hospital (*e.g.*, urban or rural) and a hospital's number of beds. See, *e.g.*, 42 U.S.C. § 1395ww(d)(5)(F)(i)(II), (iii)-(iv). Yet the government does not contend that any of those factors remains variable when CMS publishes the Medicare fractions. Gov't Br. 30. The government's contrived distinction is no coherent distinction at all.

The government also fails to identify any benefit from barring hospitals from challenging a CMS policy determination for years until a con-

tractor perfunctorily applies it to already-known numbers. Indeed, that approach is antithetical to Congress's goal of "provid[ing] hospitals with 'predict[a]bility regarding payment amounts' * * * at the earliest possible date." *Washington Hospital*, 795 F.2d at 148 (citation omitted). At the very latest, hospitals should be able to seek review of a final CMS DSH-adjustment determination once the determination's effect on the hospitals' DSH payments is known—as it was when CMS published the FY2007 Medicare fractions in June 2009.

II. The Government's Position Has Serious Harmful Effects

The timing of administrative (and judicial) review of CMS's final determinations as to Medicare payments has important real-world consequences. The government's position, which would apparently eliminate immediate review for many determinations—and all DSH-related decisions—would inflict serious harms on hospitals and their communities. The adverse effects of the government's legally unjustified position provide still more reason to reject it.

A. Delayed Review Of Unlawful Payment Determinations Harms Hospitals, Patients, And Communities

Erroneous Medicare-payment determinations that improperly reduce the amounts hospitals receive from CMS cause hospitals immediate

harm that long-after-the-fact review often cannot redress. Belated payment may come too late altogether: Many hospitals rely on DSH adjustments to provide critical services and to remain open at all. The timing of review also affects the eligibility of DSH hospitals for *other* important federal benefits, such as the 340B Drug Pricing Program. Immediate review of DSH-related determinations is thus critical to avoid lasting harms to hospitals, patients, and local economies.

1. Delayed Review Of DSH Adjustments Deprives Hospitals Of Vital Resources

Erroneously low DSH adjustments can be very costly. Because "low-income individuals are often more expensive to treat than higher income ones," *Becerra* v. *Empire Health Foundation*, 597 U.S. 424, 429 (2022), base Medicare rates do not fully cover hospitals' costs of serving low-income populations. The DSH adjustment seeks to "compensat[e] for th[is] disparity," thus "encourag[ing] hospitals to treat low-income patients." *Ibid.* DSH adjustments can reach eight figures, *e.g.*, J.A. 45, and an erroneous calculation can be worth millions of dollars, *e.g.*, *HealthAlliance Hospitals, Inc.* v. *Azar*, 346 F. Supp. 3d 43, 52 (D.D.C. 2018).

CMS, however, has historically "pa[id] out as little money as possible" in DSH adjustments. *Northeast Hospital Corp.* v. *Sebelius*, 657 F.3d

1, 20 n.1 (D.C. Cir. 2011) (Kavanaugh, J., concurring in the judgment). Courts have repeatedly corrected the agency's "systematic undercalculation[s]." *Sebelius* v. *Auburn Regional Medical Center*, 568 U.S. 145, 151 (2013); see, *e.g.*, *Legacy Emanuel Hospital & Health Center* v. *Shalala*, 97 F.3d 1261, 1263, 1266 (9th Cir. 1996). CMS itself estimates that DSH and uncompensated-care payments collectively declined by $950 million in the past year alone. 88 Fed. Reg. 58,640, 59,409 (Aug. 28, 2023). CMS's Part C policy is part of that trend.

The timing of review makes a significant financial difference. Given the time value of money, each day hospitals must wait to seek review comes at a cost. The delay between a CMS determination and review following the contractor's computation of the hospital's total payment can last years. Many hospitals did not receive their notices of program reimbursement for FY2007 until 2013, J.A. 12—four years after CMS issued the 2009 Part C determination that foreordained their reduced DSH adjustments. And it took the Board eight years to complete its own review. Cf. *Empire Health*, 597 U.S. at 432-433 (resolving dispute about 2004 DSH rule in 2022). Hospitals at the edge of DSH eligibility might receive no DSH payments for years if an adverse determination

nudges them below the threshold. See 42 U.S.C. § 1395ww(d)(5)(F)(v); 42 C.F.R. § 412.106(i).

Although hospitals might theoretically receive some interest on underpayments, the rules governing interest are strict and complicated, see 42 U.S.C. §§ 1395g(d), 1395ff(b)(2)(C)(iv), 1395*oo*(f)(2), and hospitals rarely if ever receive fully compensatory interest. Courts have held, for example, that Congress did not intend "that providers receive interest for the years it takes to resolve" administrative appeals. *National Medical Enterprises, Inc.* v. *Sullivan*, 960 F.2d 866, 869 (9th Cir. 1992).

Moreover, any eventual compensation may come too late to avert lasting harm if hospitals are forced to curtail services or close in the interim. Between 2010 and 2021, more than 130 rural hospitals shuttered due in part to low reimbursements, and the COVID-19 pandemic saw record closures. American Hospital Ass'n, *Rural Hospital Closures Threaten Access* 3-9 (2022), https://tinyurl.com/45k3t9ck. Many urban safety-net hospitals have met the same fate. David Kendall et al., *Revitalizing Safety Net Hospitals: Protecting Low-Income Americans from Losing Access to Care*, Third Way 2 (2023) (Kendall), https://tinyurl.com/yd7xbkf7.

Delayed review also creates severe financial uncertainty for hospitals, leaving them unable to predict whether they can expand or even maintain critical services. As plaintiffs explain (Br. 40-42), once hospitals receive Medicare-fraction data from CMS, they typically can calculate the DSH payments they will eventually receive and accordingly can make budgeting, staffing, and other financial decisions, even while they await their Medicare contractors' official computation. But if hospitals cannot obtain immediate review of erroneous Medicare-fraction determinations—and must instead wait many months or years to challenge them—their ability to plan ahead is impeded.

2. Erroneous DSH Determinations Can Preclude Hospitals From Receiving Other Benefits

Erroneous DSH-adjustment determinations can have harmful spillover effects, including preventing hospitals from receiving other vital benefits. And delaying review of DSH determinations can create unpredictability for hospitals regarding their eligibility for these other benefits.

The 340B Drug Pricing Program, for example, requires manufacturers to sell prescription outpatient drugs at discounted prices to hospitals that serve low-income populations. *American Hospital Ass'n* v. *Becerra*, 596 U.S. 724, 727, 730 (2022). These "340B hospitals perform

valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Id.* at 738. One measure of 340B eligibility turns on a hospital's DSH percentage, 42 U.S.C. § 256b(a)(4)(L), which is a function of the Medicare and Medicaid fractions, see *id.* § 1395ww(d)(5)(F)(iv), (vi)-(viii), (x)-(xiv). Improperly deflating a hospital's DSH statistics thus can prevent a hospital from receiving its rightful 340B discounts. And even if the hospital's DSH adjustment itself is eventually corrected, there is no remedy for lost 340B savings.

DSH eligibility also can affect a hospital's eligibility for other critical benefits. Those include payments to offset care for "patients who have no means to pay" at all, *Florida Health Sciences Center, Inc.* v. *Secretary of HHS*, 830 F.3d 515, 517 (D.C. Cir. 2016) (citing 42 U.S.C. § 1395ww(r)), and preference for grants related to drug-overdose programs, 42 U.S.C. § 290dd-4(b)(6). Erroneous DSH determinations thus can trigger cascading financial effects.

3. DSH Errors Harm Patients And Communities

These severe financial consequences for hospitals ultimately harm the vulnerable patients and communities they serve. Hospital closures in rural areas, for example, threaten access to emergency care. MedPac,

Report to the Congress: Medicare and the Health Care Delivery System 183-185 (June 15, 2021), https://tinyurl.com/2e2mm6j4. In urban areas, a hospital's inability to provide critical treatments can have devastating effects on large populations. Kendall 2. Even the *risk* of closures can be enough to drive high-quality doctors out of the areas where they are most needed. Jane Wishner et al., *A Look at Rural Hospital Closures and Implications for Access to Care: Three Case Studies*, Kaiser Family Foundation 7 (July 7, 2016) (Wishner), https://tinyurl.com/yckjytjk.

Hospital closures also undermine local economies. In many rural areas, for example, "the local hospital is one of the largest employers in the community," and a single closure "can eliminate a hundred or more jobs immediately." Wishner 9. The resulting "loss of jobs and residents" also "has a negative impact on the tax base," which "shrink[s] available resources for schools and other public services." *Ibid.* It also becomes even more difficult for low-income communities "to recruit new industries and employers" because many businesses require that "their employees have access to a hospital [emergency department] in close proximity." *Ibid.* These effects may be felt for years and can create a downward spi-

ral, as depressed economic conditions make it difficult to attract new hospitals and high-quality providers.

B. The Government's Position Creates Uncertainty And Confusion

The government's proposed approach also harms hospitals by creating needless uncertainty about which CMS determinations are reviewable and when, which the correct reading avoids. Section 1395*oo*(a)(1)(A)(ii) promotes "predict[a]bility" for hospitals. *Washington Hospital*, 795 F.2d at 148 (citation omitted). In addition to providing hospitals with payment certainty "at the earliest possible date," *ibid.*, Section 1395*oo*(a)(1)(A)(ii) also enhances predictability by prescribing a simple, bright-line rule governing reviewability. Properly construed, the provision allows hospitals to appeal any final CMS determination concerning the calculation of payment amounts under Section 1395ww(d). That straightforward approach takes most of the guesswork out of identifying which CMS actions can be challenged immediately. And it sensibly focuses the reviewability inquiry on the specific substantive determination that a hospital wishes to challenge—uncomplicated by conjecture about how other inputs might affect the final payment calculation.

The government's approach, by contrast, blurs that bright line into oblivion. Its interpretation focuses not on the determination that hospitals seek to challenge, but on *other* determinations that happen to be part of the same payment calculation. It would force hospitals already struggling to navigate the twists and turns of a statute that is "downright byzantine," *Empire Health*, 597 U.S. at 434 (citation omitted), and "mind-numbingly complex," *id.* at 445 (Kavanaugh, J., dissenting), to ascertain which other CMS determinations might be relevant and, of those, which ones are "variable" under the government's muddled definition.

The government's own arguments illustrate the difficulty of applying its test. It concedes that several types of CMS determinations are reviewable even though they appear to fail the government's standard. See pp. 18, 22, 24-25, *supra*. And in practice, the government's approach has produced perplexing results that further obscure its test. For example, the Board has repeatedly dismissed appeals under Section 1395*oo*(a)(1)(A)(ii) challenging methodological determinations set forth in federal regulations that indisputably are final and result in lower payments to hospitals, see p. 23, *supra*—determinations that would be imme-

diately reviewable in virtually any other corner of the administrative state.

The government's opaque approach disserves the principle that "jurisdictional rules should be clear." *Direct Marketing Ass'n* v. *Brohl*, 575 U.S. 1, 14 (2015) (brackets and citation omitted). It foists on hospitals, the Board, and courts the burdens of litigating and adjudicating threshold reviewability issues. And it pressures hospitals to pursue protective filings: To avoid the risk of guessing wrong, many hospitals may file duplicative appeals following a notice of program reimbursement raising the same issue as an existing appeal from a CMS determination—multiplying the number of proceedings and submissions. The Board's rules, however, generally require hospitals to "certify" that an issue being appealed "is *not* 'currently pending in another appeal for the same period for the same providers.'" D. Ct. Doc. 32, at 10 (June 18, 2020) (citation omitted; emphasis added). Hospitals seeking to preserve their rights in the face of the government's indeterminate reviewability test should not be forced to risk violating agency rules or be left relying on administrative grace. They should be able to take a statutory provision specifically designed to make immediate review broadly available at its word.

CONCLUSION

This Court should affirm the district court's ruling.

Dated: July 29, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), the undersigned certifies that this brief complies with the applicable typeface, type-style, and type-volume limitations. This brief was prepared using a proportionally spaced type (New Century Schoolbook, 14 point). Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(f) and Circuit Rule 32(e)(1), this brief contains 6,499 words. This certificate was prepared in reliance on the word-count function of the word-processing system used to prepare this brief.

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CERTIFICATE OF SERVICE

I hereby certify that, on July 29, 2024, I electronically filed the foregoing brief with the Clerk for the United States Court of Appeals for the District of Columbia Circuit using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

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ADDENDUM

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42 U.S.C. § 1395*oo*. Provider Reimbursement Review Board

(a) Establishment

Any provider of services which has filed a required cost report within the time specified in regulations may obtain a hearing with respect to such cost report by a Provider Reimbursement Review Board (hereinafter referred to as the "Board") which shall be established by the Secretary in accordance with subsection (h) and (except as provided in subsection (g)(2)) any hospital which receives payments in amounts computed under subsection (b) or (d) of section 1395ww of this title and which has submitted such reports within such time as the Secretary may require in order to make payment under such section may obtain a hearing with respect to such payment by the Board, if—

(1) such provider—

(A)(i) is dissatisfied with a final determination of the organization serving as its fiscal intermediary pursuant to section 1395h of this title as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this subchapter for the period covered by such report, or

(ii) is dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1395ww of this title,

(B) has not received such final determination from such intermediary on a timely basis after filing such report, where such report complied with the rules and regulations of the Secretary relating to such report, or

(C) has not received such final determination on a timely basis after filing a supplementary cost report, where such cost report did not so comply and such supplementary cost report did so comply,

(2) the amount in controversy is $10,000 or more, and

(3) such provider files a request for a hearing within 180 days after notice of the intermediary's final determination under

paragraph (1)(A)(i), or with respect to appeals under paragraph (1)(A)(ii), 180 days after notice of the Secretary's final determination, or with respect to appeals pursuant to paragraph (1)(B) or (C), within 180 days after notice of such determination would have been received if such determination had been made on a timely basis.

* * *

42 U.S.C. § 1395ww. Payments to hospitals for inpatient hospital services

* * *

(d) Inpatient hospital service payments on basis of prospective rates; Medicare Geographical Classification Review Board

* * *

(5)(A)(i) For discharges occurring during fiscal years ending on or before September 30, 1997, the Secretary shall provide for an additional payment for a subsection (d) hospital for any discharge in a diagnosis-related group, the length of stay of which exceeds the mean length of stay for discharges within that group by a fixed number of days, or exceeds such mean length of stay by some fixed number of standard deviations, whichever is the fewer number of days.

(ii) For cases which are not included in clause (i), a subsection (d) hospital may request additional payments in any case where charges, adjusted to cost, exceed a fixed multiple of the applicable DRG prospective payment rate, or exceed such other fixed dollar amount, whichever is greater, or, for discharges in fiscal years beginning on or after October 1, 1994, exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) and (F) plus a fixed dollar amount determined by the Secretary.

(iii) The amount of such additional payment under clauses (i) and (ii) shall be determined by the Secretary and shall (except as payments under clause (i) are required to be reduced to take into account the requirements of clause (v)) approximate the marginal cost of care beyond the cutoff point applicable under clause (i) or (ii).

(iv) The total amount of the additional payments made under this subparagraph for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year.

(v) The Secretary shall provide that—

(I) the day outlier percentage for fiscal year 1995 shall be 75 percent of the day outlier percentage for fiscal year 1994;

(II) the day outlier percentage for fiscal year 1996 shall be 50 percent of the day outlier percentage for fiscal year 1994; and

(III) the day outlier percentage for fiscal year 1997 shall be 25 percent of the day outlier percentage for fiscal year 1994.

(vi) For purposes of this subparagraph, the term "day outlier percentage" means, for a fiscal year, the percentage of the total additional payments made by the Secretary under this subparagraph for discharges in that fiscal year which are additional payments under clause (i).

* * *

(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which—

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this subchapter or State plans approved under subchapter XIX), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

(ii) Subject to clause (ix), the amount of such payment for each discharge shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for

additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A) for that discharge, by (II) the disproportionate share adjustment percentage established under clause (iii) or (iv) for the cost reporting period in which the discharge occurs.

(iii) The disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (i)(II) is equal to 35 percent.

(iv) The disproportionate share adjustment percentage for a cost reporting period for a hospital that is not described in clause (i)(II) and that—

(I) is located in an urban area and has 100 or more beds or is described in the second sentence of clause (v), is equal to the percent determined in accordance with the applicable formula described in clause (vii);

(II) is located in an urban area and has less than 100 beds, is equal to 5 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xiii);

(III) is located in a rural area and is not described in subclause (IV) or (V) or in the second sentence of clause (v), is equal to 4 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xii);

(IV) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is classified as a sole community hospital under subparagraph (D), is equal to 10 percent or, if greater, the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, the greater of the percentages determined under clause (x) or (xi);

(V) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is not classified as a sole community hospital under subparagraph (D), is equal to the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for

discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xi); or

(VI) is located in a rural area, is classified as a sole community hospital under subparagraph (D), and is not classified as a rural referral center under subparagraph (C), is 10 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (x).

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds—

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of—

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such

period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI.

(vii) The formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(I) is—

(I) in the case of such a hospital with a disproportionate patient percentage (as defined in clause (vi)) greater than 20.2—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P – 20.2)(.65) + 5.62,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P – 20.2)(.7) + 5.62,

(c) for discharges occurring on or after October 1, 1993, and on or before September 30, 1994, (P – 20.2)(.8) + 5.88, and

(d) for discharges occurring on or after October 1, 1994, (P – 20.2)(.825) + 5.88; or

(II) in the case of any other such hospital—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P – 15)(.6) + 2.5,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P – 15)(.6) + 2.5,

(c) for discharges occurring on or after October 1, 1993, (P – 15)(.65) + 2.5,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(viii) Subject to clause (xiv), the formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(IV) or (iv)(V) is the percentage determined in accordance with the following formula: (P – 30)(.6) + 4.0, where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(ix) In the case of discharges occurring—

(I) during fiscal year 1998, the additional payment amount otherwise determined under clause (ii) shall be reduced by 1 percent;

(II) during fiscal year 1999, such additional payment amount shall be reduced by 2 percent;

(III) during fiscal years 2000 and 2001, such additional payment amount shall be reduced by 3 percent and 2 percent, respectively;

(IV) during fiscal year 2002, such additional payment amount shall be reduced by 3 percent; and

(V) during fiscal year 2003 and each subsequent fiscal year, such additional payment amount shall be reduced by 0 percent.

(x) Subject to clause (xiv), for purposes of clause (iv)(VI) (relating to sole community hospitals), in the case of a hospital for a cost reporting

period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P – 15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is equal to 10 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xi) Subject to clause (xiv), for purposes of clause (iv)(V) (relating to rural referral centers), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P – 15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is determined in accordance with the following formula: (P – 30)(.6) + 5.25,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xii) Subject to clause (xiv), for purposes of clause (iv)(III) (relating to small rural hospitals generally), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P – 15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiii) Subject to clause (xiv), for purposes of clause (iv)(II) (relating to urban hospitals with less than 100 beds), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P – 15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiv)(I) In the case of discharges occurring on or after April 1, 2004, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 12 percent for a hospital that is not classified as a rural referral center under subparagraph (C) or, in the case of discharges occurring on or after October 1, 2006, as a medicare-dependent, small rural hospital under subparagraph (G)(iv).

* * *

(7) There shall be no administrative or judicial review under section 1395*oo* of this title or otherwise of—

(A) the determination of the requirement, or the proportional amount, of any adjustment effected pursuant to subsection (e)(1) or the determination of the applicable percentage increase under paragraph (12)(A)(ii),

(B) the establishment of diagnosis-related groups, of the methodology for the classification of discharges within such groups, and of the appropriate weighting factors thereof under paragraph (4), including the selection and revision of codes under paragraph (4)(D), and

(C) the determination of whether services provided prior to a patient's inpatient admission are related to the admission (as described in subsection (a)(4)).

* * *

42 U.S.C. § 256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

* * *

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

* * *

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. 1395ww(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

* * *

42 C.F.R. § 412.106. Special treatment: Hospitals that serve a disproportionate share of low-income patients

* * *

(i) *Manner and timing of payments*. (1) Interim payments are made during the payment year to each hospital that is estimated to be eligible for payments under this section at the time of the annual final rule for the hospital inpatient prospective payment system, subject to the final determination of eligibility at the time of cost report settlement for each hospital.

(2) Final payment determinations are made at the time of cost report settlement, based on the final determination of each hospital's eligibility for payment under this section.

* * *

42 C.F.R. § 413.24. Adequate cost data and cost finding

* * *

(f) *Cost reports*. For cost reporting purposes, the Medicare program requires each provider of services to submit periodic reports of its operations that generally cover a consecutive 12-month period of the provider's operations. Amended cost reports to revise cost report information that has been previously submitted by a provider may be permitted or required as determined by CMS.

* * *

(2) *Due dates for cost reports*. (i) Cost reports are due on or before the last day of the fifth month following the close of the period covered by the report. For cost reports ending on a day other than the last day of the month, cost reports are due 150 days after the last day of the cost reporting period.

(ii) Extensions of the due date for filing a cost report may be granted by the contractor only when a provider's operations are significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as flood or fire.