ORAL ARGUMENT SCHEDULED FOR APRIL 17, 2020

Nos. 19-5352, 19-5353, 19-5354

IN THE

United States Court of Appeals for the District of Columbia Circuit

AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services,

Defendant-Appellant.

On Appeal from the United States District Court for the District of Columbia
Nos. 1:18-cv-02841-RMC, 1:19-cv-00132-RMC, 1:19-cv-1745-RMC
District Judge Rosemary M. Collyer

RESPONSE BRIEF FOR APPELLEES

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February 20, 2020

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. PARTIES

1. Parties and amici appearing before the District Court and in this Court in these consolidated cases are the following:

Appellee American Hospital Association (AHA) is a national, not-for-profit organization that represents and serves nearly 5,000 hospitals, health care systems, and networks, plus 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, systems, and other related organizations. AHA has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Association of American Medical Colleges (AAMC) is a national, not-for-profit association that serves all 154 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. AAMC advocates on behalf of its members and patients in connection with national health-policy matters. AAMC has no parent corporation and no publicly held company has a 10% or greater ownership interest.

Appellee Mercy Health Muskegon is a Catholic nonprofit hospital that serves the greater Muskegon, Michigan area and surrounding communities. Mercy Health Muskegon is an operating unit of Mercy Health Partners. Mercy Health

Partners is a wholly owned subsidiary of Trinity Health Michigan, Inc. Trinity Health Michigan Inc. is a wholly owned subsidiary of Trinity Health, Inc., which has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Clallam County Public Hospital No. 2, d/b/a Olympic Medical Center is a comprehensive health care provider serving the North Olympic Peninsula with a network of facilities in Clallam County, Washington. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee York Hospital is a small community hospital located in York, Maine and serving the surrounding area. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee University of Kansas Hospital Authority is a not-for-profit teaching medical center located in Kansas City, Kansas, and affiliated with the University of Kansas School of Medicine. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Hackensack Meridian Health, d/b/a Jersey Shore University Medical Center, is a not-for-profit hospital located in Neptune, New Jersey. It is the only academic university-level teaching hospital in the coastal New Jersey and

the Central Jersey area. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Barnes-Jewish Hospital is a not-for-profit teaching hospital located in St. Louis, Missouri. It is affiliated with the Washington University School of Medicine. It is owned by BJC Health System, which is not a publicly traded company.

Appellee Barnes-Jewish West County Hospital is a not-for-profit teaching hospital in the western St. Louis County, Missouri. It is owned by BJC Healthcare, which is not a publicly traded company.

Appellee Blue Ridge Healthcare System, Inc., d/b/a CHS Blue Ridge, is a not-for-profit teaching hospital located in Morganton, North Carolina. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Carilion Medical Center is a not-for-profit teaching hospital in Roanoke, Virginia. It is owned by Carilion Clinic, which is not a publicly traded company.

Appellee Central Vermont Medical Center, Inc. is a not-for-profit hospital serving approximately 66,000 people in central Vermont. It is owned by the University of Vermont Medical Center Inc, which is not a publicly traded company.

Appellee Columbus Regional Healthcare System, Inc. is a not-for-profit hospital located in Whiteville, North Carolina. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee East Baton Rouge Medical Center, LLC, d/b/a Ochsner Medical Center – Baton Rouge is a not-for-profit hospital located in Baton Rouge, Louisiana. It is owned by Ochsner Health System, which is not a publicly traded company.

Appellee Florida Health Sciences Center Inc., d/b/a Tampa General Hospital is a not-for-profit teaching hospital located in downtown Tampa, Florida. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Franciscan Missionaries of Our Lady Health System, Inc., d/b/a Our Lady of Lourdes Regional Medical Center is a Catholic not-for-profit hospital located in Lafayette, Louisiana. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Franciscan Missionaries of Our Lady Health System, Inc., d/b/a Our Lady of the Lake Regional Medical Center is a Catholic not-for-profit hospital located in Baton Rouge, Louisiana that serves as a teaching hospital for several institutions, including Louisiana State University and Tulane University. It has no

parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Hackensack Meridian Health, d/b/a Bayshore Medical Center is a not-for-profit hospital located in Holmdel, New Jersey. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Hackensack Meridian Health, d/b/a Riverview Medical Center is a not-for-profit hospital serving the northern region of Monmouth County, New Jersey. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Heartland Regional Medical Center is a not-for-profit hospital located in Marion, Illinois. It is owned by Mosaic Health System, which is not a publicly traded company.

Appellee Lima Memorial Health System is a not-for-profit healthcare organization serving northwest Ohio. It is owned by the Lima Memorial Joint Operating Company, which is not a publicly traded company.

Appellee Mercy Medical Center, Inc. is a not-for-profit teaching hospital in Canton, Ohio. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Missouri Baptist Medical Center is a not-for-profit teaching hospital in West St. Louis County, Saint Louis, Missouri. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Montefiore Health System, Inc., d/b/a Montefiore Medical Center is a not-for-profit academic medical center located in the Norwood section of the Bronx, New York City, and is the primary teaching hospital of the Albert Einstein College of Medicine. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Montefiore Health System, Inc., d/b/a St. Luke's Cornwall Hospital is a not-for-profit hospital located in Newburgh, New York. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Montefiore Health System, Inc., d/b/a White Plains Hospital is a not-for-profit hospital located in White Plains, New York. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Northwest Medical Center is a for-profit hospital located in Springdale, Arkansas. The parent corporation of Northwest Medical Center is Community Health Systems, which is publicly traded as CHSPSC, LLC.

Appellee NYU Langone Health System is a not-for-profit teaching medical center located in New York City, New York. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee NYU Winthrop Hospital is a not-for-profit teaching medical center located in Mineola, New York. It is owned by NYU Langone Health System, which is not a publicly traded company.

Appellee Ochsner Clinic Foundation, d/b/a Oschner Medical Center is a not-for-profit teaching hospital, located in New Orleans, Louisiana. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee OSF Healthcare System, d/b/a Saint Anthony Medical Center is a not-for-profit teaching hospital located in Rockford, Illinois. It is owned by the Sisters of The Third Order of St Francis, which is not a publicly traded company.

Appellee OSF Healthcare System, d/b/a Saint Anthony's Health Center is a not-for-profit teaching hospital located in Alton, Illinois. It is owned by the Sisters of The Third Order of St Francis, which is not a publicly traded company.

Appellee OSF Healthcare System, d/b/a Saint Francis Medical Center is located in Peoria, Illinois, is a not-for-profit teaching hospital located in Peoria, Illinois. It is owned by the Sisters of the Third Order of St Francis, which is not a publicly traded company.

Appellee OSF Healthcare System, d/b/a St. Joseph Medical Center is a not-for-profit teaching hospital located in Bloomington, Illinois. It is owned by the Sisters of the Third Order of St Francis, which is not a publicly traded company.

Appellee Piedmont Newnan Hospital, Inc. is a not-for-profit hospital located in Newnan, Georgia. It is owned by Piedmont Hospital, Inc., which is not a publicly traded company.

Appellee Progress West Healthcare Center, d/b/a Progress West Hospital is a not-for-profit teaching hospital located in O'Fallon, Missouri. It is owned by BJC Health System, which is not a publicly traded company.

Appellee Rush University Medical Center is a not-for-profit teaching medical center located in Chicago, Illinois. It is owned by Rush System for Health, which is not a publicly traded company.

Appellee Sarasota Memorial Hospital is a teaching hospital located in Sarasota, Florida. It is affiliated with Florida State University College of Medicine. It is owned by Sarasota Memorial Hospital and Health Care System, which is not a publicly traded company.

Appellee Southwest General Health Center is a not-for-profit hospital, located in Middleburg Heights, Ohio. It is partnered with University Hospitals of Cleveland. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Stanford Health Care is a not-for-profit medical center, located in Stanford, California. It serves as a teaching hospital for the Stanford University School of Medicine. It is owned by Leland Stanford Junior University, which is not a publicly traded company.

Appellee Tarrant County Hospital District, d/b/a JPS Health Network is the public hospital district of Tarrant County, Texas. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee The Charlotte-Mecklenburg Hospital Authority, d/b/a Atrium Health Lincoln, is a teaching acute care hospital located in Lincolnton, North Carolina. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee The Charlotte-Mecklenburg Hospital Authority, d/b/a Atrium Health Pineville, is a teaching hospital located in Charlotte, North Carolina. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee The Charlotte-Mecklenburg Hospital Authority, d/b/a Atrium Health Union, is a teaching hospital located in Monroe, North Carolina. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee The Charlotte-Mecklenburg Hospital Authority, d/b/a Atrium Health University City is a teaching acute care hospital located in Charlotte, North Carolina. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas HealthCare System NorthEast is a teaching acute care hospital located in Concord, North Carolina. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Medical Center is a teaching hospital located in Charlotte, North Carolina. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee The Rector and Visitors of the University of Virginia, d/b/a University of Virginia Medical Center, is a not-for-profit teaching hospital located in Charlottesville, Virginia. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee University Hospitals Health System, Inc., d/b/a UH Cleveland Medical Center, is a not-for-profit teaching hospital in Cleveland, Ohio. It is an affiliate hospital of Case Western Reserve University. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee University Hospitals Health System, Inc., d/b/a UH Elyria Medical Center, is a not-for-profit teaching hospital located in Elyria, Ohio. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee University Hospitals Health System, Inc., d/b/a UH Geauga Medical Center, is a not-for-profit teaching hospital located in Chardon, Ohio. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee University of Vermont Medical Center, Inc. is a not-for-profit teaching medical center located in Burlington, Vermont. It is affiliated with the University of Vermont College of Medicine and the University of Vermont College of Nursing and Health Sciences. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellee Vanderbilt University Medical Center is a not-for-profit teaching medical complex in Nashville, Tennessee. It has no parent corporation and no publicly held company owns a 10% or greater ownership interest.

Appellant is Alex M. Azar II, in his official capacity as Secretary of Health & Human Services.

Digestive Health Physicians Association, Large Urology Group Practice Association, and The OrthoForum filed an amicus brief.

2. Parties and amici appearing before the district court, but who have not entered an appearance on appeal, are the following:

AnMed Health System, d/b/a AnMed Health d/b/a AnMed Health Medical Center participated as a party in the District Court.

AnMed Health System, d/b/a Cannon Memorial Hospital, Inc. d/b/a AnMed Health Cannon participated as a party in the District Court.

Copley Memorial Hospital, Inc., d/b/a Rush Copley Medical Center participated as a party in the District Court.

Fayette Community Hospital, Inc., d/b/a Piedmont Fayette Hospital, Inc. participated as a party in the District Court.

OSF Healthcare System, d/b/a OSF Heart of Mary Medical Center participated as a party in the District Court.

OSF Healthcare System, d/b/a OSF Sacred Heart Medical Center participated as a party in the District Court.

OSF Healthcare System, d/b/a Ottawa Regional Hospital & Healthcare Center d/b/a OSF Saint Elizabeth Medical Center participated as a party in the District Court.

OSF Healthcare System, d/b/a Saint James Hospital participated as a party in the District Court.

Piedmont Athens Regional Medical Center, Inc. participated as a party in the District Court.

Piedmont Hospital, Inc. participated as a party in the District Court.

Piedmont Mountainside Hospital, Inc. participated as a party in the District Court.

Rush Oak Park Hospital, Inc. participated as a party in the District Court.

Scotland Health Care System, d/b/a Scotland Regional participated as a party in the District Court.

The Charlotte-Mecklenburg Hospital Authority, d/b/a Atrium Health Anson participated as a party in the District Court.

The Charlotte-Mecklenburg Hospital Authority, d/b/a Atrium Health Cleveland participated as a party in the District Court.

The Charlotte-Mecklenburg Hospital Authority, d/b/a Atrium Health Kings Mountain participated as a party in the District Court.

The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas HealthCare System Stanly participated as a party in the District Court.

The Medical Center of Central Georgia, Inc. participated as a party in the District Court.

Franciscan Missionaries of Our Lady Health System, Inc., d/b/a Heart Hospital of Acadiana, LLC participated as a party in the District Court.

Franciscan Missionaries of Our Lady Health System, Inc., d/b/a Our Lady of the Angels Hospital participated as a party in the District Court.

Franciscan Missionaries of Our Lady Health System, Inc., d/b/a Our Lady of the Lake Ascension Community Hospital-St. Elizabeth Hospital participated as a party in the District Court.

Franciscan Missionaries of Our Lady Health System, Inc., d/b/a St. Francis Medical Center participated as a party in the District Court.

Hackensack Meridian Health, d/b/a Hackensack University Medical Center participated as a party in the District Court.

Hackensack Meridian Health, d/b/a JFK Medical Center participated as a party in the District Court.

Hackensack Meridian Health, d/b/a Ocean Medical Center participated as a party in the District Court.

Hackensack Meridian Health, d/b/a Palisades Medical Center participated as a party in the District Court.

Hackensack Meridian Health, d/b/a Raritan Bay Medical Center participated as a party in the District Court.

Hackensack Meridian Health, d/b/a Southern Ocean Medical Center participated as a party in the District Court.

OSF Healthcare System, d/b/a St. Mary Medical Center participated as a party in the District Court.

Shannon Medical Center participated as a party in the District Court.

The Wooster Community Hospital Auxiliary, Inc., d/b/a Wooster Community Hospital participated as a party in the District Court.

America's Essential Hospitals participated as amicus in the District Court.

B. RULINGS UNDER REVIEW

References to the rulings at issue appear in the Brief for Defendant-Appellant.

C. RELATED CASES

These cases were not previously before this Court. CMS has noted that related jurisdictional issues are pending before this Court in *American Hospital Association v. Azar*, Nos. 19-5048 & 19-5198 (D.C. Cir.) (oral argument heard on November 8, 2019). These consolidated cases involve a Medicare payment rule that governed the 2019 year. Appellees have filed separate lawsuits seeking relief with respect to the Medicare payment rule that governs the 2020 year. Those suits are pending before the U.S. District Court for the District of Columbia. *See American Hospital Association v. Azar*, No. 1:20-cv-80 (D.D.C.); *University of Kansas Hospital Authority v. Azar*, No. 1:20-cv-75 (D.D.C.).

/s/ Catherine E. Stetson
Catherine E. Stetson

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GLOSSARY

AHA	American Hospital Association
APA	Administrative Procedure Act
CMS	Centers for Medicare & Medicaid Services
OPPS	Outpatient Prospective Payment System
PBD	Provider-based department

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RESPONSE BRIEF FOR APPELLEES

INTRODUCTION

CMS's opening brief is sparse on words, and more importantly, on arguments. In the proceedings below, CMS claimed that it had authority to create a new payment scheme for outpatient clinic services provided by hospitals, and that it could use this authority to unilaterally cut Medicare payments for those services by over $700 million *per year*. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818, 59,009 (Nov. 21, 2018). Rather than locate this newfound power in the text of a statute expressly granting the agency this authority, CMS claims that a sub-sub-sub

provision of the Medicare Act implicitly permits the agency to upend the longstanding Medicare reimbursement scheme, and to replace it with the scheme of its choice.

The provision CMS cites, however, authorizes CMS to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services." 42 U.S.C. § 1395*l*(t)(2)(F). It does not say anything about payment rates at all. Instead, CMS rests its case on a double-negative: According to the agency, because "[n]othing in that language suggests that the Secretary cannot seek to control" service volume by decreasing payment rates, the agency must have that power. CMS Br. 18. That's not how it works. "Under our system of government, Congress makes laws and the President, acting at times through agencies . . . faithfully executes them." *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 327 (2014) (quoting U.S. Const. art. II, § 3; alterations and internal quotation marks omitted). If a statutory provision does not *affirmatively* grant an agency authority, the agency lacks that authority. *See Ry. Labor Execs.' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 659 (D.C. Cir. 1994).

The plain text of Subsection (t)(2)(F) permits CMS to develop a "method" of volume control "[u]nder the payment system" created by Congress. 42 U.S.C. § 1395*l*(t)(2)(F). It does not authorize CMS to devise an entirely new payment scheme for outpatient clinic services. Instead, Subsection (t)(4) sets forth the

precise formula that CMS must use to determine the "amount of payment" for Medicare services. *Id.* § 1395*l*(t)(4). The structure of the statute confirms this point: Congress authorized CMS to alter reimbursement rates in several provisions of Subsection 1395*l*(t), each of which places important limits on CMS's authority—limits CMS tries to evade by relying on a statutory provision that doesn't apply. *See, e.g., id.* § 1395*l*(t)(2)(D), (t)(2)(E), (t)(9). Under those statutory provisions, CMS may alter reimbursement rates for specific services in a budget-neutral fashion, or it may cut reimbursement rates across-the-board; Congress did not authorize CMS to make non-budget-neutral cuts to specific services. *See id.*

The legislative history, and CMS's own prior interpretation of the relevant statutory text, further demonstrate that CMS lacks the power to adopt its new payment rates for outpatient clinic services. Indeed, Congress expressly considered whether to adopt the payment scheme that CMS now seeks to impose by regulation, and it declined to do so. CMS does not have authority to override Congress's judgment as to what is "necessary" in this field.

When a federal agency acts in blatant excess of its statutory authority, its action is *ultra vires* and should be vacated. *See, e.g., Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1168 (D.C. Cir. 2003). CMS's conduct here easily meets that standard. This Court should affirm.

STATEMENT OF THE ISSUE

Whether Congress granted CMS authority under 42 U.S.C. § 1395*l*(t)(2)(F) to adopt a new payment scheme for outpatient clinic services without regard to the statutory scheme created by Congress that governs these payments.

PERTINENT STATUTES AND REGULATIONS

Pertinent provisions are reproduced in the addendum to the brief.

STATEMENT OF THE CASE

Statutory Framework. Title XVIII of the Social Security Act establishes a health insurance program for the aged and disabled, commonly known as the Medicare Act. 42 U.S.C. § 1395 *et seq.* The Medicare Act comprises four parts. Part A covers inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Part B covers, among other things, hospital services provided to patients on an outpatient basis. Those services include emergency or observation services; services furnished in an outpatient setting (*e.g.*, physician visits, same-day surgery); laboratory tests billed by the hospital for outpatients; medical supplies (*e.g.*, splints and casts); preventative and screening services; and certain drugs and biologicals. *See id.* §§ 1395j, 1395k.

As a general matter, CMS reimburses hospitals for services they provide under Medicare Part B through the Outpatient Prospective Payment System (OPPS), which sets pre-determined rates for specific services. *See id.* § 1395*l*(t);

see also Amgen Inc. v. Smith, 357 F.3d 103, 106 (D.C. Cir. 2004). Congress adopted the OPPS as part of the Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4523, 111 Stat. 251, 445.

To set and adjust the "amount of payment" made under the OPPS, CMS is required to follow specific statutory requirements. 42 U.S.C. § 1395*l*(t)(4); *see Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142, 146-147 (D.D.C. 2019). CMS first groups together services that are clinically comparable, or that require similar resources, and assigns an Ambulatory Payment Classification. 42 U.S.C. § 1395*l*(t)(2)(B). Next, CMS assigns a relative payment weight to each Ambulatory Payment Classification, which is based on the average cost of providing services in prior years. *See id.* § 1395*l*(t)(2)(C). It then multiplies the relative payment weight for each Ambulatory Payment Classification by a "conversion factor." *Id.* § 1395*l*(t)(3)(D). The same conversion factor applies to all Ambulatory Payment Classifications. *See id.* The result of this calculation is a "fee schedule amount" for a particular service or group of services, *id.* § 1395*l*(t)(4)(A), which is subject to the budget-neutral adjustments specified in Subsections (t)(2)(D) and (E) for factors such as regional wages, transitional pass-through payments, outlier costs, and "other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals." *Id.* § 1395*l*(t)(2)(D)-(E), (t)(4)(A). And finally, CMS reduces the

payment by an applicable deductible and modified by a "payment proportion." *Id.* § 1395*l*(t)(4)(B)-(C).

Each year, CMS must review "the groups, the relative payment weights, and the wage and other adjustments" for each Ambulatory Payment Classification "to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* § 1395*l*(t)(9)(A). The Medicare Act sets clear limits on these annual adjustments. Specifically, Congress mandated that "the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made." *Id.* § 1395*l*(t)(9)(B). That is a mouthful, but its meaning is plain: Any adjustments under Subsection (t)(9)(A) must be budget neutral. If CMS decreases spending through one adjustment, it must increase spending through another adjustment. Thus, CMS may not reduce the total amount of Medicare Part B spending by selectively slashing the payment rates for specific types of services.

CMS must also update the conversion factor each year. This update must account for inflation in the cost of medical services. *See id.* § 1395*l*(t)(3)(C)(iv). CMS may also adjust the conversion factor to make *non*-budget neutral cuts to OPPS payments—but it must comply with clear limits on both when and how that

authority is exercised. First, Subsection (t)(2)(F) authorizes CMS to "develop a method for controlling unnecessary increases in the volume of covered" services. *Id.* § 1395*l*(t)(2)(F). In the past, CMS has addressed increased service volume through "packaging," where "ancillary services associated with a significant procedure are packaged into a single payment for the procedure," encouraging providers to furnish services in the most efficient way. *Am. Hosp. Ass'n*, 410 F. Supp. 3d at 157 (internal quotation marks omitted).

Second, if CMS "determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." *Id.* § 1395*l*(t)(9)(C). The same conversion factor applies to *all* OPPS payments; if CMS adjusts the conversion factor, it will shrink (or grow) all OPPS payments by a set percentage. CMS thus cannot adjust the conversion factor to change the OPPS payment rate for some services but not others.

The upshot of Congress's chosen statutory structure is clear: If CMS wants to reduce outlays under the OPPS, it must cut payments across the board for all OPPS services by lowering the conversion factor. In other words, if CMS wants to reduce the size of the pie, each slice can be made slightly smaller. If CMS instead wants to reduce payments for specific services (*i.e.*, to slice the pie differently), it

must do so in a budget-neutral manner, by increasing payments for other services so that the pie remains the same size. But CMS cannot do both at the same time. In this way, the statute's careful and specific structure prevents CMS from engaging in cost-control measures that will disproportionately affect only some service providers and beneficiaries.

Off-Campus Provider-Based Departments. At issue in this case are Medicare payments for certain clinic visit services, called evaluation and management services, provided by off-campus provider-based departments (PBDs). These departments are practice locations of a hospital that are not in immediate proximity to the hospital's main building, but are so closely integrated that they are considered to be a part of the hospital, so much so that they are subject to the same detailed regulatory requirements as the hospital itself. *See* 42 C.F.R. § 413.65(e). An off-campus PBD may furnish specific services and take various forms, including a stand-alone oncology unit, an urgent care clinic, or a physician practice providing specialty services (*e.g.*, cardiology, pulmonology, neurology, and urology).

CMS has viewed the provision of medical services in off-campus locations as a less expensive, yet efficacious, alternative to hospital care. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 147-148. Off-campus PBDs provide several unique advantages to patients and allow hospitals to better serve their communities. Off-

campus PBDs may permit patients to obtain treatment in a more convenient location. *See* 83 Fed. Reg. at 59,013 (acknowledging role of rural treatment centers in promoting access to care); Declaration of Joanna Hiatt Kim ¶ 10, No. 1:18-cv-02841, ECF No. 14-2. They may also offer extended hours or specialized services that independent physician's offices do not provide. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 148; Sarasota Memorial Health Care System Comment Letter at 3, No. 1:19-cv-00132, ECF No. 7-2. In addition, there may be operational reasons for hospitals to use an off-campus location. For example, a hospital may want to place a PBD in a location that is convenient to an underserved patient population. In other cases, a hospital may lack the space on its main campus to expand, and it may open an off-campus PBD as a matter of necessity. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 148 n.1.

In some cases, off-campus PBDs and independent physician's offices may provide the same services. For example, "evaluation and management" of a patient is a type of service that may be provided in both settings. But off-campus PBDs typically have higher costs relative to an independent clinic or physician's office. *See* Medicaid Program; Clarification of Outpatient Hospital Facility (Including Outpatient Hospital Clinic) Services Definition, 73 Fed. Reg. 66,187, 66,191 (Nov. 7, 2008) (noting the "high facility overhead expenses that are associated with the delivery of services unique to an outpatient hospital or a

department of an outpatient hospital"). There are many reasons for this, including that CMS regulations require off-campus PBDs (but not independent physician's offices or clinics) to comply with the same demanding Medicare Conditions of Participation governing their affiliated hospital. *See* 42 C.F.R. § 413.65(a), (e).

Prior to 2015, Congress mandated that CMS pay for services provided by off-campus PBDs under the rates set forth in the OPPS payment scheme. In contrast, Congress required CMS to pay for services at independent physician's offices through the Medicare Physician Fee Schedule. The OPPS typically provides a higher rate of reimbursement than the Physician Fee Schedule. *See* 83 Fed. Reg. at 59,004-06.

Section 603 of the Bipartisan Budget Act of 2015. The volume of services provided by off-campus PBDs has increased significantly in recent years. Much of that increase in volume has been necessary and appropriate. The Medicare-eligible population as a whole has grown, increasing the demand for off-campus PBD services. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 148. Advances in medical technology have also permitted more services to be provided on an outpatient basis. *See id.* According to CMS—but disputed by Appellees and other commenters—another reason for the increase in service volume is the acquisition of standalone physician's offices by some hospitals, allowing those hospitals to bill for physician services at the higher OPPS rates. *See* 83 Fed. Reg. at 59,005-07; *id.*

at 59,011 (discussing commenters' concerns that CMS's conclusion is not supported by evidence).

To address this perceived problem, the Medicare Payment Advisory Commission, an independent congressional agency that advises Congress on Medicare issues, recommended that Congress eliminate payment differences between off-campus PBDs and physician's offices.[1] The Commission recognized that CMS was not authorized to make this change, and "encouraged CMS to seek legislative authority to set equal payment rates across settings for evaluation and management office visits and other select services." Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 79 Fed. Reg. 66,770, 66,912 (Nov. 10, 2014). In response, hospitals advised Congress that the Commission's "recommendation ignored the higher costs required to operate a hospital and would force some existing off-campus provider-based departments . . . to reduce their services or close completely." *Am. Hosp. Ass'n*, 410 F. Supp. 3d at 149.

Congress addressed these competing concerns when it enacted Section 603 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584,

[1] *See* Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare Payment Policy* 71-72 (Mar. 2012), *available at* https://bit.ly/2HhGgUF.

597-598. Its solution was to create two classes of off-campus PBDs. As of November 2015, Congress required CMS to continue paying existing off-campus PBDs (referred to as "excepted" off-campus PBDs) under the OPPS. *See* 42 U.S.C. § 1395*l*(t)(1)(B)(v), (t)(21)(B)(ii). But going forward, Congress required CMS to pay *newly* created or acquired off-campus PBDs (referred to as "non-excepted" off-campus PBDs) under the "applicable payment system," which CMS has interpreted to be a rate equivalent to the Physician Fee Schedule. *See id.* § 1395*l*(t)(21)(C); *see also* 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).

After CMS determined that off-campus PBDs that were mid-build at the time of Section 603's enactment were *not* entitled to reimbursement at the higher OPPS rates, *see* 81 Fed. Reg. at 79,708, Congress once again intervened. In the 21st Century Cures Act, Pub. L. No. 114-255, § 16001, 130 Stat. 1033, 1324 (2016), Congress specified that these "mid-build" departments should be reimbursed at the same OPPS rates as existing off-campus PBDs. 42 U.S.C. § 1395*l*(t)(21)(B)(iv)-(v). In a committee report, Congress explained that Section 603 "effectively grandfathered" any existing off-campus PBD from the "new payment rates," whereas "new off-campus 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 (stating 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").

The Final Rule. In 2018, CMS issued a proposed rule providing that reimbursement for clinic services furnished 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). In other words, despite Congress's decision in Section 603 to exclude specified off-campus PBDs from Physician Fee Schedule rates, CMS proposed paying *all* off-campus PBDs for clinic services under those rates. The new payment rates were not budget-neutral. *See id.* They also applied only to clinic services. *See id.* CMS nevertheless maintained that it had statutory authority to make this change—one it estimated would result in a decrease in Medicare payments to hospitals by at least $760 million *per year*. *Id.* at 37,143.

Almost 3,000 commenters submitted comments in response to the Proposed Rule, including many of the Appellees here. Among other things, Appellees pointed out that under 42 U.S.C. § 1395*l*(t)(9)(B), CMS lacked the statutory

authority to adjust payment rates for specific services in a non-budget-neutral manner. Appellees also explained that the Proposed Rule ran afoul of Congress's statutory mandate that CMS treat excepted and non-excepted off-campus PBDs differently. CMS nevertheless adopted the Final Rule, which went into effect on January 1, 2019. *See* 83 Fed. Reg. at 59,004-15. CMS announced, however, that it would phase in the Medicare payment cuts over a two-year period. *See id.* at 59,014. CMS has subsequently adopted the same rule for 2020, *see* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 84 Fed. Reg. 61,142, 61,368 (Nov. 12, 2019), which Appellees have challenged in separate lawsuits pending before the District Court.

District Court Proceedings. Appellees, who include hospitals and associations representing the hospital field, filed separate suits challenging the Final Rule in the U.S. District Court for the District of Columbia, which consolidated the actions for purposes of ruling on the parties' summary judgment motions.[2] Appellees and their members have suffered concrete and imminent harm as a result of the Final Rule, which dramatically reduced reimbursement rates for

[2] Those suits are *American Hospital Association, et al. v. Azar*, No. 1:18-cv-02841 (D.D.C.); *University of Kansas Hospital Authority, et al. v. Azar*, No. 1:19-cv-00132 (D.D.C.); and *Hackensack Meridian Health, et al. v. Azar*, No. 1:19-cv-01745 (D.D.C.).

clinic services provided by off-campus PBDs. Appellees sought summary judgment in the District Court on the ground that the Final Rule was *ultra vires*. The District Court granted the motion.

The District Court first addressed its jurisdiction to review the Final Rule. The court acknowledged that the Medicare Act prevents judicial review of volume control methods "described in paragraph (2)(F)." *Am. Hosp. Ass'n*, 410 F. Supp. 3d at 153 (quoting 42 U.S.C. § 1395*l*(t)(12)(A)). Applying this Court's precedent, however, the court held that this judicial review provision does *not* block *ultra vires* review of agency action. *See id.* (citing *Amgen*, 357 F.3d at 111). The court noted that "paragraph (t)(12)(A) plainly shields a 'method' to control volume in outpatient departments from judicial review." *Id.* "To determine whether that shield applies," however, the court "must ascertain, consistent with [Appellees'] *ultra vires* claims, whether what CMS calls a 'method' satisfies the statute." *Id.*

Turning to that question, the District Court explained that it "must 'read the words in their context and with a view to their place in the overall statutory scheme.' " *Id.* at 156 (quoting *King v. Burwell*, 135 S. Ct. 2480, 2483 (2015)). This context makes clear that a "method" to control service volume under Subsection (t)(2)(F) "is not a price-setting tool, and the government's effort to wield it in such a manner is manifestly inconsistent with the statutory scheme." *Id.* The District Court emphasized that the "elaborate statutory scheme" created by

Congress for Medicare reimbursement spells "out each step for determining the amount of payment" for OPPS services. *Id.* Under that scheme, if CMS wants to reduce reimbursement rates for these services, it must make budget-neutral cuts to specific services or cut payment rates across the board by adjusting the conversion factor. *See id.* The court rejected CMS's contention that "Congress granted it parallel authority to set payment rates in its discretion that are neither relative nor budget neutral," concluding that Congress does not "alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Id.* at 158 (internal quotation marks omitted). The District Court vacated pertinent portions of the Final Rule as inconsistent with CMS's statutory authority. *Id.* at 161.

This appeal follows.

STANDARD OF REVIEW

This Court reviews *de novo* the District Court's grant of summary judgment. *Ark Initiative v. Tidwell*, 816 F.3d 119, 126-127 (D.C. Cir. 2016). The Court's "consideration of a pure legal question of statutory interpretation" is "*de novo*." *Validus Reinsurance, Ltd. v. United States*, 786 F.3d 1039, 1042 (D.C. Cir. 2015). And the Court "may affirm on any ground properly raised and supported by the record." *Ark Initiative*, 816 F.3d at 126-127.

SUMMARY OF ARGUMENT

Where an agency action is *ultra vires*, it is subject to judicial review. Full

stop. And where an agency ignores the plain text, structure, and history of a statute, its decision should be vacated. The District Court properly concluded that Congress did not grant CMS authority, *sub silentio*, to cut Medicare reimbursement to hospitals by hundreds of millions of dollars per year based on an out-of-context interpretation of a statutory provision that does not even address payment rates. This Court should affirm.

I. Judicial review is available to determine whether an agency action is *ultra vires*, as long as Congress has not explicitly foreclosed this form of review. *See Amgen*, 357 F.3d at 111-112. Subsection (t)(12)(A) of the Medicare Act states that there "shall be no administrative or judicial review" of the "establishment of groups and relative payment weights for covered [outpatient department] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F)." 42 U.S.C. § 1395*l*(t)(12)(A). It does *not* say that *ultra vires* review of these actions is precluded. Subsection (t)(12)(A) thus precludes review *only* of payment "adjustments" and "methods" that CMS has "statutory authority to make." *Amgen*, 357 F.3d at 112. This Court has accordingly held that it has authority to conduct *ultra vires* review of "adjustments to OPPS rates" presumptively subject to Section 1395*l*(t)(12)(A). *Amgen*, 357 F.3d at 111-112. That precedent decides this issue.

CMS claims that the Court's jurisdictional ruling in *Amgen* is dicta. *See*

CMS Br. 15. But the Court in *Amgen* was required to decide the "threshold issue" of its own jurisdiction before reaching the merits of the parties' claims. 357 F.3d at 111-114. The Court's determination that it had jurisdiction to conduct *ultra vires* review was a necessary prerequisite to its conclusion that the action at issue was within the scope of the agency's authority. *See id.* at 113-114. CMS's attempt to relabel a jurisdictional holding as dicta simply because the Court ultimately agreed with the agency on the merits fails. And in any event, *Amgen* is consistent with this Court's longstanding precedent permitting *ultra vires* review of agency action. *See, e.g.*, *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1327-28 (D.C. Cir. 1996).

II. CMS's reading of the word "method" in Subsection 1395*l*(t)(2)(F) is inconsistent with the text, structure, statutory scheme, legislative history, and the agency's own prior interpretation of this provision. It is likewise inconsistent with Congress's considered legislative judgment that excepted off-campus PBDs should be reimbursed under the higher rates provided by the OPPS, rather than the Physician Fee Schedule rates.

A. Subsection (t)(2)(F) states that "the Secretary shall develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services." 42 U.S.C. § 1395*l*(t)(2)(F). The plain text of this provision authorizes CMS to develop *methods of volume control*—not to cut *payment rates*. And it

certainly does not grant CMS the power to adopt a new payment scheme for clinic services, modeled on the Physician Fee Schedule. Subsection (t)(2)(F) provides that CMS must develop methods of volume control "[u]nder the payment system" created by Congress, not outside it. *Id.* Subsection (t)(4), moreover, plainly states that the "amount of payment made from the Trust Fund" is calculated under the formula set forth in Subsections (t)(4)(A) through (C); that formula, which cross-references other provisions of Subsection (t), does not permit CMS to make non-budget-neutral adjustments to payment rates for specific services. *Id.* § 1395*l*(t)(4).

The structure of Subsection 1395*l*(t) confirms this interpretation. Subsection (t)(2)(F) is the sixth provision in a list of eight "[s]ystem requirements" for the OPPS, which include establishing groups of covered services, relative payment weights, wage adjustments, and other budget-neutral adjustments. *See* 42 U.S.C. § 1395*l*(t)(2)(A)-(H). The location of Subsection (t)(2)(F) within this list reinforces that Congress intended CMS to develop a "method" for controlling service volume that works in harmony with other statutory requirements.

CMS's interpretation of the word "method," in contrast, would render at least four provisions of Subsection 1395*l*(t) superfluous. Subsections (t)(2)(D) and (E), along with (t)(9)(B), grant CMS authority to cut payment rates for individual services, but explicitly require all reductions to be budget-neutral. *See id.*

§ 1395*l*(t)(2)(D)-(E), (t)(9)(B). Subsection (t)(9)(C) similarly permits CMS to cut payment rates under certain circumstances, but limits CMS to making an across-the-board adjustment to the conversion factor (in a subsequent year, after CMS first implements its volume-control methodology). *See id.* § 1395*l*(t)(9)(C). If CMS has the authority to create any kind of payment scheme it likes—even if it is not budget-neutral, and without adjusting the conversion factor—then all four of these provisions would be beside the point. The District Court properly rejected such an interpretation of the Medicare Act. *See Indep. Ins. Agents of Am., Inc. v. Hawke*, 211 F.3d 638, 643-644 (D.C. Cir. 2000).

Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001). If Congress had intended to grant CMS the freewheeling authority to fundamentally alter payment schemes for OPPS services—and to cut reimbursement rates for specific services in a non-budget-neutral fashion—it would have said so explicitly. It would not have buried this authority in a sub-sub-sub provision that does not even mention payment adjustments. Relevant legislative history likewise demonstrates that Congress did not intend to grant CMS this power. *See* H.R. Rep. No. 105-217, at 784 (1997) (Conf. Rep.). Prior to the Final Rule, even CMS understood its authority to be limited to making budget-neutral cuts to payment rates or to updating the conversion factor. *See* Medicare

Program; Prospective Payment System for Hospital Outpatient Services, 63 Fed. Reg. 47,552, 47,586 (proposed Sept. 8, 1998); *see also* Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002, 66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2011). CMS's contrary arguments are unconvincing.

B. What is more, Subsection (t)(2)(F) only authorizes CMS to develop a method for "controlling unnecessary increases in the volume" of outpatient services. But Congress has already made its judgment as to what is "necessary" in this field. Congress heard arguments both for and against cutting payment rates for off-campus PBDs, and it chose a middle course when it enacted Section 603, lowering payments for new off-campus PBDs but at the same time preserving OPPS rates for existing departments. CMS based its rule on its disagreement with Congress as to which services in off-campus PBDs were "necessary." CMS was not free to disregard Congress's instruction in this manner; Congress's careful balancing of competing considerations "[is] not for [the agency or for the courts] to judge or second-guess." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 461 (2002).

CMS, before the District Court, disputed that Section 603 had anything to say about payment rates for excepted off-campus PBDs. The fact that Congress excluded non-excepted off-campus PBDs from the OPPS system, it argued, did not show that Congress intended to preserve OPPS payments for excepted off-campus

PBDs. CMS relied on *Adirondack Medical Center v. Sebelius*, 740 F.3d 692 (D.C. Cir. 2014), to contend that its reading of its own statutory authority must prevail under *Chevron* even when the *expressio unius* canon would point in another direction.

But *Chevron* doesn't apply here, for the reasons explained below. *See infra* pp. 55-57. In any event, the *expressio unius* canon, like any other canon, must be examined together with the text, structure, legislative history, and purpose of the statute to arrive at the best reading of a statutory provision. And that examination confirms that Congress understood that it was preserving OPPS payment rates for existing off-campus PBDs when it enacted Section 603. In other words, when Congress made the deliberate choice to remove only new off-campus PBDs from the OPPS system, it "considered the unnamed possibility and meant to say no to it." *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003).

CMS may not rely on paragraph (t)(2)(F) to excuse its disregard for Congress's instructions. The authority to address "unnecessary increases" in volume does not carry with it the power to second-guess Congress's decision as to what is "necessary." As the Court stated in *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), "we think it quite unlikely that Congress, having minutely detailed the reimbursement rates for covered items and services, intended that the Secretary could ignore these formulas whenever she determined that the expense of an item

or service was not reasonable or necessary." *Id*. at 1282 (internal quotation marks and emphasis omitted). So too here. Congress answered the question of whether services performed in excepted off-campus PBDs are "necessary" by specifically preserving OPPS payment rates for those services when it addressed the matter in 2015. The fact that CMS wishes that Congress had resolved the issue differently does not give the agency license to ignore the legislature's judgment.

C. CMS suggests, in a single sentence, that its interpretation of Subsection (t)(2)(F) is entitled to *Chevron* deference. *See* CMS Br. 17. But CMS does not explain why this would be so, and in any event CMS would not be entitled to deference on the question whether this Court has jurisdiction to review the agency's actions, or whether its actions are *ultra vires*. *See Smith v. Berryhill*, 139 S. Ct. 1765, 1778 (2019). What is more, CMS's new interpretation of Subsection (t)(2)(F) is contrary to its own prior position, as well as the clear text of the statute, and is not entitled to deference for this reason as well. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

ARGUMENT

I. THE DISTRICT COURT PROPERLY REVIEWED THE FINAL RULE.

The "case law in this circuit is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Lutherans*, 321 F.3d at 1173 (citing *Reich*, 74 F.3d at 1327-28). There "is a strong presumption that Congress intends judicial

review of administrative action, and it can only be overcome by a clear and convincing evidence that Congress intended to preclude the suit." *Amgen*, 357 F.3d at 111 (internal citations and quotation marks omitted). "Even where, as here, a statutory provision expressly prohibits judicial review, the presumption applies to dictate that such a provision be read narrowly." *Am. Clinical Lab. Ass'n v. Azar*, 931 F.3d 1195, 1204 (D.C. Cir. 2019). "The presumption is particularly strong that Congress intends judicial review of agency action taken in excess of delegated authority." *Amgen*, 357 F.3d at 111. "Such review is favored . . . if the working of a preclusion clause is less than absolute." *Id.* at 112 (internal quotation marks omitted).

Section (t)(12)(A) states that there "shall be no administrative or judicial review" of "the establishment of groups and relative payment weights for covered [outpatient department] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F)." 42 U.S.C. § 1395*l*(t)(12)(A). That provision prohibits the federal courts from passing judgment on whether a legitimate "method" chosen by CMS is arbitrary and capricious. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 153; *see also Amgen*, 357 F.3d at 113. It does not prevent the federal courts from examining whether the Final Rule exceeds CMS's statutory authority to adopt such a "method." Otherwise, CMS could "shield any action from judicial review merely by calling it a 'method,' even if it is not that."

Am. Hosp. Ass'n, 410 F.3d at 153; *see also DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 510 (D.C. Cir. 2019) (preclusion on judicial review does not apply when "the relevant statutory bar" is "effectively coextensive with the merits"). The District Court thus properly examined whether the Final Rule was within CMS's statutory authority to adopt a "method" for controlling volume increases.

That conclusion is consistent with this Court's longstanding precedent. In *Amgen*, the Court examined the same statutory prohibition on judicial review, and concluded that it prevents review *only* of payment adjustments that "the Medicare Act authorizes the Secretary to make." 357 F.3d at 112. The preclusion on review in Subsection (t)(12)(A) thus "extends no further" than CMS's authority to act under the statute. *Id.* That makes sense: Congress may have been concerned that "piecemeal review of individual payment determinations could frustrate the efficient operation of the complex" Medicare payment system, and it thus prohibited arbitrary and capricious review of such decisions. *Id.* But there is no indication, either in the statutory text or legislative history, that Congress intended "to foreclose review of action exceeding agency authority." *Id.*

This Court reached a similar conclusion in *COMSAT Corp. v. FCC*, 114 F.3d 223 (D.C. Cir. 1997), where it examined a provision of the Communications Act of 1934 stating that "amendments pursuant to this paragraph shall not be subject to judicial review." *Id.* at 224, 227. The Court interpreted that language to

foreclose judicial review where the Commission amended a fee schedule in accordance with its statutory authority, but to permit judicial review to determine whether the Commission "acted outside the scope of its authority" in amending the fee schedule. *Id.* at 224-227. This Court has reached similar conclusions in other cases. *See, e.g.*, *Southwest Airlines Co. v. Transp. Sec. Admin.*, 554 F.3d 1065, 1071 (D.C. Cir. 2009) (conducting *ultra vires* review despite statutory provision stating that limitations on air carrier fees are not subject to judicial review); *Aid Ass'n for Lutherans*, 321 F.3d at 1172-73 (conducting *ultra vires* review despite statutory provision exempting Postal Service from Administrative Procedure Act's judicial review provisions).

In conducting *ultra vires* review of the Final Rule, the District Court properly interpreted the text, structure, and history of Subsection 1395*l*(t). Where "the determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action," the "court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review." *Amgen*, 357 F.3d at 113. In such a case, consideration of the "court's jurisdiction merges with consideration of the question whether" the agency "possessed the requisite statutory authority." *COMSAT Corp.*, 114 F.3d at 224-225. Contrary to CMS's assertion (at 16), this *ultra vires* review does not nullify

Subsection (t)(12)(A)'s preclusion of judicial review; it instead upholds the fundamental principle that where the executive branch "acts *ultra vires*, courts are normally available to reestablish the limits" of its authority. *Reich*, 74 F.3d at 1328 (internal quotation marks omitted); *see also Am. Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108 (1902) (explaining that the acts of government officials "must be justified by some law").[3]

CMS contends that the Court's interpretation of Subsection (t)(12)(A) in *Amgen* is dicta, and that the analysis in *DCH Regional Medical Center* instead controls. *See* CMS Br. 15. CMS is wrong. In *Amgen*, the Court plainly held that Subsection (t)(12)(A) allows *ultra vires* review. *See* 357 F.3d at 112-113. That holding was essential to the Court's conclusion that the payment adjustment at issue was not *ultra vires*. *See id.* at 113-114. Indeed, the Court could not have upheld the payment adjustment as within CMS's statutory authority without first deciding that it had the power to decide that question through *ultra vires* review. *See id.* *Amgen* governs this case, which involves the same statutory review provision.

[3] Appellees argued below, and maintain on appeal, that the District Court had authority to review the Final Rule under both the Administrative Procedure Act and non-statutory review. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 153 n.7. The District Court concluded that "the analysis and outcome are the same" for Appellees' APA and non-statutory claims. *Id.*

DCH Regional Medical Center does not assist CMS. That case acknowledged this Court's longstanding precedent permitting *ultra vires* review of agency action. *See* 925 F.3d at 510 (citing *Southwest Airlines* and *COMSAT*). It further recognized that, under those precedents, a court must first determine whether the preclusion on judicial review even applies: Where "the relevant statutory bar" is "effectively coextensive with the merits," the "same agency error" renders the statutory preclusion on review inapplicable and compels that the agency action be set aside. *Id.* In *DCH Regional Medical Center*, the Court did not perform this analysis because it determined that the medical center plaintiff had failed "to allege any obvious violation of a clear statutory command" and instead contended that the agency's action was "arbitrary and capricious." *Id.* at 509-510. Here, in contrast, Appellees alleged that the Final Rule violated clear statutory text prohibiting CMS from decreasing payment rates for clinic services in a non-budget-neutral manner. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 146.

CMS claims that this Court should decline to review the Final Rule because it will lead to administrative inefficiencies. *See* CMS Br. 16-17. By acting outside its statutory authority, however, CMS has created the very problem that it identifies: Had CMS paid the correct amounts for clinic services in the first place, it would not now be in the position of trying to right the ship. Despite the District Court's straightforward ruling that CMS lacks statutory authority to cut payment

rates for clinic services in a non-budget-neutral manner, CMS has announced that it will *do the same thing again* in 2020. The enormous financial and regulatory impact of CMS's decision to adopt a new payment scheme for clinic services provided by off-campus PBDs—without any input from Congress—is reason to conduct judicial review, not avoid it.[4]

II. THE DISTRICT COURT CORRECTLY HELD THAT THE FINAL RULE IS *ULTRA VIRES*.

Congress carefully crafted a statutory scheme to govern payments for Medicare providers. CMS in the Final Rule determined that it may jettison that scheme entirely and adopt a *different* scheme—the Physician Fee Schedule—to govern payment rates for clinic services at off-campus PBDs. The District Court properly held that CMS lacks statutory authority to depart from the clear text and structure of the Medicare Act, which requires CMS to act in a budget-neutral manner when cutting reimbursement rates for specific services. Indeed, Congress has already addressed whether excepted off-campus PBDs should be reimbursed at the lower Physician Fee Schedule rates, and it has concluded that they should not.

[4] CMS does not contest the District Court's conclusion that "requiring Plaintiffs to exhaust their administrative remedies here would be a wholly formalistic exercise in futility." *Am. Hosp. Ass'n*, 410 F. Supp. 3d at 154 (internal quotation marks omitted). It has thus forfeited any argument with respect to exhaustion. *See Fox v. Gov't of Dist. of Columbia*, 794 F.3d 25, 29 (D.C. Cir. 2015).

Nor should this Court entertain CMS's half-hearted suggestion that it is entitled to *Chevron* deference for its manifestly incorrect statutory interpretation.

A. Every Tool Of Statutory Interpretation Demonstrates That CMS's Interpretation Of Subsection (t)(2)(F) Is Wrong.

The Final Rule is contrary to the text, structure, statutory scheme, legislative history, and prior agency interpretations of Subsection 1395*l*(t). For each of these reasons, CMS's interpretation of the word "method" in Subsection (t)(2)(F) is wrong. But together, these tools of statutory interpretation demonstrate without a doubt that the Final Rule is *ultra vires*.

1. Text

Subsection (t)(2)(F) states that the "Secretary shall develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services." 42 U.S.C. § 1395*l*(t)(2)(F). CMS portrays this provision as a standalone grant of authority to pick any mechanism it likes for "controlling . . . volume," including adopting a new payment scheme that reduces payment rates for clinic services in a non-budget-neutral way. *See* CMS Br. 18; *see also* Memorandum Opinion at 5, No. 1:18-cv-02841, ECF No. 38 (noting that the "reduced rate" for clinic services adopted by CMS in the Final Rule operates "entirely independently of the underlying OPPS reimbursement scheme" (internal quotation marks omitted)). But Subsection (t)(2)(F) does not mention payments, or adjustments, or any other term that would even *suggest* that CMS has authority to change payment

rates for clinic services under this provision, much less to adopt a new payment scheme modeled on the Physician Fee Schedule. *Cf.* 42 U.S.C. § 1395*l*(t)(2)(D)-(E) (authorizing specific "adjustments" to "payments"). The agency's assertion that a statutory grant of authority to adopt a method of *volume control* permits the agency to concoct a new *payment scheme* is contrary to the statute's plain text.

As Appellees argued below, Subsection (t)(9)(C) makes clear that Subsection (t)(2)(F) permits CMS to adopt an analytical mechanism for *determining* whether there is an unnecessary increase in volume, which CMS may then address by adjusting the conversion factor. *See* 42 U.S.C. § 1395*l*(t)(9)(C) ("If the Secretary *determines* under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." (emphasis added)); *see also* 63 Fed. Reg. at 47,586 (proposing an "appropriate method" for determining a target volume of services as a "method" of volume control).

But even assuming for the sake of argument that Subsection (t)(2)(F) could be read to permit CMS to address service volume directly, it still does not authorize the agency to adjust *payments*, much less adopt a new payment scheme. CMS's interpretation of the word "method" to do exactly that is contrary to the

straightforward textual limitation on the agency's authority set forth at the outset of Subsection (t)(2). That provision is titled "System requirements," and it grants CMS authority to take specific actions "*[u]nder* the payment system" created by Congress for OPPS services. *Id.* § 1395*l*(t)(2) (emphasis added). This statutory language—which CMS does not even address—makes clear that CMS has authority to "develop a method" of volume control that falls *within* the existing "payment system." CMS's contention that it may simply adopt a new payment system, modeled on the Physician Fee Schedule, for clinic services is inconsistent with this clear statutory requirement.

Nor did Congress leave it up to the agency to decide which "payment system" to adopt. Instead, Subsection (t)(4) plainly states that "[t]he *amount of payment* made from the Trust Fund under this part for a covered [outpatient department] service . . . furnished in a year *is determined* . . . as follows," and then sets forth three steps that CMS must take to calculate the payment amount for OPPS services. *Id.* § 1395*l*(t)(4) (emphases added). Those steps in turn cross-reference numerous provisions of Subsection (t), *none* of which authorizes CMS to make non-budget-neutral cuts to specific services. *See, e.g.*, *id.* § 1395*l*(t)(2)(D), (t)(2)(E), (t)(3)(D), (t)(7). CMS must comply with the statute that Congress actually wrote—not the statute it wishes it had written—to determine the "amount of payment" to Medicare providers.

2. Structure

The structure of the Medicare Act confirms this interpretation. Subsection (t)(2)(F) is the sixth provision in a list of eight "system requirements" for the OPPS payment system. *Id.* § 1395*l*(t)(2) (capitalization omitted). Other "system requirements" include the establishment of "groups of covered [outpatient department] services"; "relative payment weights for covered [outpatient department] services"; "a wage adjustment factor"; and budget-neutral "outlier adjustments," "transitional pass-through payments," and "other adjustments" for "certain classes of hospitals." *Id.* § 1395*l*(t)(2)(A)-(E), (G)-(H). The location of Subsection (t)(2)(F) within this list reinforces that Congress intended CMS to select a "method" for controlling service volume that works in harmony with these detailed statutory provisions.

CMS's interpretation of the word "method" in Subsection (t)(2)(F), in contrast, would render at least four separate provisions of Subsection 1395*l*(t) superfluous. Subsections (t)(2)(D) and (E) permit CMS to make certain adjustments to payments, as long as those adjustments are implemented in a budget-neutral manner. *Id.* § 1395*l*(t)(2)(D)-(E). Subsection (t)(9)(B) similarly permits CMS to make budget-neutral adjustments to payment rates. *See id.* § 1395*l*(t)(9)(B). And Subsection (t)(9)(C) permits CMS to update the conversion

factor in response to an unnecessary increase in service volume. *Id.* § 1395*l*(t)(9)(C).

If Subsection (t)(2)(F) *already* permitted CMS to decrease payment rates in a non-budget-neutral manner, there would have been no reason for Congress to grant CMS the more limited authority to decrease payment rates in a budget-neutral manner under Subsections (t)(2)(D)-(E) and (t)(9)(B). And if Subsection (t)(2)(F) *already* permitted CMS to select a mechanism for controlling service volume that involved cuts to payment rates, there would have been no reason for Congress to grant CMS the more limited authority to update the conversion factor under Subsection (t)(9)(C). Under longstanding principles of statutory interpretation, "all words in a statute are to be assigned meaning, and . . . nothing therein is to be construed as surplusage." *Indep. Ins. Agents of Am.*, 211 F.3d at 644 (internal quotation marks omitted). The fact that CMS's interpretation of the word "method" renders four separate provisions of Subsection 1395*l*(t) meaningless demonstrates that the agency's interpretation is wrong.

This canon of statutory interpretation has particular force here, where Subsections (t)(2)(D), (t)(2)(E), (t)(9)(B), and (t)(9)(C) each impose significant limits on CMS's authority to reduce payment rates. The first three provisions require CMS to adjust payment rates in a budget-neutral manner, and the fourth provision permits CMS to reduce payment rates by adjusting the conversion factor,

which affects all OPPS services. These four provisions demonstrate that where Congress has authorized CMS to make "adjustments" to "payment" rates, it has done so expressly—and with express limitations. This Court should respect Congress's decision. As the Supreme Court held in *Knight v. Commissioner*, 552 U.S. 181 (2008), where "Congress has enacted a general rule," the federal courts "should not eviscerate that legislative judgment through an expansive reading" of a provision that would undermine that rule. *Id.* at 191 (internal quotation marks omitted).[5]

3. Statutory Scheme

CMS's interpretation of the word "method" is also flatly inconsistent with the complex payment scheme for OPPS services enacted by Congress. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 157-158 (describing detailed statutory scheme). Subsection (t)(2)(F) is a sub-provision of a sub-provision of a sub-provision governing the "[p]rospective payment system for hospital outpatient department services." 42 U.S.C. § 1395*l*(t). If Congress had intended for this sub-sub-sub provision to allow CMS to choose any payment scheme it likes for OPPS services, it would have said so explicitly. Congress "does not alter the fundamental details

[5] CMS asserts that the "requirement of budget neutrality is not designed to limit unnecessary increases in the volume of" services. CMS Br. 19. CMS, however, has adopted budget-neutral mechanisms for addressing increased service volume in the past. *See supra* p. 7 (describing packaging).

of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman*, 531 U.S. at 468; *see also Czyzewski v. Jevic Holding Corp.*, 137 S. Ct. 973, 984 (2017).

The Supreme Court, as well as this Court, has repeatedly applied that basic principle of statutory interpretation. In *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938 (2016), for example, the Supreme Court refused to interpret a definition section in one part of a statute to exclude Puerto Rico from municipal bankruptcy law, and it instead read that section more narrowly. *See id.* at 1947. The Supreme Court explained that if Congress had intended to alter the fundamental details of municipal bankruptcy, "we would expect the text of the" statute "to say so." *Id.* Similarly, in *American Chemistry Council v. Johnson*, 406 F.3d 738 (D.C. Cir. 2005), EPA argued that the Emergency Planning and Community Right-to-Know Act permitted the agency to regulate non-toxic chemicals, because a single provision of the Act did not reference "toxicity" when describing the agency's authority. *See id.* at 741. This Court rejected EPA's interpretation, concluding that "the overall scope of a statute is clearly limited by a requirement that is not explicitly mentioned in every subsection." *Id.* In the context of an elaborate statutory scheme for regulating toxic chemicals, the Court held that it was "utterly improbable" that Congress granted EPA authority to regulate non-toxic chemicals. *Id.* at 743.

Those principles govern the proper interpretation of the word "method" in this case. In Subsection 1395*l*(t), Congress established a detailed statutory scheme that requires CMS to follow specific steps for setting payment rates for services under the OPPS. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 156. To vastly simplify, that scheme requires CMS to calculate the Ambulatory Payment Classification, as adjusted for wages and other factors, less applicable deductibles, and modified by a "payment proportion." *Supra* pp. 5-6. The relative payment weight for the Ambulatory Payment Classification is then multiplied by a conversion factor to determine the amount of payment. *See id.* Given this extremely complex formula, which takes into account factors from the cost of medical care to the kind of service at issue to the market basket inflation of medical services, CMS's assertion that the word "method" in Subsection (t)(2)(F) permits it to choose any payment rate it likes for any kind of service *without regard to those factors* is "utterly improbable." *Am. Chemistry Council*, 406 F.3d at 743.

"CMS cannot shoehorn a 'method' into the multi-faceted congressional payment scheme when Congress's clear directions lack any such reference." *Am. Hosp. Ass'n*, 410 F. Supp. 3d at 156. If Congress had intended CMS to have such an all-encompassing power, "we would expect the text" of the statute to "say so." *Puerto Rico*, 136 S. Ct. at 1947. It doesn't. Congress instead laid out the structure of the OPPS statute in elaborate detail, "and relied on [that structure] to make

precise cross-references." *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 938-939 (2017); *see also United States v. Brockamp*, 519 U.S. 347, 350 (1997) (the statute "sets forth its limitations in a highly detailed technical manner, that, linguistically speaking, cannot easily be read as containing implicit exceptions"). CMS is not at liberty to rewrite the statutory scheme to treat Subsection (t)(2)(F) as a free-floating payment "adjustment" authority.

4. Legislative History And Prior Agency Interpretations

CMS's interpretation of the Medicare Act is also inconsistent with the legislative history. The conference report for the Balanced Budget Act of 1997, which added Subsection 1395*l*(t), explains that if CMS "determined that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary would be authorized to *adjust the update to the conversion factor*." H.R. Rep. No. 105-217, at 784 (emphasis added). Congress thus contemplated that CMS would address unnecessary volume increases through the conversion factor, rather than by cutting payment rates for certain services in a non-budget-neutral manner. *See id.*

Prior to adopting the Final Rule, CMS *agreed* with this interpretation. In 1998, CMS proposed a "method" for volume control under Subsection (t)(2)(F) that set a target level of service volume. 63 Fed. Reg. at 47,586. If the volume of services exceeded that target, CMS would then "adjust the update to the conversion

factor" for the following year. *Id.* CMS thus sought to apply Subsection (t)(2)(F) to develop an *analytical* method for determining the appropriate volume of services, and Subsection (t)(9)(C) to permit the agency to address unnecessary service volume by updating the conversion factor.

CMS reiterated that approach two years later, stating that Subsection (t)(9)(C) authorizes CMS "to adjust the update of the conversion factor if we determine that the volume of services paid for under the [OPPS] increases beyond *amounts we establish*" under Subsection (t)(2)(F). Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18,434, 18,502 (Apr. 7, 2000) (emphasis added). Similarly, in 2001, CMS noted that its authority to make non-budget-neutral cuts under Subsection (t)(2) was tied to adjusting the conversion factor—without any mention of a source of authority to do far more than that. *See* 66 Fed. Reg. at 59,908 (stating that Subsection (t)(2)(F) "requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient services," and Subsection (t)(9)(C) "authorizes the Secretary to adjust the update to the conversion factor if the volume of services increased beyond the amount established under" Subsection (t)(2)(F)).

Even more to the point, CMS in 1998 expressly *rejected* a "possible mechanism" for controlling service volume that would have established "updates"

for "ambulatory facility payments"—in other words, cut payments to hospital outpatient departments—if the volume of services increased beyond a certain amount. 63 Fed. Reg. at 47,586. CMS stated that "possible legislative modification would be necessary before" it could consider implementing this proposal. *Id.*[6] Instead, CMS proposed addressing unnecessary volume increases through "updates of the outpatient department conversion factor"—the precise statutory route that Congress intended.

Prior to the Final Rule, moreover, CMS has explicitly referred to the OPPS as a "budget neutral payment system" and implemented mechanisms for controlling service volume in a budget-neutral manner. For example, CMS adopted a volume control mechanism "known as 'packaging,' whereby 'ancillary services associated with a significant procedure' are 'packaged into a single payment for the procedure,' " encouraging efficient delivery of services. *Am. Hospital Ass'n*, 410 F. Supp. 3d at 157 (quoting Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, 72 Fed. Reg. 66,580, 66,610 (Nov. 27, 2007)). In explaining this approach to volume control, CMS stated that "[b]ecause the OPPS is a budget neutral payment

[6] Appellees respectfully disagree with the District Court's discussion of this issue, which does not account for CMS's explicit statement that it was contemplating cutting payment rates for services. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 157 n.8.

system," it would implement packaging in a budget-neutral manner, and that "the monies previously paid for services that were proposed to be packaged are not lost, but are redistributed to all other services." 72 Fed. Reg. at 66,615.[7] By adopting a non-budget-neutral cut to payment rates for specific services, the Final Rule marks a significant departure from CMS's prior interpretation of Subsection (t)(2)(F) and the way it has implemented that statutory provision in the past.

5. CMS's Counterarguments

CMS raises two counterarguments to the District Court's interpretation of Subsection (t)(2)(F). Neither is convincing.

First, CMS asserts that because Congress did not use the phrase "budget neutral" in Subsection (t)(2)(F), Congress must have intended for CMS to adopt "methods" of volume control that include non-budget-neutral cuts to payments for specific services. *See* CMS Br. 18. But, as discussed above, Subsection (t)(2)(F) is about *volume control*, not payment adjustments, so it is unsurprising that Congress did not discuss budget neutrality in this provision. Where Congress has authorized CMS to make non-budget-neutral adjustments to payment rates

[7] CMS claims that the District Court "inferred that an adjustment to the conversion factor" is CMS's "exclusive volume-control method." CMS Br. 20. That is plainly incorrect. The District Court explained that CMS has adopted other volume control mechanisms, including the packaging example described in the District Court's opinion. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 157.

elsewhere in the Medicare Act, it has done so explicitly, including within Subsection 1395*l*(t)(9). *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 159 (describing statutory provisions); *see also, e.g.*, 42 U.S.C. § 1395*l*(t)(7)(I), (t)(16)(D)(iii), (t)(20). If anything, the fact that Congress did *not* explicitly grant CMS authority to adopt non-budget-neutral payment adjustments in Subsection (t)(2)(F) demonstrates that CMS lacks this authority. *See Ry. Labor Execs.' Ass'n*, 29 F.3d at 659 (rejecting agency's assertion that the Court should "*presume* a delegation of power from Congress absent an express *withholding* of such power").

Second, CMS claims that policy rationales support its interpretation of Subsection (t)(2)(F). *See* CMS Br. 20-21 (arguing that "[n]othing in the statute compels HHS to penalize all outpatient departments (by adjusting the conversion factor)"). In *Utility Air*, however, the Supreme Court reaffirmed "the core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." 573 U.S. at 328. "An agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms." *Id.* at 325. Here, where CMS replaced a carefully calibrated statutory scheme for setting payment rates with a scheme "of its own choosing, it went well beyond the bounds of its statutory authority." *Id.* at 326 (internal quotation marks omitted).

Even if it were proper to take policy concerns into account, those policy concerns cut *against* CMS's position. By requiring budget neutrality for payment cuts targeting only specific services, the statute recognizes—and puts a check on—any incentive for CMS to employ draconian cost-control measures that affect only certain service providers. Congress has already experimented with permitting CMS to make non-budget-neutral cuts to physician services by changing the Sustainable Growth Rate Formula for the Physician Fee Schedule; Congress later abandoned that approach, which was "fundamentally flawed" and created "instability in the Medicare program for providers and beneficiaries." *Am. Hosp. Ass'n*, 410 F. Supp. 3d at 159-160 (internal quotation marks omitted). As described below, Congress has more recently contemplated applying the Physician Fee Schedule rates to off-campus PBD services, and it decided *against* doing so for excepted off-campus PBDs. *See infra* pp. 46-52. The Court should leave these kinds of policy decisions to Congress, where they belong.

As the District Court held below, moreover, if "CMS reads the statute correctly, its new-found authority would supersede Congress' carefully crafted relative payment system by severing the connection between a service's payment rate and its relative resource use." *Am. Hosp. Ass'n*, 410 F. Supp. 3d at 158 (noting that Congress has explicitly *denounced* such an outcome with respect to the Physician Fee Schedule, which is the statutory scheme that CMS sought to emulate

in the Final Rule); *see also id.* (describing Congress's view that distortions in the fee schedule violate the "basic principle" underlying that system).[8] And, as the District Court emphasized, the fine-tuned structure of the OPPS "makes clear that Congress intended to preserve 'the clinical integrity of the groups and weights' "—which the Final Rule fundamentally undermines by cutting payment rates only for certain services. *Id.* (quoting 42 U.S.C. § 1395*l*(t)(9)(A)). "There is no reason to think that Congress with one hand granted CMS the authority to upend such a 'basic principle' " of the OPPS, "while working with the other to preserve it." *Id.* at 158-159.

Nor, in any event, did CMS act in response to an "increase" in the volume of outpatient services, let alone an "unnecessary" one. CMS has never found the volume of clinic services to be unnecessary; instead, the agency disagreed with the *payment rate* that Congress directed it to pay for those services. *See, e.g.*, 83 Fed. Reg. at 59,009. In fact, several commenters urged the Secretary to find that off-campus PBDs were providing more intensive services, such as additional

[8] CMS cites *Amgen*, which it claims upheld CMS's decision to sever "the connection between the payment rate for Amgen's product and the product's cost." CMS Br. 18-19. *Amgen*, however, addressed the proper interpretation of Subsection (t)(2)(E), which permits CMS to make *equitable* adjustments to payment rates in a budget-neutral manner. *See* 42 U.S.C. § 1395*l*(t)(2)(E). If anything, *Amgen* suggests that where CMS seeks to make changes in payment rates based on its view of the value of different services, it must do so in a budget-neutral manner.

chemotherapy administration sessions, than physicians' offices. *See id.* at 59,010. CMS studiously declined to make such a finding, however. Instead, the agency based the Final Rule on its conclusion that the OPPS payment rates, "rather than patient acuity or medical necessity, are affecting site-of-service decision-making." *Id.* CMS reasoned that the Final Rule would ensure that "the beneficiary can safely receive the *same services* in a lower cost setting." *Id.* (emphasis added). In other words, CMS did not conclude that there had been an unnecessary increase in the volume of clinic services; the agency instead found only that the same volume of services could be provided at a lower cost. Section (t)(2)(F) does not speak to cost, however, but only to volume; there is a fundamental mismatch between the issue that CMS sought to address and the statute it invoked to do so.

If this Court were to adopt CMS's interpretation of the word "method," there would be *no limit* on CMS's ability to set any payment rate for any service, without regard to the fine-grained statutory scheme enacted by Congress. Such an outcome would be "a severe blow to the Constitution's separation of powers," where "Congress makes the laws and the President," acting through agencies, "faithfully executes them." *Util. Air Regulatory Grp.*, 573 U.S. at 327 (alteration omitted) (quoting U.S. Const. art. II, § 3). The District Court properly concluded that the Final Rule is *ultra vires*. This Court should affirm.

B. Congress Unambiguously Provided In Section 603 That Excepted Off-Campus PBDs Must Be Paid At OPPS Rates.

1. *Congress Made A Legislative Determination To Preserve OPPS Rates For Excepted Off-Campus PBDs.*

CMS exceeded its authority under Section (t)(2)(F) in a second way. CMS characterizes the payment cut for excepted off-campus PBDs as a "method" designed "for controlling unnecessary increases in the volume of covered" services. 42 U.S.C. § 1395*l*(t)(2)(F). But Congress has already made its judgment as to what is "necessary" in this field. Congress heard arguments both for and against cutting payment rates for off-campus PBDs, and it chose a middle course, lowering payments for new off-campus PBDs but at the same time preserving OPPS rates for those off-campus PBDs already in existence. CMS may now wish that Congress had struck a different balance, but the agency is not at liberty to disregard Congress's instructions.

Clinic services performed by off-campus PBDs are "hospital outpatient department services" that are paid under Medicare Part B's OPPS system. *Id.* § 1395*l*(t)(1). Because an off-campus PBD is subject to the same regulatory requirements as the main campus of a hospital (in addition to further regulatory criteria that apply to off-campus PBDs), the Medicare program considers that department to be part of the hospital. Accordingly, clinic services—like any other reimbursable outpatient services—performed at an off-campus PBD are "hospital

outpatient department services" in the same way that these services performed at the hospital's main campus would be, and are thus entitled to be paid at OPPS rates.

This treatment makes sense, even though the OPPS rate is higher than the rate that applies for independent physician's offices, given that off-campus PBDs face greater regulatory burdens, and thus experience higher overhead costs, for the critical role that they play in providing medical services to their local communities. *See* 73 Fed. Reg. at 66,191 (noting the "high facility overhead expenses that are associated with the delivery of services unique to an outpatient hospital or a department of an outpatient hospital").[9] Some stakeholders have argued, however, that this difference in payment rates gave hospitals the incentive to acquire physician's offices to gain higher Medicare reimbursement. *See* 83 Fed. Reg. at 59,006-07; *but see id.* at 59,011 (describing disagreement on this point, including commenters' position that the Final Rule "is based on unsupported assertions and assumptions regarding increases in volume").

Congress resolved these competing concerns by lowering payment rates, but only for newly built or acquired off-campus PBDs. In Section 603 of the

[9] *See also* Am. Hosp. Ass'n, Hospital Outpatient Department (HOPD) Costs Higher than Physician Offices Due to Additional Capabilities, Regulations (2014), *available at* https://www.aha.org/factsheet/2018-09-24-hospital-outpatient-department-hopd-costs-higher-physician-offices-due.

Bipartisan Budget Act of 2015, Congress amended the OPPS statute to provide that the services covered under that payment system would not include items and services "furnished on or after January 1, 2017, by an off-campus" PBD. 42 U.S.C. § 1395*l*(t)(1)(B)(v); *see* Bipartisan Budget Act of 2015, § 603, 129 Stat. at 597. For this purpose, an off-campus PBD does not include "a department of a provider . . . that was billing under this subsection with respect to covered [outpatient] services furnished prior to November 2, 2015," the date of Section 603's enactment. 42 U.S.C. § 1395*l*(t)(21)(B)(ii). The effect of this provision was to preserve OPPS payment rates for existing off-campus PBDs.

Congress revisited the issue the following year in the 21st Century Cures Act, which clarified that off-campus PBDs that were "mid-build" at the time Congress enacted Section 603 would receive the same OPPS rates that existing off-campus PBDs were entitled to receive. *See* 42 U.S.C. § 1395*l*(t)(21)(B)(iv)-(v). In so doing, Congress expressed its understanding of its prior year's enactment, explaining that Section 603 has "effectively grandfathered any off-campus PBD . . . that was billing outpatient services before [the] date of [its] enactment." H.R. Rep. No. 114-604, pt. 1, at 10. Based on this understanding of Section 603, Congress explained that its new enactment would guarantee that existing "[o]ff-campus facilities . . . continue to receive the higher payment rates that apply to an outpatient department on the campus of a hospital." *Id.* at 20. Congress, in other

words, did not leave the treatment of existing off-campus PBDs to CMS's discretion, but instead explicitly assured that OPPS payments for those facilities would be protected. *See Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 419 (1992) (subsequent amendments "confirm[ed]" the statute's meaning).

The legislative determination on this score "[is] not for [the courts] to judge or second-guess." *Sigmon Coal Co.*, 534 U.S. at 461. Congress carefully crafted a remedy that both addressed CMS's concerns and protected the reliance interests of hospitals and the communities that they serve. CMS is obliged to follow the precise terms that Congress has chosen to resolve the issue. "As with other problems of interpreting the intent of Congress in fashioning various details of this legislative compromise, the wisest course is to adhere closely to what Congress has written." *Rodriguez v. Compass Shipping Co., Ltd.*, 451 U.S. 596, 617 (1981); *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 497 (2001) (courts lack the "discretion" to "reject the balance that Congress has struck in a statute").

2. CMS Is Not Free To Disregard The Balance That Congress Struck.

Given this legislative determination, Section 603 is best read to require CMS to pay excepted off-campus PBDs for their services at OPPS rates. CMS acknowledged that Section 603 had this effect in comments to the Government

Accountability Office at the time of the statute's enactment.[10] Before the District Court, however, CMS disputed that Section 603 had anything to say about payment rates for excepted off-campus PBDs; the fact that Congress excluded *non-excepted* off-campus PBDs from the OPPS system, CMS stated, does not show what Congress may have intended for *excepted* off-campus PBDs. Characterizing Appellees' argument as arising under the *expressio unius* canon, CMS cited *Adirondack Medical Center v. Sebelius*, 740 F.3d 692 (D.C. Cir. 2014), to contend that this canon never operates to limit an agency's reading of its own statutory authority.

"This is not entirely correct," however. *Indep. Ins. Agents of Am.*, 211 F.3d at 644. In fact, this Court has expressly rejected CMS's position. *See id.* The *expressio unius* canon, like any other canon, does not automatically dictate a particular result one way or the other; instead, it must be examined together with "the text, structure, legislative history, and purpose of the statute." *Adirondack Med. Ctr. v. Sebelius*, 891 F. Supp. 2d 36, 47 (D.D.C. 2012), *aff'd*, 740 F.3d 692.

And that examination points decidedly in favor of confirming Congress's understanding that it was preserving OPPS payment rates for existing off-campus

[10] *See* U.S. Gov't Accountability Office, GAO-16-189, Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform 16 (Dec. 2015), *available at* https://www.gao.gov/products/gao-16-189.

PBDs. Congress was directly presented with proposals to cut payment rates for all such departments, but it made the deliberate choice to target its remedy to address what it saw to be the problem, the incentive that hospitals would otherwise have going forward to purchase physician's offices. As to the proposal that it extend the statute to cut payment rates for existing facilities too, "Congress considered the unnamed possibility and meant to say no to it." *Peabody Coal Co.*, 537 U.S. at 168; *see also EchoStar Satellite L.L.C. v. FCC*, 704 F.3d 992, 999 (D.C. Cir. 2013).

This case, then, is the mirror image of *Adirondack*. That case involved, first, a broad grant of authority to CMS to adjust payment rates for the Inpatient Prospective Payment System, and, second, a later-enacted provision granting CMS further adjustment authority in a more targeted manner. After examining the statute's text, structure, history, and purpose, this Court rejected the hospitals' argument that the second grant of authority cabined the scope of the first grant, reasoning that it was likely that Congress meant instead "to clarify and complement the Secretary's existing authority—i.e., to make assurance double sure." 740 F.3d at 698 (internal quotation marks omitted).

In contrast, this case does not involve a second grant of authority on top of an existing grant of authority. Rather, the statute that Congress enacted in Section 603 and re-confirmed in the 21st Century Cures Act makes clear that CMS does

not have discretion to change the payment rates for excepted off-campus PBDs to match the Physician Fee Schedule. In a case like this, the more specific provision constraining the agency's discretion—Section 603—controls over any more general grant of authority in the OPPS statute. "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." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (alterations, internal quotation marks, and citation omitted).

In sum, when it enacted Section 603 and when it refined that enactment the following year in the 21st Century Cures Act, Congress crafted legislation that addressed the "specific problem" that it saw "with specific solutions"—a targeted payment cut that applied only to newly built or acquired off-campus PBDs. Congress did not mean to leave the treatment of existing facilities to the agency's whims, but instead understood that it had preserved OPPS payment rates for those facilities, so as to ensure that vulnerable populations would continue to have access to the medical services that those facilities provide, and to safeguard investments in preexisting facilities. CMS's contrary reading cannot be squared with the statute that Congress actually enacted in Section 603.

3. Congress's Enactments Resolve The Question Of Which Outpatient Services Are "Necessary."

The Final Rule is *ultra vires* for yet another reason. Even if CMS's authority to adopt a "method" under Section (t)(2)(F) includes the authority to cut payment rates for particular services that the agency disfavors—and it does not, *see supra* pp. 30-41—CMS can exercise that power only to address "*unnecessary* increases in the volume of covered" services. 42 U.S.C. § 1395*l*(t)(2)(F) (emphasis added). CMS adopted the Final Rule "to control for unnecessary increases in volume that are due to *site-of-service* payment differentials." 83 Fed. Reg. at 59,012 (emphasis added). But Congress considered precisely the same question in 2015, and it chose to maintain OPPS rates for off-campus PBDs that were already in operation then, while at the same time cutting payment rates for newly acquired off-campus PBDs. CMS candidly bases its invocation of Section (t)(2)(F) on its disagreement with Congress's treatment of the issue. *See* 83 Fed. Reg. at 59,008 ("While the changes required by the section 603 amendments to section 1833(t) of the Act address *some of the concerns* . . . , the majority of hospital off-campus departments continue to receive full OPPS payment . . . . *Therefore*, the current site-based payment creates an incentive for an unnecessary increase in the volume of this type" of service. (emphases added)).

CMS's authority to address the claimed "unnecessary increases" in volume, however, does not carry with it the power to second-guess Congress's decision as

to the proper reimbursement rates for services provided in excepted off-campus PBDs. *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), is directly on point. There, Congress had specified a statutory reimbursement formula for branded prescription drugs, which CMS considered to be overly generous because it paid more than the statutory reimbursement formula for the generic form of those drugs. *See id.* at 1280. The agency thus sought to depart from that formula by invoking a general authority to pay for "reasonable and necessary" items and services, reasoning that it was not "reasonable or necessary" to pay for a branded drug at more than its generic rate. *Id.* (internal quotation marks omitted). The Court rejected the agency's attempt to perform "an end-run around the statute" in this manner, noting that the attempt, if successful, "would fundamentally alter the reimbursement scheme." *Id.* at 1282. "[W]e think it quite unlikely that Congress, having minutely detailed the reimbursement rates for covered items and services, intended that the Secretary could ignore these formulas whenever she determined that the *expense* of an item or service was not reasonable or necessary." *Id.* (internal quotation marks omitted).

So too here. Congress answered the question whether clinic services performed in excepted off-campus PBDs are "necessary" by specifically preserving OPPS payment rates for those services when it addressed the matter in 2015. The fact that CMS wishes that Congress had resolved the issue differently

does not give CMS license to ignore the legislature's judgment, expressed in minute detail in the OPPS statute, as to the appropriate payment rate for those services. *See Whitman*, 531 U.S. at 468; *Amgen*, 357 F.3d at 117 (the OPPS statute does not grant CMS the authority to make "basic and fundamental changes" to Congress's statutory scheme (internal quotation marks omitted)).

C. CMS's Interpretation Of The Word "Method" Is Not Entitled To *Chevron* Deference.

CMS asserts that its interpretation of the word "method" in Subsection (t)(2)(F) is "entitled to *Chevron* deference" because it is "reasonable." CMS Br. 17. But CMS does not provide *any* argument in support of its position or explain why it would be appropriate to grant *Chevron* deference here. CMS has accordingly forfeited this point. *See Neustar, Inc. v. FCC*, 857 F.3d 886, 894 (D.C. Cir. 2017) (*Chevron* deference can be forfeited); *City of Waukesha v. EPA*, 320 F.3d 228, 250 n.22 (D.C. Cir. 2003) (arguments "raised in the opening brief only summarily, without explanation or reasoning" are forfeited). Nor did CMS invoke *Chevron* below. *See Neustar*, 857 F.3d at 894; *see also Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (*Chevron* deference appropriate only when agency "recognizes that the Congress's intent is not plain from the statute's face"). *Cf. Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 21-23 (D.C. Cir. 2019) (per curiam)

(agency cannot waive *Chevron* deference where it expressly invokes *Chevron* in rulemaking), *petition for cert. filed*, No. 19-296 (Aug. 29, 2019).

In any event, *Chevron* has no place in this case, where the question is whether CMS's action is *ultra vires*. "*Chevron* deference is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps." *Smith*, 139 S. Ct. at 1778 (internal quotation marks omitted). "The scope of judicial review, meanwhile, is hardly the kind of question that the Court presumes that Congress implicitly delegated to an agency." *Id.*; *see also Gentiva Healthcare Corp. v. Sebelius*, 723 F.3d 292, 297 (D.C. Cir. 2013). Rather than according deference to an agency's attempt to insulate its own actions from judicial review, if a statute is "reasonably susceptible to divergent interpretation" on the question, a court should instead adopt the reading that permits review. *Kucana v. Holder*, 558 U.S. 233, 251 (2010) (internal quotation marks omitted).

Here, moreover, the relevant question is whether CMS acted *outside* its statutory authority in promulgating the Final Rule. *See supra* pp. 30-41, 46-52. "[I]t is fundamental that an agency may not bootstrap itself into an area in which it has no jurisdiction." *Smith*, 139 S. Ct. at 1778 (internal quotation marks omitted). CMS is not entitled to deference on the ultimate question whether its actions are outside statutory bounds.

And even if it were otherwise appropriate to apply *Chevron* deference on *ultra vires* review, it would not be appropriate here; for CMS has not taken a consistent position with respect to the proper interpretation of the word "method" in Subsection (t)(2)(F). *See supra* pp. 38-41. The agency previously acknowledged that "possible legislative modification" would be required before it could use its authority under Subsection (t)(2)(F) to make non-budget-neutral changes to payment rates. 63 Fed. Reg. at 47,586; *see also* 66 Fed. Reg. at 59,908 (describing relationship between Sections (t)(2)(F) and (t)(9)(C) in a manner contrary to the agency's current expansive view). Nowhere in the record has CMS offered an adequate explanation for its change in position, and it is thus not entitled to deference. *See Encino Motorcars*, 136 S. Ct. at 2127. And even if *that* were not a problem, CMS cannot demonstrate that its interpretation of the word "method" is reasonable: As explained above, CMS's position is contrary to clear textual and structural limits on the agency's authority, and is thus *un*reasonable (and *ultra vires*). *See supra* pp. 30-41, 46-52.

CONCLUSION

For the foregoing reasons the District Court's Order should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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ADDENDUM

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42 U.S.C. § 1395*l*. Payment of benefits

* * *

(t) Prospective payment system for hospital outpatient department services

(1) Amount of payment

(A) In general

With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) Definition of covered OPD services

For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1395x(s) of this title;

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1395m(k) of this title or section 1395m(l) of this title and does not include screening mammography (as defined in section 1395x(jj) of this title), diagnostic mammography, or personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) System requirements

Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median

cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 360bb of title 21.

(3) Calculation of base amounts

(A) Aggregate amounts that would be payable if deductibles were disregarded

The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under subsection (b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under subsection (b) did not apply.

(B) Unadjusted copayment amount

(i) In general

For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) Adjusted to be 20 percent when fully phased in

If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) Rules for new services

The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) Calculation of conversion factors

(i) For 1999

(I) In general

The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) Product described

The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) Subsequent years

Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) Adjustment for service mix changes

Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD fee schedule increase factor

For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket

percentage increase applicable under section 1395ww(b)(3)(B)(iii) of this title to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) Calculation of medicare OPD fee schedule amounts

The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) Pre-deductible payment percentage

The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) Productivity and other adjustment

After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment

rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) Other adjustment

For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;
(ii) for each of 2012 and 2013, 0.1 percentage point;
(iii) for 2014, 0.3 percentage point;
(iv) for each of 2015 and 2016, 0.2 percentage point; and
(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) Medicare payment amount

The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) Fee schedule adjustments

The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) Subtract applicable deductible

Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under subsection (b), to the extent applicable.

(C) Apply payment proportion to remainder

The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) Outlier adjustment

(A) In general

Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) Amount of adjustment

The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) Limit on aggregate outlier adjustments

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage

For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) Transitional authority

In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) Exclusion of separate drug and biological APCS from outlier payments

No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

* * *

(7) Transitional adjustment to limit decline in payment

(A) Before 2002

Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002

Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003

Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) Hold harmless provisions

(i) Temporary treatment for certain rural hospitals

(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be

increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) Permanent treatment for cancer hospitals and children's hospitals

In the case of a hospital described in clause (iii) or (v) of section 1395ww(d)(1)(B) of this title, for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS amount defined

In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this subchapter for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1395cc(a)(2)(A)(ii) of this title, and the deductible under subsection (b).

(F) Pre-BBA amount defined

(i) In general

In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) Base payment-to-cost ratio defined

For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) Interim payments

The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) No effect on copayments

Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) Application without regard to budget neutrality

The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) Copayment amount

(A) In general

Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) Election to offer reduced copayment amount

The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) Limitation on copayment amount

(i) To inpatient hospital deductible amount

In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1395e(b) of this title for that year.

(ii) To specified percentage

The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) No impact on deductibles

Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under subsection (b).

(E) Computation ignoring outlier and pass-through adjustments

The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) Periodic review and adjustments components of prospective payment system

(A) Periodic review

The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget neutrality adjustment

If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) Update factor

If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) Special rule for ambulance services

The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1395x(v)(1)(U) of this title, or, if applicable, the fee schedule established under section 1395m(l) of this title.

(11) Special rules for certain hospitals

In the case of hospitals described in clause (iii) or (v) of section 1395ww(d)(1)(B) of this title—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

* * *

(16) Miscellaneous provisions

(A) Application of reclassification of certain hospitals

If a hospital is being treated as being located in a rural area under section 1395ww(d)(8)(E) of this title, that hospital shall be treated under this subsection as being located in that rural area.

(B) Threshold for establishment of separate APCS for drugs

The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) Payment for devices of brachytherapy and therapeutic radiopharmaceuticals at charges adjusted to cost

Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) Special payment rule

(i) In general

In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multi-source Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) Hospital described

A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1395ww(d)(2)(D) of this title);

(II) classified as a rural referral center under section 1395ww(d)(5)(C) of this title; or

(III) a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title).

(iii) Not budget neutral

In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) Application of appropriate use criteria for certain imaging services

For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1395m(q) of this title.

(F) Payment incentive for the transition from traditional X-ray imaging to digital radiography

Notwithstanding the previous provisions of this subsection:

(i) Limitation on payment for film X-ray imaging services

In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) Phased-in limitation on payment for computed radiography imaging services

In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1395w–4(b)(9)(C) of this title)—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) Application without regard to budget neutrality

The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) Implementation

In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

* * *

(18) Authorization of adjustment for cancer hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(C) Target PCR adjustment

In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1395ww(d)(1)(B)(v) of this title. In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(19) Floor on area wage adjustment factor for hospital outpatient department services in frontier States

(A) In general

Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor

applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1395ww(d)(3)(E)(iii)(II) of this title) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) Limitation

This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

(20) Not budget neutral application of reduced expenditures resulting from quality incentives for computed tomography

The Secretary shall not take into account the reduced expenditures that result from the application of section 1395m(p) of this title in making any budget neutrality adjustments this subsection.

(21) Services furnished by an off-campus outpatient department of a provider

(A) Applicable items and services

For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) Off-campus outpatient department of a provider

(i) In general

For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of November 2, 2015) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) Exception

For purposes of paragraph (1)(B)(v) and this paragraph, the term "off-campus outpatient department of a provider" shall not include a

department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015.

(iii) Deemed treatment for 2017

For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) Alternative exception beginning with 2018

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after December 13, 2016), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1395cc(j) of this title; and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after December 13, 2016, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) Mid-build requirement described

The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi) Exclusion for certain cancer hospitals

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1395ww(d)(1)(B)(v) of this title and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before December 13, 2016, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date; or

(II) in the case of a department that meets such requirements after such date, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) Audit

Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term "off-campus outpatient department of a provider" under such clause.

(viii) Implementation

For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of title 44 shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until December 31, 2018. For

purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until expended.

(C) Availability of payment under other payment systems

Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) Information needed for implementation

Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1395cc(j) of this title).

(E) Limitations

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

* * *

CERTIFICATE OF SERVICE

I certify that on February 20, 2020, the foregoing brief was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson
Catherine E. Stetson