No. 20-1113

IN THE

Supreme Court of the United States

AMERICAN HOSPITAL ASSOCIATION, ET AL.,

v.

Petitioners,

NORRIS COCHRAN, IN HIS OFFICIAL CAPACITY AS ACTING SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF AMICI CURIAE 33 STATE AND REGIONAL HOSPITAL ASSOCIATIONS IN SUPPORT OF PETITIONERS

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California Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 (Sept. 24, 2018)	16
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Healthcare Association of New York State, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 (Sept. 24, 2018)	
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Minnesota Health & Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 (Sept. 24, 2018)	16
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2020), available at https://www.health	
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INTEREST OF AMICI CURIAE¹

Amici curiae are 33 non-profit state and regional hospital associations.² They represent thousands of hospitals and health systems across the United States. Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. Off-site health care facilities, commonly known as "off-campus provider-based departments" (PBDs), allow *amici*'s members' patients to receive this superior level of care without having to travel long distances to hospital campuses. By taking direct aim at off-campus PBDs, however, the final rule at issue in this case will drastically shrink amici's members' ability to reach these vulnerable patients. See Azar v. Allina Health Servs., 139 S. Ct. 1804, 1808 (2019) ("[E]ven seemingly modest modifications to the [Medicare] program can affect the lives of millions."). As such, the rule's massive cuts to Medicare reimbursement rates for PBDs threaten the vital role PBDs play in communities across the country. These consequences, on their own, demonstrate amici's interest in this case.

On top of that, the question presented in this case is vitally important to *amici*. The Petition for Writ of Certiorari explains why the court of appeals erred in applying deference under *Chevron*, U.S.A., Inc. v.

¹ Pursuant to Supreme Court Rule 37.6, counsel for *amici curiae* states that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party, or any other person other than *amici curiae* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented in writing to the filing of this brief.

² A complete list of *amici curiae* can be found in the appendix.

NRDC, 467 U.S. 837 (1984). As frequent participants in rulemaking processes, *amici* have an interest in the proper application of *Chevron* deference.

If that were not enough, *amici* explain below why the decision to apply such deference changed the result in this case—and for the worse. Specifically, many amici submitted comments to the Centers for Medicare and Medicaid Services (CMS) explaining why the agency lacked the statutory authority to issue the final rule. Critically, CMS offered only conclusory responses to *amici*'s arguments, thereby demonstrating the weakness of the agency's own legal arguments. Had the court of appeals not applied *Chevron* deference, this error would have resulted in the invalidation of the agency's rule. Because that rule harms hospitals, patients, and communities across the country, and because the agency had no authority to issue it, amici have a strong interest in this Court's decision to review the question presented here.

INTRODUCTION AND SUMMARY OF ARGUMENT

For those of us who live in or near metropolitan areas, the problem of access to medical care may not seem real. We can easily find a hospital, urgent-care facility, or doctor's office in just about every urban or suburban neighborhood where we live. But *amici* represent hospitals and health systems in all types of communities across the United States—from denselypopulated urban areas to remote rural locations. As such, *amici* know better than anyone that the farther one travels from American cities—and especially as one approaches its vast rural areas—millions of patients cannot so easily obtain the medical care they need. In fact, the federal government itself has designated nearly 80 percent of rural America as "medically underserved." *See* Eli Saslow, 'Out here, it's just me': In the medical desert of rural America, one doctor for 11,000 square miles, *Washington Post* (Sep. 28, 2019).

In these so-called "medical deserts," *amici's* member-hospitals must support large geographic areas with a limited number of physicians. As a result, *amici*'s members have carefully organized their facilities and physicians to best serve their patients, wherever those patients may be located. Off-campus provider-based departments (PBDs) are a critical tool in helping hospitals address "medical deserts" and other problems with access to care. In particular, they allow *amici*'s hospitals and health systems to reach vulnerable populations that would otherwise have to travel hours to main hospital campuses. Put simply, PBDs provide an oasis of care for some of America's sickest, most medically-complex patients.

The final rule at issue in this case—which cuts Medicare reimbursements to PBDs by more than \$600 million *annually*—will increase the desertification of America's health care system. One *amici* state hospital association put it well during the rulemaking process:

This substantial reduction in a small state like Maine is unprecedented, devastating, and a true game-changer for Maine's hospitals and the state's entire healthcare delivery system. Maine's hospitals have survived on average operating margins of below two percent for each of the past five years. Nine of the sixteen hospitals impacted by this cut experienced negative operating margins in the most recent year for which the data is available. Losses of an additional \$30-\$40 million in Medicare reimbursement will clearly result in hospital closures and other reductions in services to Medicare and other patients.

Maine Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 2 (Sept. 17, 2018); *see* Kentucky Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 2 (Sept. 17, 2018) ("Kentucky hospitals are already losing money on outpatient services from Medicare payments that fail to cover costs, and these losses are worsening.... Kentucky's hospitals cannot survive with declining payments from the Medicare program, and the loss of off-campus provider based departments will only exacerbate the lack of access to health care services in the Commonwealth.").

To make matters worse, these reimbursement cuts could not come at a more precarious time for *amici*'s members. Hospitals have struggled to survive during the COVID-19 pandemic.³ Rural hospitals have strug-

³ See, e.g., Lauren Coleman-Lochner, Shaky U.S. Hospitals Risk Bankruptcy in Latest Covid Wave, Bloomberg (Oct. 14, 2020), at https://finance.yahoo.com/news/shaky-u-hospitals-riskbankruptcy-133423429.html ("A grim reality is setting in across the U.S. hospital sector: a surge in coronavirus infections is encroaching while most facilities are still recovering from the onset of the pandemic. The growing number of cases is threatening the very survival of hospitals just when the country needs them most. Hundreds were already in shaky circumstances before the virus remade the world, and the impact of caring for Covid patients has put hundreds more in jeopardy."); Ron Shinkman, Ratings agencies issue foreboding reports on hospital finances as AHA seeks \$100B to respond to COVID-19, Health Care Dive (March 20, 2020), https://www.healthcaredive.com/ news/ratings-agencies-issue-foreboding-reports-on-hospital-finan ces-as-aha-seeks/574541/ ("Most U.S. hospitals typically operate on thin margins," and recent financial reporting indicates that

gled more than most. See, e.g., Ge Bai and Gerard F. Anderson, COVID-19 And The Financial Viability Of US Rural Hospitals, Health Affairs (July 1, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200 630.208205/full/; Hoag Levins, Already in Fiscal Crisis, Rural Hospitals Face COVID-19 (June 2020), https://ldi.upenn.edu/news/already-fiscal-crisis-ruralhospitals-face-covid-19. For these hospitals and health systems, this case is critically important, and it is therefore critically important for this Court to hear it.

This case also presents weighty legal questions that require this Court's attention. Petitioners have persuasively explained why this Court should grant certiorari on the question whether the court of appeals appropriately applied *Chevron* deference when considering a statutory provision involving jurisdictional and merits questions that are "one and the same." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1239 (D.C. Cir. 2020). Rather than repeat those arguments, *amici* will home in on a particularly egregious feature of CMS's reasoning and the court of appeals' analysis that further demonstrates the need for this Court's review.

Numerous commenters—including many *amici* argued during the rulemaking process that the agency lacked statutory authority to reduce Medicare reimbursement rates because Congress intentionally chose to grandfather certain PBDs from any such cuts when it enacted Section 603 of the Bipartisan Budget Reform Act of 2015. But when faced with comments about Section 603, CMS did not meaningfully respond to them. Instead, it offered only a conclusory response.

[&]quot;the fiscal fortunes of the nation's hospitals are apparently shrinking.").

As a general matter, that failure highlights the shoddiness of the rulemaking process and the agency's results-oriented approach. More to the point, the agency's inability to meaningfully answer Section 603 underscores just how much work *Chevron* deference did for the agency. If the court of appeals had not applied such deference, Section 603 would have been fatal to the final rule. This case therefore presents a perfect vehicle to address the important *Chevron*related question presented in the Petition for Writ of Certiorari.

ARGUMENT

I. CMS Could Not Answer A Central Legal Argument Raised In Numerous Comments

A. Section 603 of the Bipartisan Budget Reform Act of 2015 Resolved the Policy Debate About How to Reimburse Off-Campus Provider-Based Departments

Years before CMS issued the final rule at issue in this case, a policy debate emerged about how CMS should reimburse off-campus facilities for certain medical services. Prior to the passage of Section 603 of the Bipartisan Budget Reform Act of 2015, CMS had long reimbursed off-campus facilities the same amount for outpatient care as it would for services provided at the main hospital. CMS reasoned that the reimbursement rates should be the same because on- and off-campus facilities "are part of the same [hospital] system and face the same regulatory requirements and regulatory costs." *Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142, 148 (D.D.C. 2019).

Medicare "traditionally welcomed" the use of offcampus PBDs because they offer many advantages as compared to requiring patients to visit hospitals or an independent physician's office. *Id.* For example, off-campus facilities are often "cheaper" than oncampus alternatives. Id. One reason for this is that off-campus PBDs can provide services where the "patient does not spend the night," thereby reducing costs. Id. What is more, off-campus facilities are often more convenient because they can be located farther away from a hospital's main campus. Many hospital systems have thus taken advantage of PBDs to reach underserved populations and neighborhoods. Id. at 148 n.1. In addition, some hospital systems have used off-campus facilities to provide special services, such as an urgent care clinic, an oncology unit, or some kind of specialized medical practice like cardiology or urology, often because space constraints prevent the hospital from developing those practices on its main campus. Id. Finally, off-campus PBDs often provide different services to patients than a typical physician office does, particularly because "physicians often refer more difficult and complex patients to a [hospital outpatient department (HOPD)] setting as opposed to a regular physician office." Maine Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 2 (Sept. 17, 2018). For example, "[p]atients are twice as likely to receive care from a nurse in addition to a physician at a [PBD], and other important services such as laboratory, imaging, chemotherapy, surgical and many other reasonable and necessary services are available to Medicare beneficiaries in these settings." Id. In general, as the district court in this case recognized, off-campus PBDs allow hospitals to "offer more comprehensive services to their patients." Azar, 410 F. Supp. 3d. at 148.

At the same time, some off-campus PBDs provide the same kinds of services as free-standing, independent physician's offices. For example, both PBDs and independent physician's offices offer "evaluation and management" services. Id. But PBDs were historically reimbursed at a higher rate for those services because, unlike independent physician's offices, PBDs have increased regulatory requirements and costs due to their affiliation with hospitals. Id.; see also 42 C.F.R. § 413.65(a),(e) (requiring PBDs to comply with the same exacting Medicare Conditions of Participation as their affiliated hospital); Medicaid Program; Clarification of Outpatient Hospital Facility (Including Outpatient Hospital Clinic) Services Definition, 73 Fed. Reg. 66,187, 66,191 (Nov. 7, 2008) (noting that PBDs typically have higher costs relative to an independent clinic or physician's office because of "high facility overhead expenses").

In the decade before 2015, the total volume of services provided by off-campus PBDs increased. Id. As the district court in this case correctly recognized, "[t]here are many possible explanations for this increase." Id. Some attribute this increase to the overall increase in the Medicare-eligible population during this period. Id. Others attribute it to improvements in technology that have allowed services traditionally provided in in-patient settings to now be offered in outpatient settings like PBDs. Ken Abrams, Andreea Balan-Cohen & Priyanshi Durbha, Growth in Outpatient Care, Deloitte (Aug. 15, 2018), https:// www2.deloitte.com/us/en/insights/industry/health-care /outpatient-hospital-services-medicare-incentives-value -quality.html. Others have attributed this growth in off-campus services to the financial incentives that the Medicare reimbursement system presented.

One influential stakeholder, the Medicare Payment Advisory Commission (MedPAC), has endorsed this

In its view, "because off-campus latter position. provider-based departments are paid at higher rates than physician offices ... hospitals were buying existing physician offices and converting them into offcampus provider-based departments, sometimes without a change of location or patients, unnecessarily causing CMS to incur higher costs." Azar, 410 F. Supp. 3d at 149. MedPAC's March 2014 report to Congress is illustrative of this viewpoint. In that report, MedPAC recommended that Congress "adjust[] the rates paid for certain services when they are provided in hospital outpatient departments (HOPDs) so they more closely align with the rates paid in freestanding physician offices." MedPAC, Report to the Congress: Medicare Payment Policy 53 (Mar. 2014), http://www.medpac.gov/docs/default-source/reports/ma r14 entirereport.pdf. Adjusting the rates in this manner would address what MedPAC perceived as a "financial incentive for hospitals to purchase freestanding physicians' offices and convert them to HOPDs without changing their location or patient mix." Id.

To be clear, MedPAC's view is deeply controversial and has long been disputed, including by Petitioners and many commenters during the rulemaking process here. See 83 Fed. Reg. at 59,005-07; *id.* at 59,011 ("[C]ommenters expressed concern that there was no data-driven basis to conclude that OPD services have increased unnecessarily. The commenters also claimed that the proposal is based on unsupported assertions and assumptions regarding increases in volume."). But despite this sharp difference of opinion, Congress could not ignore MedPAC's view. After all, MedPAC is an independent *Congressional* agency that was created to advise *Congress* on issues affecting the Medicare program. See MedPAC, About MedPAC, http://www.medpac.gov/-about-medpac-; *see id*. ("MedPAC meets publicly to discuss policy issues and formulate its recommendations to the Congress.... Two reports—issued in March and June each year—are the primary outlet for Commission recommendations.").

Congress finally addressed this long-running policy debate when it enacted Section 603 of the Bipartisan Budget Reform Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 597-598. Critically, Section 603 rejected MedPAC's recommendation. See Medicare Payment Advisory Commission (MedPAC), Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 1-2 (Sept. 21, 2018) ("In 2012 and 2014, MedPAC recommended an approach different from the approach detailed in section 603 to address the issue of the higher Medicare payments that result from hospitals converting freestanding offices into off-campus PBDs.... [W]e recognize that with section 603 of BBA 15, the Congress took a different approach than ours that is based on whether an off-campus PBD began billing under the OPPS after a certain date, and CMS must implement that approach." (emphasis added)). Instead, Congress struck a balance between the competing positions on how Medicare should reimburse PBDs.

Section 603 created two categories of PBDs: (1) those established before November 2015 and (2) those established after November 2015. For the pre-November 2015 PBDs, Congress required CMS to continue paying off-campus PBDs (referred to in the statute as "excepted" off-campus PBDs) at the same rate as hospitals. See 42 U.S.C. § 1395l(t)(1)(B)(v), (t)(21)(B)(ii). For post-November 2015 PBDs, Congress required CMS to reimburse PBDs at the same rate as independent physician's offices. See id. § 1395l(t)(21)(C); see generally Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016).

The following year, Congress doubled-down on its compromise approach. Faced with the question of how to reimburse PBDs that were "mid-build" at the time of Section 603's enactment, Congress again rejected MedPAC's recommendation to equalize PBD and physician-office payments across the board. Instead, in the 21st Century Cures Act, Pub. L. No. 114-255, § 16001, 130 Stat. 1033, 1324 (2016), Congress provided that "mid-build" PBDs should be reimbursed at the same rates as existing, pre-November 2015 offcampus PBDs, *i.e.*, the same rate as hospitals. See 42 U.S.C. § 1395l(t)(21)(B)(iv)-(v). An accompanying committee report explained that Section 603 "effectively grandfathered" any existing off-campus PBD from the "new payment rates," whereas "new offcampus PBD[s]" would "be eligible for only [the] physician fee schedule" payment rate "rather than the higher hospital outpatient payment rate." H.R. Rep. No. 114-604, pt. 1, at 10 (2016); see also id. at 20 (noting that excepted off-campus PBDs would "continue to receive the higher payment rates that apply to an outpatient department on the campus of a hospital").4

⁴ MedPAC continued to recommend to Congress that Medicare should reimburse all off-campus PBDs the same as independent physician's offices. As CMS recognized in the final rule here, MedPAC's March 2017 Report to Congress recommended that Congress direct the Secretary to reduce or eliminate differences in payment rates between hospital outpatient departments and physician offices. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical

B. Many Commenters Explained That Section 603 of the Bipartisan Budget Reform Act of 2015 Foreclosed CMS's Attempt to Further Reduce Reimbursement Rates for Grandfathered PBDs

Even though Congress resolved this policy debate in 2015, CMS issued a proposed rule in 2018 that would slash reimbursement rates for "excepted" pre-November 2015 PBDs. Specifically, the proposed rule stated that reimbursement for clinic services offered by "excepted" off-campus PBDs "would now be equivalent to the payment rate for" clinic visits provided by non-excepted off-campus PBDs. Medicare Program: **Proposed Changes to Hospital Outpatient Prospective** Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 37,046, 37,142 (proposed July 31, 2018). CMS claimed it had the statutory authority to impose such cuts under 42 U.S.C. § 1395l(t)(2)(F), which permits the agency to "develop a method for controlling unnecessary increases in the volume of covered OPD services." 83 Fed. Reg. at 37,142-37,143.

In so doing, CMS endorsed the very MedPAC position that Congress rejected in 2015, 2016, and since. It stated that "the differences in payment for ... services" continued to be "a significant factor in the shift in services from the physician's office to the hospital outpatient department, . . . unnecessarily increasing hospital outpatient department volume." *Id.* at 37,142. In particular, CMS insisted that the "higher payment that is made under the OPPS, as compared to payment under the [Physician Fee

Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818, 59,007 (Nov. 21, 2018). Congress *still* has not adopted this recommendation.

Schedule], [was] likely to be incentivizing providers to furnish care in the hospital outpatient setting." *Id.* at 37,141. According to CMS, this shift in services was "unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives." *Id.* at 37,142. Accordingly, HHS asserted its purported authority under Section 13951(t)(2)(F) to cut Medicare payments to hospitals by roughly \$760 million per year. *Id.* at 37,143.

Thousands of commenters responded to CMS's proposed rule—especially its assertion of statutory authority to make such dramatic cuts to off-campus PBD reimbursement rates. Specifically, numerous commenters focused on Section 603 of the Bipartisan Budget Reform Act of 2015. These many commenters argued that Congress intentionally barred the type of across-the-board cuts to off-campus PBD reimbursements that CMS sought to impose in its proposed rule.

Petitioner American Hospital Association, for example, offered a thoughtful legal argument why Section 603 precluded CMS's proposed cuts. It stated that "Congress expressly chose *not* to confer on CMS the authority to reimburse excepted off-campus PBDs at the reduced rates paid to nonexcepted off-campus PBDs," and that CMS ignored the "express and statutorily-mandated grandfathering exception created by section 603." American Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 5-6 (Sept. 24, 2018). Petitioner further explained that

[a]llowing CMS to render the statutory exception a legal nullity would violate a fundamental tenet of statutory construction requiring, whenever possible, that statutes be "construed so that effect is given to all [] provisions, so that no part will be inoperative or superfluous, void or insignificant."

• • • •

CMS does not have the authority to implement the Medicare Act in a fashion that eliminates an exception that was expressly established by statute. When it enacted section 603, Congress made a clear policy choice that excepted PBDs would not be subject to the same site-neutrality policies that apply to nonexcepted PBDs. CMS's proposal *disagrees with and seeks to overturn* the policy choice made by Congress. But it is well established that federal agencies may not ignore statutory mandates or prohibitions merely because of policy disagreements with Congress.

Id. at 6 (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004); other internal citations and quotation marks omitted).

Several *amici* state hospital associations offered similar comments:

Amicus Maine Hospital Association stated: "When Congress passed Section 603 of the Bipartisan Budget Act of 2015, it was a clear and deliberate action to preserve the existing OPPS rate structure for 'excepted' or 'grandfathered' HOPDs.... [I]t is inconceivable that CMS would disregard Section 603 of the Bipartisan Budget Act of 2015 entirely and propose an enormous 60 percent Medicare rate reduction for such large amounts of critical physician services provided in Maine and around the country." Maine Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 5-6 (Sept. 17, 2018).

- Amicus Tennessee Hospital Association "urge[d]" CMS to rescind the proposed policy "because CMS lacks the legal authority to pay for clinic visits furnished in excepted off-campus PBDs at the same rate that they are paid in non-excepted offcampus PBDs. We believe this proposed policy misinterprets and conflicts with Congressional intent, which explicitly intended payment levels for excepted and non-excepted facilities to be different." Tennessee Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 2 (Sept. 23, 2018).
- Amicus California Hospital Association explained: "CMS lacks the statutory authority to reduce payments to excepted PBDs.... CHA is very concerned that CMS has completely ignored congressional intent in protecting those offcampus PBDs that were open prior to November 2, 2015. Congress intended there to be a material distinction in payment rates between excepted and nonexcepted PBDs — this was made clear when it exempted certain PBDs from the payment changes under Section 603 of the BBA. Congress even went so far as to further clarify which providers are excepted and non-excepted when it passed the 21st Century Cures Act, which allows

providers that were mid-build to qualify for an exemption to this payment policy." California Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 3 (Sept. 24, 2018).

- Amicus Healthcare Association of New York State explained that "Section 603 of the Bipartisan Budget Act (BBA) of 2015 clearly protects off-campus PBDs billing Medicare for outpatient services on or before Nov. 2, 2015 (referred to as "excepted sites") from site-neutral payment reductions. However, in its proposed rule, CMS ignores the intent of Congress by proposing to pay the site-neutral 40% OPPS payment level to "excepted" offcampus PBDs for a basic clinic visit...." Healthcare Association of New York State, Proposed Rule Comment Letter on Change 83 Fed. Reg 37,046 at 2 (Sept. 24, 2018).
- Amicus Minnesota Hospital Association stated: "CMS lacks statutory authority to reduce payments to excepted PBDs to the level of nonexcepted PBDs.... Congress expressly chose not to confer on CMS authority to reimburse excepted off-campus PBDs at the reduced rates paid to nonexcepted off-campus PBDs – it clearly intended for there to be a material distinction in payment rates between excepted and nonexcepted PBDs." Minnesota Health & Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 7 (Sept. 24, 2018).

An additional comment letter is worth spotlighting. During the rulemaking process, a bipartisan group of 48 United States Senators submitted a letter to CMS explaining their opposition to the proposed reimbursement cuts. Much like the comments from Petitioner and *amici*, this letter challenged CMS's legal authority to promulgate the proposed rule:

When Congress passed Section 603 of the Bipartisan Budget Act of 2015, we sought to establish a clear distinction between hospital outpatient departments (HOPDs) that were billing under the OPPS at that point in time versus all new HOPDs that would seek reimbursements following the passage of the Act. Congress then reaffirmed the position that this distinction was to apply to all services rendered in an HOPD that had received the grandfathered status under Section 603 by passing Section 16001 of the 21st Century Cures Act in 2016.

Senator Rob Portman, et al., Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 1 (Sept. 28, 2018), *available at* https://images.magnetmail.net/ images/clients/AHA_MCHF/attach/2018/October/Port man_Stabenow_Site_Neutral_Letter_092918.pdf. The bipartisan group of Senators went on to explain that "[i]n passing Section 603, Congress was clear in its intention to grandfather existing facilities, so that only new off-campus sites would have payments reduced." *Id*. In their view, then, CMS lacked the statutory authority to implement its proposed rule.⁵

⁵ These 48 Senators were not the only legislators who expressed their view of Congress' intent in enacting Section 603. Two years earlier, another bipartisan group of 51 Senators and

C. CMS Offered a Conclusory Response to the Many Comments Explaining That Section 603 of the Bipartisan Budget Reform Act of 2015 Foreclosed CMS' Attempt to Further Reduce Reimbursement Rates for Grandfathered PBDs

Despite the many comments setting forth nuanced legal arguments for why Section 603 barred CMS's proposed reimbursement cuts, the agency forged ahead and included those cuts in its final rule. Remarkably, it did so without giving a meaningful legal argument in response. Quite the contrary, the final rule offered only a conclusory answer to the comments explaining that Section 603 deprived CMS of the statutory authority to reduce reimbursement payments for certain services provided at off-campus PBDs.

CMS was aware that numerous commenters raised this argument about Section 603. The final rule recognized that the "commenters stated that Congress expressly chose in section 603 of the Bipartisan Budget Act of 2015 not to confer on CMS authority to pay excepted off-campus PBDs at the reduced rates paid to nonexcepted off-campus PBDs." Medicare

²³⁵ members of the House of Representatives sent a letter to the Acting Administrator of CMS explaining that Section 603 was intended to "establish[] lower payment levels for new off-campus hospital patient departments" and urging CMS not to adopt various interpretations that would "trigger payment reductions under [s]ection 603" for facilities that "were billing under the OPPS prior to November 2, 2015." See Letter to Andrew M. Slavitt, Acting Administrator, CMS, from 235 members of the House of Representatives and 51 Senators (May 24, 2016) (cited in American Hospital Association, Comment Letter on Proposed Rule Change 83 Fed. Reg 37,046 at 5-6 n.5 (Sept. 24, 2018)).

Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818, 59,012 (Nov. 21, 2018). Further, the final rule noted that the "commenters asserted that CMS is ignoring the express and statutorily mandated grandfathering exception created by section 603." *Id*.

The agency's response, however, did not meaningfully engage with this legal argument. It instead gave a primarily policy-based response. CMS began by attacking Section 603's efficacy. It insisted that Section 603 addressed only "some of the concerns related to shifts in settings of care and overutilization of services in the hospital outpatient setting." Id. Echoing the MedPAC position that Congress repeatedly rejected, CMS then explained that "the current site-based payment creates an incentive for an unnecessary increase in the volume of this type of OPD service, which results in higher costs for the Medicare program, beneficiaries, and taxpayers more generally." Id. In fact, CMS directly criticized Congress' policy choice in Section 603: "While it is clear that the action Congress took in 2015 to address certain offcampus PBDs helped stem the tide of these increases in the volume of OPD services, it is likewise clear that the more specific payment adjustment has not adequately addressed the overall increase in the volume of these types of OPD services because most offcampus PBDs continue to be paid the higher OPPS amount for these services." Id.

When the agency eventually turned to the comments' legal arguments, its answers were entirely conclusory. Rather than engaging with the legal points made in the comments, CMS merely stated: "We do not believe that the section 603 amendments

to section 1833(t) of the Act, which exclude applicable items and services furnished by nonexcepted offcampus PBDs from payments under the OPPS, preclude us from exercising our authority in section 1833(t)(2)(F) of the Act to develop a method for controlling unnecessary increases in the volume of covered outpatient department services under the OPPS." *Id.* In making that point about the statutory authority it was relying on, the agency did *not* address the commenters argument regarding Congress' intent in shielding grandfathered off-campus PBDs from reimbursement reductions or any of their other legal contentions about Section 603.

II. CMS's Conclusory Response To Section 603 Underscores The Weakness Of Its Legal Analysis And Why This Case Provides A Clean Vehicle For This Court's Review

Petitioners have convincingly explained why the question presented warrants this Court's review. The need for review on that *Chevron* question is bolstered by the agency's failure to meaningfully address the numerous comments about Section 603. In particular, the agency's inability to muster any response to Section 603 demonstrates that, without *Chevron* deference, its legal interpretation of 42 U.S.C. 13951(t)(12)(A) could not be upheld.

Much like the agency, the court of appeals' analysis reflects an overreliance on *Chevron* and an underreliance on Section 603. Critically, the court of appeals upheld CMS's statutory authority only after it incorrectly (and without explanation) hived off the Section 603 issue from its analysis of Section 1395l(t)(12)(A). *See Azar*, 964 F.3d 1245 ("The Hospitals argue in the alternative that HHS's decision to reduce E&M reimbursement to off-campus PBDs contravenes section 603 of the Bipartisan Budget Act of 2015."). In reality, the two statutes are closely intertwined and Petitioner argued them as such in the court of appeals. *See* Appellee's Br. at 49-52. Without *Chevron* deference and with a proper understanding of the relationship between Sections 603 and § 1395l(t)(12)(A), this case would have been decided in Petitioners' favor.

As numerous commenters explained during the rulemaking process, Section 603 places important limitations on Respondent's legal authority to slash reimbursements for certain PBDs. See infra at 13-17 The statutory design and context, coupled with bedrock canons of statutory construction, provide irrefutable evidence that Section 603 definitively decided the long-running policy question whether CMS would have the authority to cut reimbursement rates for excepted PBDs. For example, as Petitioners explained below (Appellee's Br. at 52), the issue whether CMS had statutory authority under Section 1395l(t)(12)(A) cannot be answered without considering whether a more specific piece of legislation-Section 603delimited that purported general authority. E.g., RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 645 (2012) ("It is a commonplace of statutory construction that the specific governs the general. That is particularly true where . . . Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions."). Yet the court of appeals answered the Section 1395l(t)(12)(A) question both as if it were wholly separate from the Section 603 question and more important for whether this Court should grant certiorari—with a heavy thumb on the scale due to *Chevron* deference.⁶

Not only did the court of appeals never respond to this specific-governs-the-general canon, it never explained why it treated Section 603 as merely an "alternative" argument and relegated its analysis of that provision to an entirely separate section of its opinion from its analysis of Section 1395l(t)(12)(A). Azar, 964 F.3d 1245. Section 603, after all, is part of the same statutory scheme as Section 1395l(t)(12)(A); in fact, they are codified together in the same section of the U.S. Code. Sure, the court of appeals recognized that the "broader statutory context" was relevant to its interpretation of Section 1395l(t)(12)(A). Azar, 964 F.3d 1241. But it somehow chose not to consider Section 603 when construing Section 1395l(t)(12)(A), instead letting *Chevron* deference do most of the work in its statutory analysis.⁷

⁶ In dicta, the court of appeals briefly addressed the merits of whether Section 603 barred the final rule's reimbursement cuts. It stated that "[n]othing in the text of section 603 indicates that preexisting off-campus PBDs are forever exempt from adjustments to their reimbursement." *Azar*, 964 F.3d 1246. That analysis, incomplete and incorrect as it is, is beside the point. What matters for purpose of the question presented in the Petition for Writ of Certiorari is that the court of appeals' three-sentence dicta regarding Section 603 was three sentences more than CMS gave during the rulemaking process and was inexplicably divorced from any analysis of Section 1395l(t)(12)(A).

⁷ The court of appeals' separate consideration of each statutory provision was particularly curious because the district court had correctly viewed the two questions as related. *See Azar*, 410 F. Supp. 3d at 159-60 (holding that Section 603 proves that Congress "demonstrated that it retains for itself the authority to make these and similarly selective funding decisions in this highly complicated intersection of patient needs, medical care, and government funding through the relative payment weight

These misguided choices confirm the need for this Court's review. Section 603 is directly relevant to the meaning of Section 1395l(t)(12)(A). See infra at 13-17, 21; Pet. for Cert. at 27. And, as Petitioners' have explained, there is a deep circuit split on the issue whether *Chevron* deference applies to a statutory interpretation question that determines both the lawfulness of agency action and the court's jurisdiction. See Pet. for Cert. at 13-20. Indeed, four courts of appeals would not have deferred to CMS's interpretation of Section 1395l(t)(12)(A). See id. If de novo review were applied, as it would have been elsewhere throughout the country, the final rule could not have survived judicial review because Section 603 bars the agency's devastating reimbursement cuts for grandfathered PBDs. Consequently, this case provides a clean vehicle to address the important question presented in the Petition for Writ of Certiorari.

CONCLUSION

This Court should grant the Petition for a Writ of Certiorari.

Respectfully submitted,

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system," but CMS's interpretation of Section 1395l(t)(12)(A) would erroneously acquire unilateral authority to pick and choose what to pay for OPD services, which clearly was not Congress' intention.").

APPENDIX

1a APPENDIX

Arizona Hospital and Healthcare Association Arkansas Hospital Association California Hospital Association **Connecticut Hospital Association** Florida Hospital Association Georgia Hospital Association **Greater New York Hospital Association** Healthcare Association of New York State Idaho Hospital Association **Illinois Hospital Association** Iowa Hospital Association Kansas Hospital Association Kentucky Hospital Association Maine Hospital Association Massachusetts Health & Hospital Association Michigan Health & Hospital Association Minnesota Hospital Association Mississippi Hospital Association Missouri Hospital Association Nebraska Hospital Association New Hampshire Hospital Association

New Jersey Hospital Association

New Mexico Hospital Association

North Carolina Healthcare Association

North Dakota Hospital Association

Ohio Hospital Association

Oregon Association of Hospitals and Health Systems

The Hospital and Healthsystem Association of Pennsylvania

South Carolina Hospital Association

Tennessee Hospital Association

Texas Hospital Association

Washington State Hospital Association

West Virginia Hospital Association