Federation of American Hospitals®

HEALTH FINANCING COMMITTEE MEETING

Tuesday, September 27, 2022
1:45 pm – 3:15 pm (ET)
Conservatory Ballroom A

Phone Number: 301-715-8592
Meeting ID: 847 7534 1847
Passcode: 493699

Nathan Summar, Chair
Vice President, Revenue Management
Community Health Systems
4000 Meridian Boulevard
Franklin, TN 37067
nathan_summar@chs.net

Steve Aleman
Prime Healthcare Services
3480 E. Guasti Road
Ontario, CA 91761
909-638-0068
saleman2@primehealthcare.com

Greg Allen
Regional Vice President - Managed Government Progr
HCA Healthcare
3031 N Rocky Point Dr W Ste 400
Tampa, FL 33607
813-402-9443
gregallen@hcahealthcare.com

Laura Bailey
Policy and Regulatory Consultant
HCA Healthcare
1 Park Plaza, B2-3W
Nashville, TN 37203
615-344-6215
laura.bailey1@hcahealthcare.com

Thomas Bateman
Assistant Vice President, Reimbursement
HCA Healthcare
6100 Tower Circle, Ste. 400
Franklin, TN 37067
615-344-6299
tom.bateman@hcahealthcare.com

Elizabeth Brisley
Senior Manager, Government Affairs
Encompass Health Corporation
25 Massachusetts Ave, NW, Suite 500-H
Washington, DC 20001
202-448-1452
elisabeth.brisley@encompasshealth.com

Jeff Cohen
Senior Vice President, Government Relations
HCA Healthcare
1 Park Plaza, 1-4 West
Nashville, TN 37203
615-344-2092
jeff.cohen@hcahealthcare.com

Brian Craven
Chief Financial Officer, Community Hospitals
ScionHealth
629-253-5126
brian.craven@scionhealth.com

David Critchlow
Senior Vice President, Government Relations
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7676
david.critchlow@lpnt.net

Corey Davison
Vice President, Government Relations
Tenet Healthcare Corporation
14201 Dallas Parkway
Dallas, TX 75254
469-893-2293
corey.davison@tenethealth.com

Julie Duck
Senior Vice President, Inpatient Operations
Encompass Health Corporation
3660 Grandview Parkway, Suite 200
Birmingham, AL 35243
205-970-7829
julie.duck@encompasshealth.com

David Fausett
Senior Vice President, Risk Management
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7271
david.fausett@lpnt.net

Shannon Fiser
Senior Vice President, Finance Operations
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7554
shannon.fiser@lpnt.net

Gail Garrett
Vice President, Regulatory Compliance Support
HCA Healthcare
1 Park Plaza, Bldg 2 - 3W
Nashville, TN 0
615-344-6365
gail.garrett@hcahealthcare.com

Justin Gibbs
Assistant Vice President
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7357
justin.gibbs@LPNT.net

Chuck Girard
Vice President, Government Relations
HCA Healthcare
One Park Plaza, Bldg. 1-2E
Nashville, TN 37203
615-344-4659
charles.girard@hcahealthcare.com

Robert Halinski, MBA
Staff Vice President of Reimbursement
Universal Health Services, Inc.
367 South Gulph Road
King of Prussia, PA 0
610-768-3413
bob.halinski@uhsinc.com

Tizgel High
Chief Compliance Officer and Privacy Officer
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7634
tizgel.high@lpnt.net

Cari Hollis
AVP Telehealth
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7650
cari.hollis@lpnt.net

Justin Hunter
Senior Vice President, Public Policy, Legislation
Encompass Health Corporation
300 New Jersey Avenue, NW
Washington, DC 20001
202-448-1649
justin.hunter@encompasshealth.com

James Johnston
Regional Vice President - Managed Government Progr
HCA Healthcare
4900 South Monaco, Suite 380
Denver, CO 80237
303-788-2563
jim.johnston@hcahealthcare.com

Alfred Lumsdaine
Executive Vice President, Chief Financial Officer
Ardent Health Services
One Burton Hills Boulevard, Suite 250
Nashville, TN 37215
615-296-3427
alfred.lumsdaine@ardenthealth.com

Timothy Miner
Vice President, Reimbursement
Ardent Health Services
One Burton Hills Boulevard
Nashville, TN 37215
615-296-3339
Tim.Miner@ArdentHealth.com

Kyle Moore
Universal Health Services, Inc.
367 South Gulph Road
King of Prussia, PA 19406
610-382-3424
kyle.moore@uhsinc.com

Merrick S. Morgan, MBA
Director of Reimbursement-Medicaid Programs, Acute
Universal Health Services, Inc.
160 Rosemont Pkwy
Covington, GA 30016
484-690-2877
merrick.morgan@uhsinc.com

Dan L. Mullins
Division Vice President of Reimbursement
Universal Health Services, Inc.
110 Westwood Pl
Brentwood, TN 37027
615-312-5854
dan.mullins@uhsinc.com

Angelo Pagano
AVP, Reimbursement
HCA Healthcare
6100 Tower Circle, Suite 400
Franklin, TN 37067
615-344-6185
angelo.pagano@hcahealthcare.com

Russell Palk
Assistant Vice President, Government Relations
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7604
russell.palk@lpnt.net

Jennifer C. Peters
Executive Vice President, General Counsel
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7641
jennifer.peters@lpnt.net

Brock Phillips
Director, Federal Affairs
Tenet Healthcare Corporation
1455 Pennsylvania Ave NW, Suite 400
Washington, DC 20004
202-465-0727
brock.phillips@tenethealth.com

Jason Pinkall
Senior Counsel
Tenet Healthcare Corporation
14201 Dallas Parkway
Dallas, TX 75254
469-893-2514
jason.pinkall@tenethealth.com

Rebecca Pitt
VP, Communications and Public Relations
Community Health Systems
4000 Meridian Boulevard
Franklin, TN 37067
615-465-2750
rebecca_pitt@chs.net

Mark Poppell
Senior Vice President, Reimbursement
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7284
mark.poppell@lpnt.net

Sunitha Reddy
VP-Operations
Prime Healthcare Services
3480 E. Guasti Road
Ontario, CA 91761
909-657-5748
SReddy@primehealthcare.com

Joel Richlin
Vice President and General Counsel
Prime Healthcare Services
3480 E. Guasti Road
Ontario, California 91761
909-235-4235
JRichlin@primehealthcare.com

Jason Ross
Senior Vice President, Revenue and Network
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7386
jason.ross@lpnt.net

Deanna Schiavone
CFO - Hospital Division
ScionHealth
502-596-7679
deanna.schiavone@kindred.com

Kathleen Shuey
Director, State Government Relations
Encompass Health Corporation
3660 Grandview Parkway, Suite 200
Birmingham, AL 35243
205-968-6304
katie.shuey@encompasshealth.com

Eric Smith
VP, Reimbursement
HCA Healthcare
2000 Health Park Dr. 2N
Brentwood, TN 37027
615-373-7635
eric.smith@hcahealthcare.com

Margaret Stavitz
Director, Patient Financial Services
Universal Health Services, Inc.
367 S Gulph Rd
King of Prussia, PA 19406
610-992-4592
margaret.stavitz@uhsinc.com

Diana Strupp
Vice President, Government Programs
Tenet Healthcare Corporation
14201 Dallas Parkway
Dallas, TX 75254
469-893-6778
diana.strupp@tenethealth.com

Warren Tardy
Government Relations Consultant
HCA Healthcare
warren.tardy@hcahealthcare.com

Kara Townsend
Director, Policy
HCA Healthcare
One Park Plaza, Bldg. 1-2E
Nashville, TN 37203
615-344-4942
kara.townsend@hcahealthcare.com

Robert M. Wisner
Senior Vice President, Reimbursement
Encompass Health Corporation
3660 Grandview Parkway, Suite 200
Birmingham, AL 0
205-970-5702
robert.wisner@encompasshealth.com

Jason Zachariah
Chief Operating Officer
LifePoint Health
330 Seven Springs Way
Brentwood, TN 37027
615-920-7704
jason.zachariah@lpnt.net

FAH STAFF:

Don May
Senior Vice President, Policy
Federation of American Hospitals
750 9th St NW
Washington, DC 20001
202-624-1531
dmay@fah.org

FAH STAFF:

Steve Speil
Executive Vice President, Policy
Federation of American Hospitals
750 9th St NW
Washington, DC 20001
202-624-1529
sspeil@fah.org

TAB 1

Antitrust Statement
Federation of American Hospitals

To Be Recited By Chairman

I would like to remind everyone that the Federation, its representatives, and its members, are committed to the continued existence of competitive health care delivery systems and markets, and ongoing compliance with all applicable federal and state antitrust laws.

As such, you are reminded that the Federation will not permit at this meeting, or in any other of its forums, any discussion or remarks that suggest or invite anti-competitive conduct among its member hospitals and/or health care systems.

Political and Policy Landscape

September 2022

(Prepared on September 15)

Congress

- Congress returns this month for a short work period before adjourning to campaign.
- With limited floor time available, Congress will focus on:
    - Continuing Resolution (CR) to fund the government through mid-December.
        - Administration requested $47B in supplemental funding for Ukraine, COVID, monkeypox and disaster relief.
            - COVID and monkeypox relief highly unlikely.
        - FAH advocating for inclusion of rural health extenders (LVH & MDH).
    - Senate confirmation of judicial nominations.
- Prior to the August recess, Democrats passed the *Inflation Reduction Act* through the reconciliation process to address health care, climate/energy, tax, and deficit reduction before the midterms. Notably, the legislation:
    - Allows Medicare to negotiate certain prescription drug prices and caps out-of-pocket costs for seniors at $2,000.
    - Extends expanded *ACA* subsidies through 2025 (key FAH priority).
    - Establishes a 15% Corporate Minimum Tax applied to billion-dollar companies.
    - Establishes a stock buyback 1% excise tax.

2022 Midterm Election Preview

- Republicans appear likely to gain control of the House, though a "red wave" may now be out of reach due to the *Dobbs* impact on voter turnout as well as recent Democratic legislative wins, yet still dependent on economic conditions.
- Control of the Senate remains a toss-up, though the odds of Democrats retaining control have modestly improved.

Lame Duck Priorities

- Congress will return after the election to focus on a long-term government spending bill.
    - FAH will focus advocacy on waiving statutory PAYGO (4% Medicare sequester) and establishing long-term extension of rural health programs.
- FAH also will focus on legislation to streamline and improve Medicare Advantage prior authorization, telehealth, mental health, and pandemic preparedness.
- Outcome of the election – and margins of control – will have a major impact on Democratic and Republican leadership teams selected in the House. Many view current Republican Leader McCarthy and Whip Scalise as odds-on favorites to ascend to Speaker and Majority Leader, respectively, in a Republican House, though margins matter.
- Senate Leadership is expected to stay the same regardless of election outcome.

Medicare Part B / 340B Drug Payment Adjustment

September 2022

- In 2018, CMS put in place a policy that reduced by 28.5% (ASP minus 22.5%) Medicare outpatient payments for drugs acquired under the 340B program.

- As required by the Medicare outpatient prospective payment (OPPS) law, the estimated $1.6 billion in savings from the reduced 340B payment was put back into the base payment for all non-drug services, a 3.2% payment increase for all OPPS hospitals.

- CMS maintained that policy through 2022.

- In June of this year, the Supreme Court struck down the policy that reduced drug payments to 340B hospitals for 2018 and 2019 (the years being litigated) but was silent on the remedy and remanded the case to the lower courts.

- In a series of lower court motions and responses on which the court has not yet ruled:
    - AHA petitioned the US District Court for swift payment of ASP+6% for 2018 – 2022; no recoupment of past increased payments; and immediate restoration of ASP+6%.
    - FAH submitted an amicus brief arguing for a non-budget neutral remedy and no recoupment of past increased payments.
    - HHS conceded that the Supreme Court decision effectively also covered 2020 – 2022 and asked the District Court to remand the case to the agency to determine the remedy, leaving all options open, including a survey (the absence of which led the Supreme Court to nullify the 340B cut) to determine the appropriate payment, as well as clawing back the increased payments.

- Meanwhile, FAH submitted detailed comments on CMS's CY2023 OPPS proposed rule, criticizing the agency for abandoning the policy that clearly benefited patients and the vast majority of hospitals; making the case for why CMS should not, and, by law, may not recoup past payments; and opposing the imposition of a payment reduction for CY2023 – 4.04% – that exceeds the current 3.2% budget neutrality offset and would produce a net permanent reduction to the base rate.

- FAH will meet with CMS leadership in October, and previously retained high profile counsel, well regarded within the Administration, to prepare our legal brief and represent us on the budget neutrality issue.

Federation of American Hospitals®

American Hospital Association v. Becerra: Constraints on Remedy

Following the Supreme Court decision in *American Hospital Association v. Becerra* that CMS acted unlawfully in reducing the OPPS reimbursement rate for 340B drugs in 2018 and 2019, CMS indicated in the CY2023 OPPS proposed rule that it intends to revert to its prior policy of paying ASP plus 6 percent. In addition, CMS sought comment on how to structure a potential remedy for CYs 2018-2022, and has signaled that it may be considering a budget neutral remedy for those 5 years, which would mean recouping payments from the vast majority of hospitals paid under the OPPS.

During each of those years that CMS reduced the reimbursement rate for 340B drugs, it complied with the budget neutrality provision under the OPPS statute by offsetting estimated savings that it projected for the coming year with an estimated 3.2 percent upward payment adjustment for non-drug items and services that it projected for the coming year. It is noteworthy that the Court did not disturb the payment increase funded with the reduction to 340B drug payments.

The Federation of American Hospitals (FAH) believes a budget neutral remedy would not reflect fair or sound policy as it would cause considerable harm to hospitals and their patients. Further, a budget neutral remedy would not be legally defensible as the Medicare Act simply does not permit such a remedy.

Hospitals relied on the OPPS's prospectively set reimbursement rates over the past five years to provide the full range of outpatient items and services, including emergency services, treatment of life-threatening and debilitating conditions, and preventive care; to continue operations in rural and urban areas, often with razor-thin margins; and to attract and hire employees, while facing unprecedented workforce shortages. Recent historic challenges, including record inflation and the COVID-19 pandemic, have put enormous strain on hospitals, jeopardizing the financial health of many hospitals, especially rural hospitals. A budget neutral remedy that seeks to recoup the 3.2 percent payment increase for five years could put many hospitals in an untenable position, particularly in light of already strained financial conditions: MedPAC's most recent report concluded that in 2020 Medicare margins fell to negative 12.6% without federal pandemic relief funds, which have now largely expired.

Beyond the compelling policy concerns surrounding a budget neutral remedy, such retrospective recoupment is unlawful. The OPPS is a ***prospective*** payment system. The notion that reimbursement will be made at a ***pre-determined*** rate, which is final and predictable, is the foundation of a prospective payment system. Once reimbursement rates are set ***in advance*** based on ***estimated*** budget neutrality, there is no retrospective true-up ***after the fact*** that ensures ***actual*** budget neutrality. Nothing in the statute authorizes CMS to claw back

amounts in the name of budget neutrality, and CMS has never identified any instance where the agency has retroactively recouped amounts in the name of budget neutrality, absent a specific Congressional authorization to do so. Nor may CMS make a future adjustment to indirectly apply a retrospective recoupment – the OPPS budget neutrality provision requires that any estimated adjustment to offset any estimated cost must concern the coming year, not a past year. Indeed, there is clear precedent for CMS providing non-budget neutral remedies when the agency has violated the law.

Charles N. Kahn III
President and CEO

September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

RE: CMS-1772-P, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating, July 26, 2022.

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Proposed Rule and provide our comments on specific proposals below.

V.B.6. CY 2023 OPPS Payment Methodology for 340B Purchased Drugs

The FAH regrets that CMS has indicated it intends in the final rule to abandon the current prospective budget-neutral 340B payment policy that pays Average Sales Price (ASP) minus 22.5 percent for 340B-acquired drugs and increases the conversion factor by an amount commensurate with the savings generated by the 340B payment adjustment.

In 2018, CMS took an important step to directly benefit seniors and improve the accuracy of Medicare's payment for outpatient hospital services across all hospitals treating Medicare beneficiaries. The agency said it was implementing this change to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur" while also ensuring that Medicare beneficiaries "share in the savings on drugs acquired through the 340B Program." We believe the policy has achieved this important goal and advanced Congressional intent underlying the OPPS statute to promote efficiency, equity, and patient-centered care through, for example, reduced copayments for Medicare beneficiaries, especially for cancer patients.

That action, to better align Medicare payment with 340B hospital acquisition costs, had two immediate benefits. First, seniors who get their drugs at a 340B hospital pay less because the lower Medicare OPPS payment to the hospital means a lower copayment for the Medicare beneficiary. This is due to the Medicare copayment structure, which requires seniors to pay 20% of the amount Medicare reimburses the hospital, not 20% of what it costs the hospital to buy the drugs. The prior payment policy resulted in a significant, negative impact on beneficiaries. Because Medicare payment rates far exceeded 340B hospitals' acquisition costs, beneficiaries were making disproportionately large coinsurance payments compared to 340B hospitals' costs of acquiring the drugs. A study issued by Avalere Health[1] in 2021 noted that reversing the CMS 340B payment policy in 2021 would have increased beneficiaries' drug co-payments by an estimated 37% on average, or $472.8 million, at 340B hospitals.

Second, all hospitals, including 340B hospitals, have been getting a much-needed 3.2 percent bump in Medicare payment for primary and emergency care, as well as outpatient procedures and other non-drug services – a welcome increase in a chronically underfunded system. The inefficiencies of the pre-2018 drug payment policies had tangible impacts on non-340B hospitals and the communities they serve. Because of the OPPS prospective payment budget neutrality requirement, the gains realized by 340B hospitals as a result of the mismatch between acquisition costs and payment rates came at the expense of non-340B hospitals, who received lower OPPS payments to account for the comparatively inflated payments relative to costs to 340B hospitals. The pre-2018 OPPS payment rates to non-340B hospitals increased the financial burden of providing outpatient services, by requiring non-340B hospitals to effectively subsidize the provision of similar services to 340B hospitals serving comparable patient populations. Along those lines, an examination of the latest cost reports as contained in the CMS Healthcare Provider Cost Reporting Information System file dated June 30, 2022, reveals that non-340B hospitals had marginally higher uncompensated care cost rates than 340B hospitals – 3.7 percent of total operating costs compared to 3.5 percent. FAH member hospitals had an even

[1] Avalere Health, Report: OPPS Medicare Part B Payment Impact Analysis, page 11 (https://www.fah.org/wp-content/uploads/2021/04/20210326_OPPS_Analysis_for_FAH.pdf).

higher uncompensated care cost rate of 5.7 per cent. Charity care cost rates were comparable at 340B and non-340B hospitals at 2.5 percent, and higher, 4.4 percent, at FAH hospitals.

CMS' actions have leveled the playing field across all OPPS hospitals, reinforcing the purpose of the Medicare OPPS to incentivize efficient and equitable behavior. Yet reversing CMS' current 340B payment policy for separately payable drugs and removing the proposed 4.04 percent increase to the base rate for all non-drug OPPS services to all OPPS hospitals as CMS indicated in the Proposed Rule it plans to do in the final rule would result in a stunning negative hospital impact: 80% of all hospitals paid under the OPPS – including 86% of rural hospitals, and even 52% of all 340B hospitals – would experience a net payment decrease in 2023 based on CMS's published data. The negative impact to rural hospitals, struggling to survive and closing at an alarming rate, would be particularly damaging.

The policy foundation supporting CMS' current policy is clearly compelling, and the FAH strongly urges CMS to maintain that policy consistent with the limited decision rendered by the Supreme Court for CYs 2018 and 2019.

Budget Neutral Reversal of the 340B Purchased Drug Policy for CY 2023

In the OPPS Proposed Rule, CMS proposes to continue to pay ASP minus 22.5 percent for 340B-acquired drugs in CY 2023, but indicates that, in light of the Supreme Court's decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (June 15, 2022), it anticipates reverting to its prior policy of paying ASP plus 6 percent. The Proposed Rule indicates that this alternative proposal would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor (a 4.04% payment reduction for non-drug items and services). This proposed negative budget neutrality adjustment exceeds the currently effective budget neutrality adjustment associated with the policy (3.2 percent) such that the reversal of the 340B drug payment policy would produce a net permanent reduction to the OPPS conversion factor of 0.84 percent. ***The FAH strongly opposes the imposition of any payment reduction for CY 2023 that does more than make the offsetting budget neutrality adjustment associated with the abandonment of the 340B drug payment policy.*** Simply stated, it would be inappropriate for CMS's unravelling of its payment methodology for 340B purchased drugs to produce a *net permanent reduction* to the OPPS conversion factor.

CMS determined the budget neutrality factor associated with the 340B drug payment policy when it first adopted the policy for CY 2018 and left it unchanged through CY 2022. CMS should not now recalculate the budgetary impact of the policy after steadfastly refusing to do so over the past four years. In comments on the CY 2022 OPPS Proposed Rule, stakeholders argued that the 340B drug payment policy was not actually operating in a budget neutral manner and that the 3.2 percent increase to the conversion factor was insufficient to fully offset the reduction in payments for 340B-acquired drugs. In the Final Rule, however, CMS declined to update the budget neutrality adjustment, emphasizing the prospective nature of budget neutrality adjustments and that the "broader budget neutrality adjustments" adopted annually adequately address changes in drug utilization and payment such that the existing budget neutrality adjustment remained appropriate as long as the 340B drug payment policy remained in place. 86 Fed. Reg. 63,458, 63,648 (Nov. 16, 2021). Given CMS's assurance that a continued positive 3.2 percent budget neutrality adjustment would be appropriate in connection with a continuation of

the 340B drug payment policy, it likewise stands to reason that a simple reversal of that budget neutrality adjustment is appropriate in connection with the termination of that policy. Moreover, the alternative approach would result in the inappropriate erosion of OPPS payment rates, to the ultimate detriment of program beneficiaries.

Remedies for CYs 2018-2022

CMS also seeks public comment on how to structure any potential remedy for CYs 2018-2022, given that the Supreme Court did not specify a remedy in its ruling in *American Hospital Association v. Becerra*, 142 S. Ct. 1896. 87 Fed. Reg. 44,649. In the course of litigation, the American Hospital Association ("AHA") correctly stated that the Secretary may make 340B hospitals whole for past shortfalls without offsetting budget neutrality reductions. The Supreme Court noted the AHA's position, and, although the Court did not specify a remedy, it explicitly rejected the Secretary's argument that judicial review was unavailable based on budget neutrality concerns. ***As the FAH has explained in prior OPPS rulemaking comments, the Medicare Act does not permit CMS to make any offsets to achieve actual or retrospective budget neutrality, and, to the extent that CMS ultimately provides relief to 340B hospitals through payments designed to compensate such hospitals for past underpayments, those payments may not be adopted in a budget neutral fashion because any offsetting payment reduction would unlawfully recoup past payments that were properly made for non-drug OPPS items and services.***

The Medicare Act requires that CMS *prospectively* adjust payment rates within OPPS in a budget neutral manner to account for the decreased payments for 340B drugs *in advance of* the commencement of each OPPS fiscal year. *See* 42 U.S.C. § 1395*l*(t)(9)(B). Importantly, while Congress very clearly intended that budget neutrality be reached within this *prospective* payment system, Congress only permits that the Secretary make adjustments to achieve a *prospective estimate* of budget neutrality. To conceive of budget neutrality as a retrospective requirement would be inconsistent with the text and structure of the statute and wreak havoc on Medicare's payment systems and the reliance interest of stakeholders throughout the health care system.

The text of the Medicare Act plainly conveys the prospective-only nature of the budget neutrality requirement:

> 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.

42 U.S.C. § 1395*l*(t)(9)(B) (emphases added).[2] Paragraph (9) is entitled "Periodic review and adjustments components of prospective payment system," and subparagraph (A), which triggers the budget neutrality provision, requires the Secretary to review and revise "the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)"

[2] 42 U.S.C.§ 1395*l*(t)(14)(H) does not add to this requirement; instead, it simply refers back to subsection (t)(9)(B) in providing that expenditures resulting from paragraph (14) are taken into account under paragraph (9) only starting in 2006.

not less than annually to take into account various factors and information. 42 U.S.C. § 1395*l*(t)(9)(A). These statutory provisions describe the OPPS prospective rulemakings CMS undertakes prior to the start of each calendar year. The budget neutrality provision cited above addresses only *estimated* costs for the *following* calendar year. The estimates are just one of the inputs into the OPPS formula subject to the agency's notice-and-comment rulemaking each year—and, critically, after a rule is finalized for a particular year, the estimates do not change as a result of unanticipated increases or decreases in spending, and the budget neutrality provision, by its plain terms, has no further application. CMS itself has long-recognized the prospective nature of this budget neutrality requirement. *See, e.g.*, CY 2003 Final Rule, 67 Fed. Reg. 66,718, 66,754 (Nov. 1, 2002) ("With respect to budget neutrality, section 1833(t)(9)(B) of the Act [42 U.S.C.§ 1395*l*(t)(9)(B)] makes clear that any adjustments to the OPPS made by the Secretary may not cause *estimated* expenditures to increase or decrease.") (emphasis added). While budget neutrality remains a rate-setting requirement guiding adjustments *prospectively*, the law does not permit *post-hoc* reconciliation or recoupment to achieve budget neutrality *after* actual payments are made to providers.

Likewise, in setting OPPS rates for future years, it would be improper for the Secretary to attempt to indirectly recoup payments that resulted from CMS' lawfully applied and unchallenged 3.2% budget neutrality adjustment, which the agency adopted in CY 2018 and maintained without further adjustment through CY 2022, or to otherwise attempt to offset any relief to 340B hospitals. ***Put simply, the Secretary did not err in applying a positive adjustment to non-340B claims in order to achieve budget neutrality based on his estimates in the CY 2018 OPPS Final Rule. And any future adjustment, under the plain terms of the budget neutrality provision, must concern estimated savings and costs in the <u>following</u> year, not any <u>prior</u> year. Thus, any remedy should not and may not either directly or indirectly seek to recoup non-drug payments, which were properly made under the OPPS Final Rules in CYs 2018-2022.***

Critically, the Medicare Act does not permit after-the-fact reconciliation to achieve *actual* budget neutrality in a given payment year under any prospective payment system (except in very narrow circumstances explicitly prescribed by Congress). Thus, where, for *any* reason, a prospective payment system ultimately produces "excessive payments" (*i.e.*, payments beyond those anticipated), such excessive payments may not be recouped absent specific statutory authorization. By way of example, the provisions of the Medicare Act establishing the inpatient prospective payment system ("IPPS") and those establishing the OPPS each contain language authorizing the Secretary to adopt prospective adjustments to the IPPS or OPPS payment amounts to eliminate estimated *future* (but not past) changes in aggregate payments that are due to changes in the coding or classification of inpatient discharges or covered outpatient department services that do not reflect real changes in case mix or service mix. 42 U.S.C. §§ 1395ww(d)(3)(A)(vi), 1395*l*(t)(3)(C)(iii).[3]

[3] In relevant part, the statutory language provides as follows: "Insofar as the Secretary determines that [certain IPPS or OPPS] adjustments . . . for a previous fiscal year (or estimates that such adjustments for a future fiscal 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 [discharges or covered outpatient department services] that do not reflect real changes in [case mix or service mix], the Secretary may adjust [the average standardized amounts or the conversion factor] computed under this [paragraph or

Although the Medicare Act permits CMS to implement *prospective* adjustments to eliminate anticipated excessive payments in future years (42 U.S.C. § 1395ww(d)(3)(A)(vi)), the statute includes no general authority for CMS to recoup excessive payments in prior years. A narrow exception proves this general rule: In 2007, Congress passed the TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–87 (2007) ("TMA"), to specifically authorize additional adjustments during specified fiscal years to recoup certain excessive payments related to inpatient discharges in FY 2008 and FY 2009. And in 2013, Congress amended the TMA to authorize additional adjustments during specified fiscal years to recoup $11 billion in purported excessive payments between FY 2008 through 2013. American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013) ("ATRA"). Tellingly, Congressional action was required to specifically authorize such after-the-fact reconciliation. *See, e.g.*, Hospital IPPS and Fiscal Year 2014 Rates, 78 Fed. Reg. 50,496, 50,514 (Aug. 19, 2013) (acknowledging that any FY 2010 through 2012 "overpayments could not be recovered by CMS [prior to the passage of ATRA] as section 7(b)(1)(B) of Public Law 110–90 [TMA] limited recoupments to overpayments made in FY 2008 and FY 2009"). No comparable specific statutory authorization for recoupment of amounts properly paid at the prospectively set CYs 2018-2022 OPPS rates exists here.

Bolstering this plain understanding of the statute, as CMS routinely has opined and various courts have agreed, the idea that payment will be made at a predetermined, specified rate serves as the foundation of the Medicare prospective payment systems, of which the OPPS is one. *See, e.g.*, *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1232 (D.C. Cir. 1994); *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1169 (D.C. Cir. 2015); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996). The D.C. Circuit has recognized these core principles of predictability and finality, finding that "the Secretary's emphasis on finality protects Medicare providers as well as the Secretary from unexpected shifts in basic reimbursement rates" and permits hospitals to rely on the predetermined rates and resulting payments made thereunder. *Methodist Hosp.*, 38 F.3d at 1232. Any attempt at after-the-fact rebalancing would be contrary to such principles and therefore fundamentally at odds with Congress's intent that rates be established *prospectively* under the OPPS.

In line with the finality and predictability principles underlying the OPPS, the FAH's members relied on and already have received reimbursement at the prospectively set payment rates for the outpatient non-drug items and services they provided to Medicare beneficiaries over the five-year period the 340B drug payment policy has been in place. The government recognized in H. Lee Moffitt Cancer Center that "retroactively recalculating payments under the OPPS" could "adversely impact[] the reliance interests of hospitals operating under the OPPS." Gov't MSJ (ECF No. 17), H. Lee Moffitt Cancer Ctr. v. Azar, 324 F. Supp. 3d 1 (D.D.C. No. 1:16-cv-02337-CKK). The same fundamental fairness concern exists here. In line with the finality and predictability principles underlying the OPPS, the FAH's member hospitals relied on, received reimbursement under, and have long-since used or obligated funds from amounts paid at the prospectively-set payment rates for 2018 through 2022 to deliver services to Medicare patients. And, as discussed above, the Secretary may not attempt to remedy any underpayments

subparagraph] for subsequent fiscal years so as to eliminate the effect of such coding or classification changes."

to 340B hospitals in CYs 2018-2022 by increasing payments for 340B drugs in a future payment year in a budget neutral manner (i.e., by reducing payments for non-340B items and services) because this would amount to an unlawful retroactive recoupment of past payments that were properly made for non-drug items and services under the OPPS Final Rules for CYs 2018-2022, and would represent an impermissible application of the forward-looking-only budget neutrality provision. Moreover, such an approach would be inherently inequitable and arbitrary because, among other things, it would artificially depress OPPS payments for non-drug items and services, unevenly distribute additional payments among 340B hospitals, and inflate beneficiary cost sharing for 340B-acquired drugs.

What is more, there is clear precedent for CMS providing non-budget neutral remedies for the agency's violations of the law, which do not disrupt the interests of finality and predictability by directly or indirectly recouping payments from a prior year. In fact, CMS has retroactively corrected underpayments in a non-budget neutral fashion under 42 U.S.C. § 1395*l*(t), without "suggest[ing] any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d 1, 15 (D.D.C. 2018). For example, in 2006, CMS made a "retroactive payment adjustment" under 42 U.S.C. § 1395*l*(t)(2)(E) that applied to a group of rural hospitals the agency said it had mistakenly excluded from that year's prospective adjustment. Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates, 71 Fed. Reg. 67,960, 68,010 (Nov. 24, 2006). In later litigation involving OPPS payments to cancer hospitals, the court noted that CMS did not offset this 2006 retroactive payment adjustment with any recoupment and "did not suggest any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15. CMS should (and must) do no differently here.

Any direct recoupment or prospective reduction in OPPS payments for non-drug items and services to offset relief provided to 340B hospitals would be not just unlawful—it would also risk harm to Medicare beneficiaries by placing unnecessary and unfair additional financial strain on hospitals already grappling with the destabilizing effects of the COVID-19 pandemic, record inflation, and acute labor shortages. For more than two years, hospitals have been on the front lines of the COVID-19 pandemic, which has significantly strained an already-fragile healthcare workforce with over 80 million cases, over 4.6 million hospitalizations, and nearly 1 million deaths. *Massive Growth in Expenses & Rising Inflation Fuel Continued Financial Challenges for America's Hospitals & Health Systems,* Am. Hosp. Ass'n, https://www.aha.org/guidesreports/2022-04-22-massive-growth-expenses-and-rising-inflation-fuel-continued-financial (last visited Aug. 12, 2022).

The pandemic also coincided with a range of other financial and operational challenges like historic volume and revenue losses and skyrocketing expenses. Record inflation has made increases in expenses "severely detrimental to hospital finances, leading to billions in losses and over 33% of hospitals operating on negative margins." *Id.* "[H]ospital margins are still in the red" more than halfway through 2022. Erik Swanson, *National Hospital Flash Report: July 2022,* Kaufman Hall (Aug. 1, 2022), https://www.kaufmanhall.com/insights/research-report/national-hospital- flash-report-july-2022. Hospital "expenses remain at historic highs, leaving hospitals with cumulatively negative margins" that "remain significantly lower than pre-pandemic levels." *Id.* This instability necessarily creates risks for beneficiaries who depend on

their community hospitals for care and provides all the more reason that CMS should not seek to retroactively recoup OPPS reimbursements or to prospectively offset relief to 340B hospitals with payment reductions.

In sum, the FAH's members relied on and were properly paid under an OPPS payment rate properly designed to be budget neutral based on CMS estimates. That the CY 2018-2022 OPPS payment rates may not ultimately result in *actual* budget neutrality, whether due to the Supreme Court's decision, fluctuations in service volumes, or any host of other factors, should not (and lawfully cannot) directly or indirectly jeopardize the payments that were made under the prospectively set payment rates. ***Therefore, the FAH strongly opposes any effort to offset any relief to 340B hospitals or to otherwise provide relief to such hospitals on a budget-neutral basis.*** Instead, the FAH urges CMS to take the most pragmatic and equitable approach to swiftly remedying the 340B payment reduction: Make each 340B hospital whole with a lump sum payment based on its actual claims for 340B-acquired drugs in CY 2018 through CY 2022 without waiting for the CY 2024 OPPS rulemaking (*e.g.*, through a CMS Ruling). This approach would avoid the legal and policy concerns set forth above and would provide finality after five years of litigation. Critically, the simple payment of make-whole relief to 340B hospitals holds non-340B hospitals harmless for the five years they rightfully relied on OPPS payment rates for non-drug items and services.

II.B. Proposed CY 2023 Outpatient Hospital Conversion Factor Update

The Projected Inflation Undergirding CMS' Proposed Market Basket Fails to Capture Hospitals' Actual Experience of Record Inflation

The FAH is concerned that the historical data upon which both the proposed CY 2023 forecast of the market basket increase and the FY 2023 final rule IPPS market basket are based falls far short of reflecting the real rate of increase that hospitals are experiencing. CMS' recent September 2, 2022, data release is instructive. While the data remains incomplete for CY 2022, CMS projections show that the market basket update is less than half of the current estimates for 2022 inflation -- 5.5 percent compared to the 2.7 percent market basket update adopted by CMS. That means hospitals are arguably being underpaid today by 2.8 percent for services they are providing in CY 2022. We are concerned that CMS' estimates for CY 2023 (expected at 4.1 percent) will also result in structural underpayments, and we urge CMS to use its authority to further increase the update for hospitals, which are struggling with COVID and inflationary pressures that are unprecedented in the history of the outpatient prospective system.

Recent data released by Kaufman Hall reflect the continued pressure on total hospital expenses, with year-over-year cost growth of 7.6 percent from July 2021 to July 2022. Total labor expenses were up 8.9 percent year-over-year and labor expenses per adjusted discharge were up a staggering 13.5 percent. Unfortunately, the pressure on hospital expenses shows no sign of abating.

One reason that CMS' market basket data may be reflecting lower increases in staffing costs compared to what hospitals are experiencing relates to the use of contract labor. Hospitals have confronted worrying shortages of hospital workers during the COVID-19 pandemic, necessitating an outsized reliance on contract staff – particularly travel nurses – to meet patient demand. In 2019, hospitals spent a median of 4.7 percent of their total nurse labor expenses for contract travel nurses, which skyrocketed to a median of 38.6 percent in January 2022. A quarter of hospitals – those that have had to rely disproportionately on contract travel nurses in order to serve their communities during a global pandemic – saw their costs for contract travel nurses account for over 50 percent of their total nurse labor expenses.[4] **We understand that the BLS' ECI only captures the salary increases associated with employed staff, and thus wholly fails to capture the extraordinary growth in labor costs associated with hospitals' necessary reliance on nursing personnel that are contracted through staffing agencies during a time of labor supply shortages.**

Accounting for Understatement of Market Baskets

Given the unprecedented nature of the pandemic and its extraordinary impact on hospital costs alongside record inflation, the FAH urges CMS to consider a one-time adjustment to ensure that the CY 2023 rate increase is applied to a base rate that more accurately accounts for actual inflation during CY 2022. Without such an adjustment, OPPS rates will fail to keep pace with rising hospital costs, compounding the instability already produced by the COVID-19 pandemic. As noted above, the projected market basket used to update OPPS rates for CY 2022 is now 2.8 percentage points below the actual rate of hospital cost inflation. The unique and unprecedented circumstances confronted by hospitals today highlight the challenges of inadequate payment and accelerating costs and we urge CMS to exercise its full authority to remedy this situation.

Total Factor Productivity

Pursuant to section 1833(t)(3)(F)(i) of the Act, the Secretary reduces the OPPS market basket increase by the "10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as produced by the Secretary for the 10-year period ending with the applicable fiscal year)." The theory behind the offsets for economy wide total productivity is that the hospital sector should be able to realize the same productivity gains as the general economy. Even before the pandemic, however, OACT questioned the wisdom underlying this assumption. An OACT analysis from 2016 indicated:

> The most recent 10-year moving average growth of hospital MFP, ending in 2013, ranges from 0.1 percent to 0.5 percent, compared to 0.8 percent growth in private nonfarm business MFP. In addition, more recently published estimates of hospital productivity by other researchers seem to indicate that hospitals are unable to

4 Massive Growth in Expenses and Rising Inflation Fuel Continued Financial Challenges for America's Hospitals and Health Systems, American Hospital Association, April 2022.

achieve the productivity gains of the general economy over the long run. In the 2015 Trustees Report, it was assumed that hospitals could achieve productivity gains of 0.4 percent per year over the long range; this growth rate is relative to the assumed growth in private nonfarm business MFP of 1.1 percent.[5]

The FAH shares OACT's skepticism regarding the offset to the hospital market basket for the 10-year average in economy-wide nonfarm total factor productivity. One reason that hospitals may not be able to realize the same growth in general economy wide productivity is that hospital services are highly labor intensive. As labor represents nearly 70 percent of the index, hospitals have little opportunity to obtain productivity gains from non-labor inputs as may be occurring in other industries that are less labor intensive**.**

Another factor to consider during recent years is instability in the level of productivity improvements both economy-wide and specifically for hospitals resulting from the COVID-19 pandemic. While use of a 10-year moving average may be designed to improve predictability of the offset when there are year-to-year swings in productivity, it also has the effect of minimizing the impact of lower productivity growth during a once-in-a-century pandemic. Two recent periods of decreased productivity occurred during the COVID-19 pandemic – a 0.4 percent decline in July 2021 and a 0.6 percent decline in January 2022.[6] Yet these substantial declines that disproportionately impact hospitals are significantly discounted in a 10-year moving average**.** The FAH believes that the highly unusual circumstances of the COVID-19 pandemic are sufficient reason for the Secretary to provide a one-time adjustment that offsets application of the otherwise applicable productivity adjustment for CY 2023.

II.C. Proposed Wage Index Changes

The FAH commends CMS' continued commitment to supporting rural hospitals by mitigating the negative feedback loop created by the wage index through an increase to the wage index values of low wage index hospitals. Rural hospitals are imperative in ensuring access to care for the more than 60 million Americans living in rural areas across the United States, including close to one quarter of all Medicare beneficiaries. Because Medicare beneficiaries disproportionately rely upon rural hospitals for care, Medicare reimbursement tends to impact rural hospitals' revenue more than non-rural hospitals. As CMS has previously noted in the FY 2020 IPPS rulemaking, the wage index has created a "downward spiral" whereby low wage index hospitals receive lower reimbursement, thereby weakening their capacity to invest in recruitment or employee retention, and further depressing reimbursement exacerbating the workforce shortage challenge that is especially acute in rural America. The FAH, however,

[5] ***Paul Spitalnic, Steve Heffler, Bridget Dickensheets and Mollie Knight, Hospital Multifactor Productivity, An Updated Presentation of Two Methodologies, page 2 (Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies (cms.gov))***

[6] FTI Consulting, Report: Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, page 8.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.* *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as the Secretary of Health and Human Services, *et al.*, *Defendants*.	No. 18-2084 (RC)

BRIEF OF THE FEDERATION OF AMERICAN HOSPITALS AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS

Sean Marotta (D.C. Bar No. 1006494)
Ken Choe (D.C. Bar No. 1024576)
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-4881
sean.marotta@hoganlovells.com

Counsel for Federation of American of Hospitals

Dated: August 12, 2022

CORPORATE DISCLOSURE STATEMENT

Amicus Curiae Federation of American Hospitals is a nonprofit trade association of health systems. The Federation is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. The Federation has no parent company, and no publicly held company holds more than a ten percent interest in the Federation.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES:

* Authorities upon which we chiefly rely are marked with an asterisk.

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

LEGISLATIVE MATERIAL:

OTHER AUTHORITIES:

TABLE OF AUTHORITIES—Continued

Page

STATEMENT OF IDENTITY, INTERESTS, AND AUTHORITY TO FILE[1]

Amicus Curiae the Federation of American Hospitals (Federation) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. Dedicated to a market-based philosophy, the Federation provides representation and advocacy on behalf of its members to Congress, the Executive Branch, the judiciary, media, academia, accrediting organizations, and the public. The Federation's members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals in urban and rural America and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The Federation's members are deeply affected by any changes to Medicare reimbursement rates that the Department of Health and Human Services (HHS) determines for hospital outpatient services according to an intricate statutory system known as the Outpatient Prospective Payment System (OPPS). *See* 42 U.S.C. § 1395*l*(t). That is why the Federation routinely submits comments to the Centers for Medicare & Medicaid Services (CMS) on Medicare payment rulemakings and offers guidance to courts regarding Medicare reimbursement principles in this space.

In 2018, HHS decreased the Medicare reimbursement rate for drugs purchased by hospitals under the 340B program, reasoning that the decrease was justified because 340B hospitals acquire drugs at significantly reduced prices. *See* Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and

[1] No party or counsel for a party authored this brief in whole or in part, no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief, and no person or entity other than the Federation or its counsel made a monetary contribution to this brief's preparation or submission. All parties have consented to the brief's filing.

Quality Reporting Programs, 82 Fed. Reg. 52,356 (Nov. 13, 2017). The agency estimated that this negative payment adjustment for 340B drugs would reduce expenditures for 2018 by $1.6 billion. Because of the statute's budget-neutrality provision, HHS redistributed those savings by making an offsetting 3.2% increase in the reimbursement rates for non-drug outpatient items and services provided by all OPPS hospitals. *Id*. at 52,623. HHS adopted the same adjusted rate and maintained the 3.2% increase in each of the last five years. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818, 58,975-77 (Nov. 21, 2018); Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 84 Fed. Reg. 61,142, 61,321-27 (Nov. 12, 2019); Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 85 Fed. Reg. 85,866, 86,042-55 (Dec. 29, 2020); Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 86 Fed. Reg. 63,458, 63,461, 63,645-46, 63,648 (Nov. 16, 2021). More than two thousand non-340B hospitals benefited from the 3.2% positive adjustment, including the Federation's member hospitals. *See* Avalere Health, OPPS Medicare Part B Payment Impact Analysis, at 9-10 (Mar. 2021), *available at* https://www.fah.org/wp-content/uploads/2021/04/20210326_OPPS_Analysis_for_FAH.pdf (Avalere Health Analysis).

A few months ago, the Supreme Court held that HHS acted unlawfully by reducing the drug reimbursement rates for 340B hospitals relative to other hospitals in the 2018 and 2019 OPPS. *American Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896 (2022). But the Supreme Court did

not address the proper remedy to which 340B hospitals are now entitled, leaving the question of remedy to this Court.

The Federation writes to explain that, in crafting relief for the 340B hospitals resulting from the invalidation of the OPPS Rules, the Medicare statute forecloses any attempt to offset remedial payments through retroactive recoupments of funds from non-340B hospitals. Nor does the budget-neutrality provision of the OPPS, as the government has previously suggested, allow—let alone require—the retroactive recoupment and reallocation of funds already paid out as reimbursements for items and services provided in past calendar years. The budget-neutrality provision requires only that HHS adopt prospective budget neutrality adjustments based on its estimates for the following calendar year. The agency is fully capable of remedying its past underpayments to 340B hospitals without disturbing the funds already distributed to non-340B hospitals.

The Federation also writes to help inform the Court's consideration of the equities at issue by offering the non-340B hospitals' perspective on the harmful effects that wholesale, retrospective changes to prospectively-set hospital outpatient payment rates would have on American health care. The Federation's members relied on those OPPS payment rates and have already received reimbursement for services rendered in 2018 through 2022 under those prospectively-set payment rates. This reality reinforces that any relief awarded to 340B hospitals in this action should not affect payments made or expected to be made to non-340B hospitals.

ARGUMENT

Throughout this litigation, HHS has wielded "budget neutrality" as a shield to judicial review. HHS insisted all the way to the Supreme Court that a judicial ruling invalidating its past reimbursement rates for outpatient services rendered by certain hospitals would require

retroactive offsets elsewhere in the OPPS—a prospect that the agency deemed so "impractical" that it should suffice to block judicial review entirely. *American Hosp. Ass'n*, 142 S. Ct. 1896, slip op. at 8. The Supreme Court unanimously rejected that view as inconsistent with the statutory text and traditional presumption in favor of judicial review of administrative action, *id.* at 7-8, and went on to invalidate the 2018 and 2019 OPPS 340B drug reimbursement policy, *id.* at 9. Following the Supreme Court's decision, the government cannot now brandish budget neutrality as a justification for retroactively recouping reimbursements already made under the OPPS. It is not. Nothing in the Medicare Act—budget-neutrality provisions or otherwise—allows HHS to claw back lawful payments to non-340B hospitals.

I. THE MEDICARE STATUTE DOES NOT ALLOW HHS TO MAKE ANY OFFSETS TO ACHIEVE ACTUAL OR RETROSPECTIVE BUDGET NEUTRALITY.

As the Supreme Court said just months ago, the text and structure of the Medicare statute "make this a straightforward case." *American Hosp. Ass'n*, 142 S. Ct. 1896, slip op. at 10. The statute does not authorize the agency to recoup five years-worth of payments for hospital outpatient items and services because it failed to comply with its own statutory obligations, and the agency cannot ignore that reality under the guise of an obligation of budget neutrality.

A. The OPPS's statutory text does not allow HHS to retroactively recoup reimbursements in the name of budget neutrality.

The Medicare statute does not allow HHS to recoup or reallocate actual payments under the OPPS such that unanticipated expenditures in one area are offset by retroactive clawbacks elsewhere. That absence of authority makes sense: The relevant subsection is entitled "*Prospective* payment system for hospital outpatient department services" and (unsurprisingly) addresses the factors HHS must consider when determining the OPPS rates for the *following* calendar year. 42 U.S.C. § 1395*l*(t) (emphasis added). HHS revises the OPPS rates each year

via notice-and-comment rulemaking and publishes them before they go into effect. Hospitals then receive the predetermined OPPS rate for a service in every instance in which they provide the service, meaning that "hospitals are not reimbursed for the actual costs incurred in providing care." *American Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1234 (D.C. Cir. 2020), *cert. denied sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2853 (2021), *reh'g denied*, 142 S. Ct. 920 (2021).

Nothing in the text authorizes HHS to claw back funds from previous years because HHS miscalculated or misapplied some portion of the OPPS formula. And the narrow exception to the Medicare statute's general prohibition on retroactive rulemaking—when "retroactive application is necessary to comply with statutory requirements," 42 U.S.C. § 1395hh(e)(1)(A)(i)—does not, as the government has suggested in earlier phases of this litigation, Defs.' Br. on Remedy at 8, ECF No. 31, provide the requisite specific statutory authorization for recoupment. The OPPS is a *prospective* payment system, meaning that "retroactive application" of a new rule is never "necessary to comply" with statutory requirements of the OPPS. 42 U.S.C. § 1395hh(e)(1)(A)(i). The government cannot locate a "newfound power" to retroactively recoup and reallocate Medicare reimbursements in such broad language of an "'ancillary provision[]' . . . designed to function as a gap filler" that has never been employed in this manner. *West Virginia v. EPA*, 142 S. Ct. 2587, 2610 (2022) (citation omitted).

Nor can any retroactive-recoupment power be divined from the statute's budget-neutrality provision. *See* 42 U.S.C. § 1395*l*(t)(9)(B), (14)(H). When HHS adjusts the groups, relative payment weights, and wage indices in the OPPS for the upcoming year, budget neutrality requires that any changes "may not cause the estimated amount of expenditures . . . to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made." 42 U.S.C. § 1395*l*(t)(9)(B). In plain English: The

impact of any adjustment, up or down, must be estimated and offset elsewhere so that the total estimated budget remains the same.

The government's past litigation posture presumes there must be actual equivalence between the prospectively-estimated budget neutrality calculations and actual payments furnished in a particular year, or that unanticipated additional payments must be offset by retroactive savings elsewhere. But careful readers will notice that the budget neutrality provision applies just to the "*estimated* amount of expenditures"—not the *actual* amount of expenditures. The budget-neutrality provision addresses only estimated costs for the following calendar year. The estimates are just one of the inputs into the OPPS formula subject to the agency's notice-and-comment rulemaking each year—but after those rules are issued for a particular year, the estimates do not change as a result of unanticipated increases in spending. And while budget neutrality remains a rate-setting requirement guiding rate adjustments going forward, the law does not permit retroactive reconciliation or recoupment to achieve budget neutrality after actual payments are made to providers. That the payment rates for the last five calendar years may not ultimately result in actual budget neutrality, whether due to HHS's misinterpretation of its statutory obligations, fluctuations in service volumes, or any host of other factors, does not jeopardize the actual payments made during those years under the prospectively-set payment rates. Accordingly, once expenditures are actual rather than estimated, the budget-neutrality requirement is inapplicable by its own terms.[2]

[2] Nor does *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), support the government's position, as it has previously insisted, *see* Defs.' Opp'n Br. on Remedy at 12-13 n.5, ECF No. 36. *Amgen*, which involved neither budget neutrality nor retroactive recoupments, held only that the court could not review the particular adjustments challenged there. *Amgen*, 357 F.3d at 112-118. Moreover, any credit the court may have lent to the government's argument that judicial review would "interfere with the Secretary's ability to ensure budget neutrality," *id*. at 112, does not

B. Common sense and the OPPS's structure confirm that HHS cannot retroactively recoup reimbursements in the name of budget neutrality.

Transforming budget neutrality into a retroactive requirement—retroactively recalculating payments under the OPPS, recouping funds already paid out, and then redistributing them—would wreak havoc on Medicare's payment system. *Cf. Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1233 (D.C. Cir. 1994) (upholding HHS determination that corrections in wage rates used to determine Medicare reimbursement would not be applied retroactively and noting that "retroactive corrections would cause a significant, if not debilitating, disruption to the Secretary's administration of the already-complex Medicare program"). Indeed, "'common sense as to the manner in which Congress would have been likely to delegate' such power" to HHS makes it very unlikely that Congress actually did so. *West Virginia*, 142 S. Ct. at 2609 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)) (brackets omitted).

If Congress intended the agency to implement such a sea change in Medicare reimbursement policy in the name of budget neutrality, it would have said so explicitly. "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Id.* at 2607 (quoting *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989)). Congress could have conveyed the power of retroactive recoupment explicitly. Or it could have referred to actual rather than estimated costs in creating the OPPS, as it did in other subsections in the same statute. *See, e.g.*, 42 U.S.C. § 1395*l*(i)(2)(A)(i) (referring to "actual audited costs incurred . . . in providing such

---

survive the Supreme Court's decision in *American Hospital Association*, which flatly rejected HHS's argument that judicial review was foreclosed "[d]ue to that budget-neutrality requirement" because it "lack[ed] any textual basis." 142 S. Ct. 1896, slip op. at 8. Any retroactive recoupment power is similarly atextual.

services"); *id.* § 1395*l*(dd)(1) (setting repayments for certain colorectal cancer screening tests as "the lesser of the actual charge for the service" and the amount determined under the OPPS). These other provisions demonstrate that "Congress knows exactly how" to give HHS express authority to offset past Medicare overpayments "when it wishes," yet did not do so here. *Ysleta Del Sur Pueblo v. Texas*, 142 S. Ct. 1929, 1942 (2022).

The budget-neutrality provision says nothing about retroactively recouping repayments in the event of administrative error and so does not convey that power either. Extraordinary grants of regulatory authority are rarely accomplished through "modest words," "vague terms," or "subtle device[s]." *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468 (2001). "Nor does Congress typically use oblique or elliptical language to empower an agency to make a 'radical or fundamental change' to a statutory scheme." *West Virginia*, 142 S. Ct. at 2609 (quoting *MCI Telecomms. Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 229 (1994)).

Moreover, the statute's structure suggests that Congress could have foreseen the possibility that judicial intervention would invalidate some portion of the OPPS—and declined to permit, in such a circumstance, a wholesale retroactive allocation of payments already made. The OPPS did not eliminate the statutory right of a hospital to contest a reimbursement determination with HHS and then in court. 42 U.S.C. § 1395ff(b); *see, e.g.*, *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 7-9 (2000). Here, Congress required HHS to treat groups of hospitals the same absent a study of acquisition costs, *American Hosp. Ass'n*, 142 S. Ct. 1896, slip op. at 12, and "HHS may fairly be held to that duty" without presuming that Congress conveyed the extraordinary recoupment powers the government has suggested it possesses. *See H. Lee Moffitt Cancer Ctr. & Rsch. Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 16 (D.D.C. 2018).

C. The statutory and regulatory history of the OPPS further reinforce that HHS lacks authority to retroactively recoup reimbursements in the name of budget neutrality.

While the Medicare statute directs HHS to make certain adjustments to the OPPS prospective payment rates in a manner that is expected to be budget neutral across all hospitals, *see* 42 U.S.C. § 1395*l*(t)(9), the statute does not require actual equivalence between the prospectively estimated budget-neutrality calculations and the actual payment made for a calendar year. Nor does it allow HHS to retroactively disturb payments made under an appropriately budget-neutral system of prospectively set rates to offset later unanticipated additional payments. It could hardly be otherwise, because requiring budget neutrality as to actual expenditures would force the agency to repeatedly make additional payments or recoup costs to account for each ultimate inaccuracy in the relevant estimates—including, for instance, differences between expected and actual amounts of drugs furnished—something that the agency simply does not do under the prospective payment systems.

OPPS's history confirms that it applies only prospectively and does not authorize retroactive reallocations. Before the enactment of the OPPS, HHS reimbursed hospitals retrospectively based on the reasonable costs incurred related to services actually provided. *See* Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18,434, 18,436 (Apr. 7, 2000). Congress overhauled that system by adopting the OPPS and required HHS to set reimbursement amounts for hospital outpatient services prospectively at payment rates intended to approximate the costs incurred by efficient providers to encourage more efficient delivery of care. H.R. Rep. No. 105-149, at 1323 (1997). The idea that payments are made at a predetermined, specified rate is the foundation of all Medicare prospective payment systems, including OPPS. *See, e.g.*, *Methodist Hosp. of*

Sacramento, 38 F.3d at 1232; *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1169 (D.C. Cir. 2015); *Skagit Cnty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996). The core principles of predictability and finality "protect[] Medicare providers as well as the Secretary from unexpected shifts in basic reimbursement rates," permitting hospitals to rely on the predetermined rates and resulting payments. *Methodist Hosp.*, 38 F.3d at 1232.

Indeed, the government has historically maintained that budget neutrality applies on a prospective basis only. *See* Mem. in Supp. of Def.'s Cross-Mot. for Summ. J. and in Opp. to Plf.'s Mot. for Summ. J. (Gov't MSJ), *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d 1 (No. 1:16-cv-02337-CKK), 2017 WL 11579190 (arguing that HHS "reasonably interpreted § 1395*l*(t)(18)(B) to require payment adjustments on a prospective basis, as is consistent with the OPPS itself and prospective payment systems in general"); *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1016-20 (D.C. Cir. 1999) (HHS's longstanding interpretation of the Medicare Act's outlier-payment provision as including "no necessary connection between the amount of *estimated* outlier payments and the *actual* payments made to hospitals" was reasonable (emphases added and citation omitted)).

And where changes to a prospective payment system produced past allegedly excessive payments, HHS sought specific statutory authorization to recoup the funds—offering further support that the budget-neutrality provision does not *itself* authorize retroactive recalculations. After HHS determined that coding changes had increased inpatient hospital payments in federal fiscal years 2008 through 2013 by approximately $11 billion, Congress acted to provide narrow authority for HHS to reduce future payments in specified years to recoup $11 billion. *See* TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986-987 (2007), *as amended by* American Taxpayer Relief Act of 2012 (ATRA), Pub.

L. No. 112-240, § 631(b), 126 Stat. 2313, 2353-54 (2013). HHS did not claim any preexisting authority to recoup those funds; instead, the explicit and limited authority set forth in section 7(b) of the TMA and section 631(b) of ATRA was necessary to recoup for purported excessive payments in prior years. *See, e.g.*, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates, 78 Fed. Reg. 50,496, 50,514 (Aug. 19, 2013) (acknowledging that any overpayments in fiscal years 2010 through 2012 "could not be recovered" prior to the passage of ATRA); *see also* Medicare Program; Physician Fee Schedule Update for Calendar Year 2003, 68 Fed. Reg. 9,567, 9,568 (Feb. 28, 2003) (noting that "estimates" used to determine sustainable growth rates for Physician Fee Schedule in fiscal years 1998 and 1999 may not be "recalculated to reflect later, after-the-fact actual data" absent specific congressional authorization). Despite years of litigation, HHS has not identified any instance in which it has exercised systematic recoupment authority absent congressional authorization—perhaps because it never has.

Moreover, HHS has retroactively corrected underpayments in a non-budget neutral fashion under Section 1395*l*(t) voluntarily, without "suggest[ing] any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15. For example, in 2006, HHS made a "retroactive payment adjustment" under § (t)(2)(E) that applied to a group of rural hospitals the agency said it had mistakenly excluded from that year's prospective adjustment. Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates, 71 Fed. Reg. 67,960, 68,010 (Nov. 24, 2006). The agency did not offset the cost of doing so by retroactively recouping payments it had already made to other providers. *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15.

This history confirms that budget neutrality does not apply retroactively. And as HHS has long acknowledged, a prospective-only policy preserves the expectations of all parties and facilitates the economic incentives and predictability that Congress intended. HHS cannot remedy its statutory violation by recouping the 3.2% adjustment that was lawfully applied to non-drug OPPS claims, whether by recovering past payments or by implementing a prospective negative adjustment.

II. ECONOMIC REALITIES CURRENTLY FACED BY HOSPITALS PROVIDE ALL THE MORE REASON TO CONCLUDE THAT HHS LACKS AUTHORITY TO RETROACTIVELY RECOUP OPPS PAYMENTS.

The government retroactively recouping funds from non-340B hospitals is not just illegal. It is also terrible policy. Any attempted recoupment would cause chaos for hospitals and come at the worst possible time for them and their finances.

A. Non-340B hospitals relied on OPPS payment rates in past years and have already received reimbursements at those rates for services rendered in those years, and retroactive recoupment would imperil the critical community services these hospitals provide.

Retroactive recoupment of Medicare reimbursements means that hospitals would be forced to return or forgo vital funding, despite providing essential healthcare services at exceedingly low (or often negative) margins. Indeed, hospitals' Medicare overall operating margin was negative 8.5% in 2020—and negative 12.6% absent federal pandemic relief funds, which have now largely expired. MedPAC, Report to the Congress: Medicare Payment Policy, at 69 (Mar. 2022), *available at* https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf.

Federation members, all of which are ineligible for 340B discounts as tax-paying hospitals, serve as essential health care institutions for some of the nation's most-vulnerable communities, providing uncompensated and discounted care to patients who have few, if any,

alternatives to address their health care needs. Federation member hospitals provide these underserved patient populations the full range of healthcare services, including emergency services, preventative care, and the treatment of life-threatening and debilitating conditions in rural and urban areas across the United States. More than two thousand non-340B hospitals, including Federation members, saw an increase in Medicare payments as a result of the 3.2% payment adjustment in each of the last five years, providing much-needed additional resources to care for some of the country's most at-risk populations. *See* Avalere Health Analysis at 9-10.

Many Federation member hospitals meet and exceed the applicable low-income patient population thresholds that would make them eligible to participate in the 340B program if tax-paying hospitals were not statutorily excluded. *See* 42 U.S.C. § 256b(a)(4)(L)(i). Indeed, non-340B hospitals spend the same 2.5% of total operating costs on charitable services as 340B hospitals.[3] Federation member hospitals spend an even greater 4.4% share. Uncompensated care services—a broader measure of unreimbursed care recognized by CMS, *see* 42 C.F.R. § 412.106(g)(1)(iii)(C)(5)—account for just 3.5% of total operating costs at 340B hospitals, but account for 3.7% at non-340B hospitals and 5.7% at Federation member hospitals.

The government recognized in *H. Lee Moffitt Cancer Center* that "retroactively recalculating payments under the OPPS" could "adversely impact[ ] the reliance interests of hospitals operating under the OPPS." Gov't MSJ, *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d 1 (No. 1:16-cv-02337-CKK). It should do the same here. In line with the finality and predictability principles underlying the OPPS, the Federation's member hospitals relied on,

[3] This cost information was developed from the latest cost reports for hospitals with cost reporting periods ending between 10/1/2020 and 12/31/2021 as contained in the CMS Healthcare Provider Cost Reporting Information System file dated June 30, 2022, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports.

received reimbursement under, and have long-since used or obligated funds from the prospectively-set payment rates for 2018 through 2022 to deliver services to Medicare patients. The Court should not tolerate hospitals nationwide bearing the cost of HHS's own error in calculating the drug reimbursement rate for 340B hospitals, particularly when non-340B hospitals had no reason to think that the 3.2% positive adjustment could retroactively disappear five years later. Simple fairness dictates that the government not penalize non-340B hospitals for its own mistake. *See Freeman v. Pitts*, 503 U.S. 467, 487 (1992) ("Equitable remedies must be flexible if these underlying principles are to be enforced with fairness . . . .").

B. A trifecta of historic challenges—COVID-19, inflation, and hospital-staffing shortages—renders any attempted retroactive recoupment particularly ill-advised.

Most of the nation's hospitals and health systems operated on razor-thin margins before the COVID-19 pandemic. *See* FTI Consulting, Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, at 2 (2022), *available at* https://www.fticonsulting.com/-/media/files/us-files/insights/reports/2022/jun/assessing-adequacy-proposed-updates-hospital-inpatient-payment-system.pdf (FTI Consulting Report). Unprecedented growth in hospital expenses, coupled with potential future COVID-19 surges and record inflation, now place hospitals in an even-more-precarious situation. Retroactively recouping a significant share of half a decade's worth of OPPS payments would be nothing short of disastrous for hospitals already on the brink of financial ruin.

For more than two years, hospitals have been on the front lines of the COVID-19 pandemic, which has significantly strained an already-fragile healthcare workforce with over 80 million cases, over 4.6 million hospitalizations, and nearly 1 million deaths. *Massive Growth in Expenses & Rising Inflation Fuel Continued Financial Challenges for America's Hospitals &*

Health Systems, Am. Hosp. Ass'n, https://www.aha.org/guidesreports/2022-04-22-massive-growth-expenses-and-rising-inflation-fuel-continued-financial (last visited Aug. 12, 2022). The pandemic also coincided with a range of other financial and operational challenges like historic volume and revenue losses and skyrocketing expenses. Record inflation has made increases in expenses "severely detrimental to hospital finances, leading to billions in losses and over 33% of hospitals operating on negative margins." *Id.* "[H]ospital margins are still in the red" more than halfway through 2022. Erik Swanson, *National Hospital Flash Report: July 2022*, Kaufman Hall (Aug. 1, 2022), https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-july-2022. Hospital "expenses remain at historic highs, leaving hospitals with cumulatively negative margins" that "remain significantly lower than pre-pandemic levels." *Id.*

Labor costs are a significant driver of these historic expenses. The pandemic further accelerated competition between hospitals and travel and temporary nurse staffing firms that are attracting a greater share of the workforce. FTI Consulting Report at 3-4. "The cost of contract labor relative to total labor expenses increased five-fold in 2022 compared to 2019," largely the result of hospitals needing "to replace departing staff nurses with travel or agency nurses." *Id.* Contract nurses come at a significantly-increased cost, forcing hospitals to shell out triple the median wages of employed nurses in March 2022. *Id.*

The financial health of rural hospitals, including many Federation members, is particularly perilous. Forty-six percent of rural hospitals have a negative operating margin, and over 100 rural hospitals have closed since 2010. *See* The Chartis Group, Crises Collide: The COVID-19 Pandemic And The Stability Of The Rural Health Safety Net, at 2 (Feb. 2021), https://www.chartis.com/sites/default/files/documents/COVID%20and%20the%20Stability%20of%20the%20Rural%20Health%20Safety%20Net.pdf. As it has everywhere else, the COVID-19

pandemic has only exacerbated those financial challenges, forcing some rural hospitals to reduce or suspend outpatient services. *Id*. at 1, 6. The median distance to the most common healthcare services increases by 20 miles when rural hospitals close, resulting in even greater barriers to care for communities. U.S. Gov't Accountability Off., GAO-21-93, Rural Hospital Closures: Affected Residents Had Reduced Access To Health Care Services, at 14-15 (Dec. 2020), https://www.gao.gov/assets/gao-21-93.pdf.

The economic realities facing hospitals provide all the more reason to conclude that HHS lacks the authority to retroactively recoup OPPS reimbursements. *See West Virginia*, 142 S. Ct. at 2608-09. The OPPS does not allow—let alone require—HHS to remedy its mistake by robbing Peter to pay Paul. And any remedy here should not inadvertently suggest that HHS has the ability to retroactively reallocate OPPS payments, which would be an unprecedented development in the history of Medicare reimbursement, given that the statute does not convey that power. HHS has the tools it needs to make Plaintiffs whole—without touching OPPS reimbursements to non-340B hospitals.

CONCLUSION

For the foregoing reasons, any relief granted to the 340B hospitals should not affect payments to non-340B hospitals.

Respectfully submitted,

/s/ Sean Marotta
Sean Marotta (D.C. Bar No. 1006494)
Ken Choe (D.C. Bar No. 1024576)
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-4881
sean.marotta@hoganlovells.com

Counsel for Federation of American Hospitals

Dated: August 12, 2022

CERTIFICATE OF SERVICE

I hereby certify that, on August 12, 2022, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all counsel, who are registered users.

/s/ Sean Marotta
Sean Marotta

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES *v.* EMPIRE HEALTH FOUNDATION, FOR VALLEY HOSPITAL MEDICAL CENTER

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 20–1312. Argued November 29, 2021—Decided June 24, 2022

Once a person turns 65 or has received federal disability benefits for 24 months, he becomes "entitled" to benefits under Part A of Medicare. 42 U. S. C. §§426(a)–(b). Part A provides coverage for, among other things, inpatient hospital treatment. See §1395d(a). Medicare pays hospitals a fixed rate for such treatment based on the patient's diagnosis, regardless of the hospital's actual cost and subject to certain adjustments. §§1395ww(d)(1)–(5). One such adjustment is the "disproportionate share hospital" (DSH) adjustment, which provides higher-than-usual rates to hospitals that serve a higher-than-usual percentage of low-income patients. To calculate the DSH adjustment, the Department of Health and Human Services (HHS) adds together two statutorily described fractions: the Medicare fraction—which represents the proportion of a hospital's Medicare patients who have low incomes—and the Medicaid fraction—which represents the proportion of a hospital's total patients who are not entitled to Medicare and have low incomes. Together those fractions produce the "disproportionate-patient percentage," which determines whether a hospital will receive a DSH adjustment, and how large it will be.

Not all patients who qualify for Medicare Part A have their hospital treatment paid for by the program. Non-payment may occur, for example, if a patient's stay exceeds Medicare's 90-day cap per spell of illness, see §1395d, or if a patient is covered by a private insurance plan, see §1395y(b)(2)(A). Such limits on Medicare's coverage prompt the question raised here: whether patients whom Medicare insures but does not pay for on a given day are patients "who (for such days) were

entitled to [Medicare Part A] benefits" for purposes of computing a hospital's disproportionate-patient percentage. §1395ww(d)(5)(F)(vi)(I).

A 2004 HHS regulation says yes: If the patient meets the basic statutory criteria for Medicare (*i.e.*, is over 65 or disabled), then the patient counts in the denominator and, if poor, in the numerator of the Medicare fraction. See 69 Fed. Reg. 49098–49099. Respondent Empire Health Foundation challenged that regulation as inconsistent with the statute. The Ninth Circuit agreed. That court focused on the statute's use of two different phrases: "entitled to [Medicare Part A] benefits" and "eligible for [Medicaid] assistance." The Ninth Circuit read the latter phrase to mean that a patient qualifies for Medicaid and the former phrase to mean that a patient has an absolute right to payment from Medicare. The Court granted certiorari to resolve a conflict between the Ninth Circuit and two other Circuit Courts, which had approved of HHS's regulation.

Held: In calculating the Medicare fraction, individuals "entitled to [Medicare Part A] benefits" are all those qualifying for the program, regardless of whether they receive Medicare payments for part or all of a hospital stay. Pp. 7–19.

HHS's regulation is consistent with the text, context, and structure of the DSH provisions. The agency has interpreted the phrase "entitled to benefits" in those provisions to mean just what it means throughout the Medicare statute: qualifying for benefits. And counting everyone who qualifies for Medicare benefits in the Medicare fraction—and no one who qualifies for those benefits in the Medicaid fraction—accords with the statute's attempt to capture, through two separate measurements, two different segments of a hospital's low-income patient population.

(a) Empire's textual argument has a two-part structure. Echoing the Ninth Circuit, Empire primarily contends that the words "entitled" and "eligible" have different meanings. According to Empire, to be "eligible" for a benefit is to be "qualified" to seek it; to be "entitled" to a benefit means instead to have an "absolute right" to its payment. But throughout the Medicare statute, "entitled to benefits" is essentially a term of art meaning "qualifying for benefits," *i.e.*, being over 65 or disabled. And in the end, Empire basically concedes that point. It must devise a way to give "entitled to benefits" a different meaning in the fraction descriptions than everywhere else in the Medicare statute. So Empire shifts gears, relying now on the parenthetical phrase "(for such days)" to transform the usual statutory meaning of "entitled to benefits" to something different and novel. But those three little words do not accomplish what Empire would like, having the much less radical function of excluding days of a patient's hospital stay before he qualifies for Medicare (*e.g.*, turns 65). Pp. 8–15.

(1) The Medicare statute explicitly states that "[e]very individual" who "has attained age 65" and is entitled to ordinary social security payments and "every individual" under age 65 who has been entitled to federal disability benefits for at least 24 months "shall be entitled to" Medicare Part A benefits. §§426(a)–(b). This broad meaning of "entitlement" coexists with limitations on payment. The entitlement to benefits, the statute repeatedly says, is an entitlement to payment under specified conditions. So a person remains entitled to benefits even if he has run into one of the statute's conditions, such as the 90-day cap on inpatient hospital services. For example, the statute twice refers to patients who are "entitled to benefits under part A but ha[ve] exhausted benefits for inpatient hospital services." §§1395*l*(a)(8)(B)(i), 1395*l*(t)(1)(B)(ii). In thus describing the Part A entitlement, the statute reflects the complexity of health insurance: An insured who hits some limit on coverage for, say, eye care is still insured. His policy will pay for more eye care in the next coverage period and meanwhile will pay for his knee replacement.

If "entitled to benefits" instead bore Empire's meaning, Medicare beneficiaries would lose important rights and protections, such as the ability to enroll in other Medicare programs. See §§1395*o*(a), 1395w-21(a)(3), 1395w–101(a)(3)(A). Empire's interpretation would also make a hash of provisions designed to inform Medicare beneficiaries of their benefits, see §1395b–2(a), and to protect beneficiaries from misleading marketing materials, see §1395w–21(a)(3). Congress could not have intended to write a statute whose safeguards would apply or not apply, or fluctuate constantly, based on the happenstance of whether Medicare paid for hospital care on a given day. Pp. 9–13.

(2) Empire concedes that its interpretation cannot be applied throughout the Medicare statute. To get around this, Empire claims that the parenthetical in "patients who (for such days) were entitled to [Part A] benefits," §1395ww(d)(5)(F)(vi)(I), converts the usual statutory meaning of "entitled to benefits" to something different: actually receiving payment. That slight phrase, however, cannot bear so much interpretive weight. Instead, the parenthetical works as HHS says: hand in hand with the ordinary statutory meaning of "entitled to benefits." It directs HHS to count only those individuals who qualify for Medicare on a particular day. So if a patient turns 65 on the 15th day of a 30-day hospital stay, HHS will count only 15 days. Pp. 13–15.

(b) The structure of the relevant statutory provisions reinforces the conclusion that "entitled to benefits" means qualifying for benefits. The statute recompenses hospitals for serving two different low-income populations: low-income Medicare patients and low-income non-Medicare patients. HHS's reading of "entitled" comports with this

structure: a low-income Medicare patient always count in the Medicare fraction. That is so regardless of whether the Medicare program is actually paying for a day of his care—because that fact has no relationship to his financial status. Empire's interpretation, by contrast, fits poorly with the statutory structure. Its who-paid-for-a-day-of-care test has no relationship to a patient's financial status. So on Empire's view, a patient could phase in and out of the Medicare fraction regardless of income. Empire responds by asserting that any low-income person excluded from the Medicare fraction (say, because of exhaustion of benefits) would get counted instead in the Medicaid fraction. But even if that is true, Empire's scheme would result in patients ping-ponging back and forth between the two fractions based on the happenstance of actual Medicare payments. In any event, Empire is too quick to claim that those who (on its view) are tossed from the Medicare fraction for non-income-based reasons like exhaustion of benefits would still wind up in the Medicaid fraction. Applying Empire's reading of "for such days," a low-income patient who has exhausted his coverage would not get counted at all, in either fraction, but he would remain just as low-income and impose just as high costs on the hospital treating him. Empire's only response is to insist that its interpretation must be right because it usually (though not always) leads to higher DSH payments. But the point of the statute is not to pay hospitals the most money possible; it is to compensate them for serving a disproportionate share of low-income patients. Pp. 15–18.

958 F. 3d 873, reversed and remanded.

KAGAN, J., delivered the opinion of the Court, in which THOMAS, BREYER, SOTOMAYOR, and BARRETT, JJ., joined. KAVANAUGH, J., filed a dissenting opinion, in which ROBERTS, C. J., and ALITO and GORSUCH, JJ., joined.

SUPREME COURT OF THE UNITED STATES

No. 20–1312

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER *v.* EMPIRE HEALTH FOUNDATION, FOR VALLEY HOSPITAL MEDICAL CENTER

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

[June 24, 2022]

JUSTICE KAGAN delivered the opinion of the Court.

The Medicare program reimburses hospitals at higher-than-usual rates when they serve a higher-than-usual percentage of low-income patients. The enhanced rates are calculated by adding together two fractions, called the Medicare fraction and the Medicaid fraction. Roughly speaking, the former measures the hospital's low-income senior-citizen population, and the latter the hospital's low-income non-senior population.

This case raises a technical but important question about the Medicare fraction. The statutory description of that fraction refers to "the number of [a] hospital's patient days" attributable to low-income patients "who (for such days) were entitled to benefits under part A of [Medicare]." 42 U. S. C. §1395ww(d)(5)(F)(vi)(I). According to the Department of Health and Human Services (HHS), a person is "entitled to [Part A] benefits" under the statute if he qualifies for the Medicare program—essentially, if he is over 65 or

disabled. That remains so even when Medicare is not paying for part or all of his hospital stay—for example, because a private insurer is legally responsible or because he has used up his allotted coverage. Today, we approve HHS's understanding of the Medicare fraction.

I

The Medicare program provides Government-funded health insurance to over 64 million elderly or disabled Americans. (The vast majority of that number are senior citizens.) When a person turns 65 or has received federal disability benefits for 24 months, he automatically (*i.e.*, without application or other filing) becomes "entitled" to benefits under Medicare Part A. §§426(a)–(b). The most significant Part A benefit is coverage for inpatient hospital treatment; Part A also covers associated physician and skilled nursing services. See §1395d(a); HHS, CMS Ruling No. CMS–1498–R, p. 10 (Apr. 28, 2010), https://www.cms.gov/regulations-and-guidance/guidance/rulings/downloads/cms1498r.pdf (CMS–1498–R). In addition, entitlement to Part A generally enables a patient to enroll (if he wishes) in Medicare's other programs: Part B's coverage for outpatient care; Part C's coverage through privately administered Medicare Advantage plans; and Part D's coverage for prescription drugs. See §§1395*o*(a)(1), 1395w–21(a)(3), 1395w–101(a)(3)(A).

The Medicare program pays a hospital a fixed rate for treating each Medicare patient, based on the patient's diagnosis and regardless of the hospital's actual costs. §§1395ww(d)(1)–(4). The rates are designed to reflect the amounts an efficiently run hospital, in the same region, would expend to treat a patient with the same diagnosis. See 42 CFR §412.2 (2022). If the hospital spends anything more, it suffers a financial loss. The flat-rate payment system thus gives hospitals an incentive to provide efficient levels of medical service.

But Congress, recognizing complexity in healthcare, provided for various hospital-specific rate adjustments—including the one at issue here for treating low-income patients. The "disproportionate share hospital" (DSH) adjustment gives hospitals serving an "unusually high percentage of low-income patients" enhanced Medicare payments. *Sebelius* v. *Auburn Regional Medical Center*, 568 U. S. 145, 150 (2013). The mark-up reflects that low-income individuals are often more expensive to treat than higher income ones, even for the same medical conditions. In compensating for that disparity, the DSH adjustment encourages hospitals to treat low-income patients.

To calculate a hospital's DSH adjustment, HHS adds together two statutorily described fractions, usually called the Medicare fraction and the Medicaid fraction. Those fractions are designed to capture two different low-income populations that a hospital serves. The *Medicare* fraction represents the proportion of a hospital's Medicare patients who have low incomes, as identified by their entitlement to supplementary security income (SSI) benefits. SSI is a "welfare program" providing benefits to "financially needy individuals" who (like Medicare patients generally) are over 65 or disabled. *Bowen* v. *Galbreath*, 485 U. S. 74, 75 (1988); see §§1382(a)(1), 1382c(a)(1). The *Medicaid* fraction represents the proportion of a hospital's patients who are not entitled to Medicare and have low incomes, as identified by their eligibility for Medicaid. The Medicaid program provides health insurance to all low-income individuals, regardless of age or disability. See §1396d(a). So at a high level of generality, the Medicare fraction is a measure of a hospital's senior (or disabled) low-income population, while the Medicaid fraction is a measure of a hospital's non-senior (except for disabled) low-income population.

With that under your belt, you might be ready to absorb the relevant statutory language (but don't bet on it). The Medicare fraction is described as:

> "[a] fraction (expressed as a percentage), the numerator of which is the number of [a] hospital's patient days for [the fiscal year] which were made up of patients who (for such days) were entitled to benefits under part A of [Medicare] and were entitled to [SSI] benefits[], and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under [Medicare] part A." §1395ww(d)(5)(F)(vi)(I).

That is a mouthful (and without the brackets, it's even worse). So again, in general terms: The numerator is the number of patient days attributable to Medicare patients who are poor. The denominator is the number of patient days attributable to all Medicare patients. Divide the former by the latter to get the fraction "expressed as a percentage." *Ibid.*

And similarly for the Medicaid fraction. That fraction is described as:

> "[a] fraction (expressed as a percentage), the numerator of which is the number of [a] hospital's patient days for [the fiscal year] which consist of patients who (for such days) were eligible for medical assistance under [Medicaid], but who were not entitled to benefits under part A of [Medicare], and the denominator of which is the total number of the hospital's patient days for such [fiscal year]." §1395ww(d)(5)(F)(vi)(II).

That too is a lot to digest. So again, in general terms: The numerator is the number of patient days attributable to non-Medicare patients who are poor. The denominator is the total number of patient days. Divide the former by the latter to get the second percentage the DSH calculation requires.[1]

---

[1] You may have noticed that the denominator of the Medicare fraction

Once both percentages have been calculated, they are added together to produce the "disproportionate-patient percentage." That percentage determines whether a hospital will receive a DSH adjustment, and if so, how large it will be. The combined percentage must usually equal or exceed 15% for a hospital to get an adjustment. See §1395ww(d)(5)(F)(v). So, for example, if a hospital's Medicare fraction is 10% and its Medicaid fraction is 5%, then the hospital would qualify for increased rates. The higher the disproportionate-patient percentage goes, the greater the rate mark-up that the hospital will receive. §§1395ww(d)(5)(F)(vii)–(xiv).

This case is about how to count patients who qualify for Medicare Part A—because they are over 65 or disabled—at times when the program is not paying for their hospital treatment. Such non-payment may occur for a number of reasons. For one, Medicare usually pays for only the first 90 days of a hospital stay associated with a single "spell of illness." See §1395d; 42 CFR §409.61(a). If a patient's stay for an illness exceeds that limit, his coverage is "exhausted." §409.61(a). For another, Medicare pays for hospital treatment only once a patient has used up other medical insurance. See §1395y(b)(2)(A). So if a patient has a private insurance plan, or is injured by a tortfeasor with insurance, Medicare will not pay unless and until that other

---

(the number of patient days attributable to Medicare patients) is smaller than the denominator of the Medicaid fraction (the total number of patient days). That means each low-income patient day included in the Medicare fraction will count for more than each low-income patient day included in the Medicaid fraction. So, to use an overly simplified example, a hospital with 100 of the former will get a larger rate adjustment than a hospital with 100 of the latter. Although Congress did not explain that difference, it presumably reflects the Medicare-centric perspective of what is, after all, a Medicare payment scheme. (The Medicaid statute separately requires States to make DSH payments, using a different formula that focuses on a hospital's Medicaid population. See 42 U. S. C. §1396r–4. But that statutory provision is not at issue here.)

policy runs dry. Limits like those prompt the question presented here: Are patients whom Medicare insures but does not pay for on a given day "entitled to [Medicare Part A] benefits," for purposes of computing a hospital's disproportionate-patient percentage? §§1395ww(d)(5)(F)(vi)(I–II).

An HHS regulation, issued in 2004, says those patients remain so entitled. See 69 Fed. Reg. 48916. Under the regulation, whether Medicare is actually paying for a patient's hospital treatment is irrelevant. So, for example, it does not matter that a patient has exhausted his 90 days of coverage for an illness, or that a private insurer is paying for his hospital stay. As long as the patient meets the basic statutory criteria for Medicare (*i.e.*, he is over 65 or disabled), then the patient counts in the denominator and, if he is poor, in the numerator of the Medicare fraction (as "entitled to [Medicare Part A] benefits"). See *id.*, at 49098–49099. And by the same token, he does *not* count in the numerator of the Medicaid fraction (which includes only those "not entitled to [Medicare Part A] benefits"). See *ibid.* As HHS explained in 2004, the effect of the regulation varies depending on the makeup of a hospital's patient population. See *ibid.* But for most hospitals, the regulation has worked to decrease DSH payments, because as beneficiaries are added to the Medicare fraction's denominator (even though poor beneficiaries are also added to its numerator), a hospital's Medicare fraction generally (though not always) goes down. See Letter from E. Prelogar, Solicitor General, to S. Harris, Clerk of Court (Nov. 23, 2021).

Respondent Empire Health Foundation challenged the regulation as inconsistent with the statutory fraction descriptions, and the Court of Appeals for the Ninth Circuit agreed. See *Empire Health Foundation* v. *Azar*, 958 F. 3d 873 (2020). The court focused on the statute's use of two different phrases: "entitled to [Medicare Part A] benefits" and (in the Medicaid fraction alone) "eligible for [Medicaid] assistance." *Id.*, at 885. Relying on Circuit precedent, the

court read the latter, "eligible" phrase to "mean that a patient simply meets the Medicaid statutory criteria"—regardless of whether "Medicaid actually paid" for a given service on a given day. *Ibid.* That approach, of course, is analogous to the one the HHS regulation adopts for Medicare beneficiaries. But the Ninth Circuit reasoned that the statutory language relating to Medicare is different: It asks whether a person is "entitled to" (not "eligible for") benefits. And the word "entitled," the court held (relying on the same precedent), "mean[s] that a patient has an 'absolute right . . . to payment.'" *Ibid.* (ellipsis in original). So even if a patient is over 65, he is not "entitled to [Medicare Part A] benefits" within the meaning of the statute for any hospital stay, or part thereof, Medicare is not paying for.

As the Ninth Circuit recognized, two other Courts of Appeals had deferred to HHS's contrary view of the statute and upheld the regulation. See *Metropolitan Hospital* v. *Department of Health and Human Servs.*, 712 F. 3d 248 (CA6 2013); *Catholic Health Initiatives Iowa Corp.* v. *Sebelius*, 718 F. 3d 914 (CADC 2013). We granted certiorari to resolve the conflict. See 594 U. S. ___ (2021).[2]

II

HHS's regulation correctly construes the statutory language at issue. The ordinary meaning of the fraction descriptions, as is obvious to any ordinary reader, does not exactly leap off the page. See *Catholic Health Initiatives*, 718 F. 3d, at 916 (The "language is downright byzantine"). The provisions are technical: They call to mind Justice Frankfurter's injunction that when a statute is "addressed to specialists, [it] must be read by judges with the minds of the specialists." Some Reflections on the Reading of Statutes, 47 Colum. L. Rev. 527, 536 (1947). But when read in that

[2] This case does not raise the question whether HHS has properly interpreted the phrase "entitled to [SSI] benefits" in the Medicare fraction. Accordingly, we express no view on that issue.

suitable way, the fraction descriptions disclose a surprisingly clear meaning—the one chosen by HHS. The text and context support the agency's reading: HHS has interpreted the words in those provisions to mean just what they mean throughout the Medicare statute. And so too the structure of the DSH provisions supports HHS: Counting everyone who qualifies for Medicare benefits in the Medicare fraction—and no one who qualifies for those benefits in the Medicaid fraction—accords with the statute's attempt to capture, through two separate measurements, two different segments of a hospital's low-income patient population.

A

Speaking of twos, Empire's textual argument also has a bifurcated structure—but neither part can produce its desired result. Empire primarily contends, echoing the Ninth Circuit, that "different words [mean] different things" when used in a single statute—and so "entitled" means something different from "eligible." Brief for Respondent 22. To be "eligible" for a benefit, Empire says, is to be "qualified" to seek it; to be "entitled" to a benefit means instead to have an "absolute right" to its payment. *Id.*, at 4, 30. But that reading, even if plausible in the abstract, does not work in the Medicare statute. There, "entitled to benefits" is essentially a term of art, used over and over to mean qualifying (or, yes, being eligible) for benefits—*i.e.*, being over 65 or disabled. And in the end, Empire basically concedes that point. It must devise a way to give "entitled to benefits" a different meaning in the fraction descriptions than the phrase has everywhere else in the Medicare law. See Tr. of Oral Arg. 37–41. So Empire shifts gears, relying now on the parenthetical phrase "(for such days)" to do its work—to transform the usual statutory meaning of "entitled to benefits" to something different and novel. See *ibid.*; §1395ww(d)(5)(F)(vi)(I) ("patients who (for such days) were entitled to [Medicare Part A] benefits"). (The dissent, for

its part, focuses most of its energies on this latter stage of Empire's argument.) But those three little words do not accomplish what Empire would like, having the much less radical function of excluding days of a patient's hospital stay before he qualifies for Medicare (*e.g.*, turns 65). So contrary to Empire's claim, being "entitled" to Medicare benefits still means—in the fraction descriptions, as throughout the statute—meeting the basic statutory criteria, not actually receiving payment for a given day's treatment.

1

First and foremost, the Medicare statute explicitly identifies which individuals are "entitled to hospital insurance benefits under part A"—all people who meet the basic statutory criteria. §§426(a)–(b). "Every individual," the law states, who "has attained age 65" and is entitled to ordinary social security payments "shall be entitled to" Medicare Part A benefits. §426(a). So too, "every individual" under age 65 who has been entitled to federal disability benefits for at least 24 months "shall be entitled" to Medicare Part A benefits. §426(b). The "[e]ntitlement to hospital insurance benefits" (as the section caption reads) is "automatic": Age or disability makes a person "entitled" to Part A benefits without an application or anything more. §426; *Hall* v. *Sebelius*, 667 F. 3d 1293, 1294–1296 (CADC 2012). Turn 65 or receive disability benefits for 24 months, and you have an entitlement to Part A benefits—because the latter is, according to the statute, simply a legal status arising from the former.[3]

---

[3] Another way of putting the point is to say that the Medicare statute uses the term "entitled" to benefits in the same way as the Medicaid statute uses the term "eligible" for benefits. Compare 42 U. S. C. §426 ("entitled" in Medicare context) with, *e.g.*, §§1396, 1396d ("eligible" in Medicaid context). That difference in overall statutory terminology is mirrored in the fraction provisions—"entitled to [Medicare Part A] benefits" and "eligible for [Medicaid] assistance." §§1395ww(d)(5)(F)(vi)(I–II). As the D. C. Circuit put the point: "Congress has, throughout the various

That broad meaning of "entitlement" coexists with limitations on payment, as several statutory provisions show. The entitlement to *benefits*, the statute repeatedly says, is an entitlement to *payment under specified conditions*. To quote one provision: "entitlement of an individual" to Medicare Part A benefits "consist[s] of entitlement to have payment made under, and subject to the limitations in, part A." §426(c)(1); see §1395d(a) (similarly stating that the entitlement to benefits entails the receipt of "payment[s] . . . subject to the provisions of this part"). Those limits on payment include, as described earlier, the 90-day hospital-stay cap. See *supra*, at 5–6. And indeed the statute twice refers to patients who are "entitled to benefits under part A but ha[ve] exhausted benefits for inpatient hospital services." §§1395*l*(a)(8)(B)(i), 1395*l*(t)(1)(B)(ii). Under Empire's reading, that statement makes no sense: A patient is not, Empire argues, "entitled to benefits" when the statute precludes payment. See *supra*, at 8. But the statute says otherwise. It considers those who have exhausted their coverage (and so cannot receive further payments for a hospital stay) still "entitled to [Part A] benefits."

In thus describing the Part A entitlement, the Medicare statute reflects the complexity of health insurance. Consider your own health plan (maybe it *is* Medicare). You might have hit some limit on coverage as to one medical service—let's say, eye care. But you're still insured: Your policy will pay for more eye care in the next coverage period and meanwhile will pay for your knee replacement. So it is with Medicare Part A. As the 2004 regulation explains, patients "who have exhausted their Medicare Part A inpatient coverage may still be entitled to other Part A benefits." 69

Medicare and Medicaid statutory provisions, consistently used the words 'eligible' to refer to potential Medicaid beneficiaries and 'entitled' to refer to potential Medicare beneficiaries." *Northeast Hospital Corp.* v. *Sebelius*, 657 F. 3d 1, 12 (2011). Congress simply followed suit when referring to the two programs in the fraction provisions.

Fed. Reg. 49098. Medicare Part A also covers, "for example, certain physician services and skilled nursing services" outside the hospital setting. See CMS–1498–R, at 10. And even as to hospital care, another 90 days of coverage will be available for another illness. See *supra*, at 5. For that reason among others, HHS has noted, the stoppage of payment for any given service cannot be thought to affect the broader statutory entitlement to Part A benefits. See 69 Fed. Reg. 49098. That entitlement arises when a person meets the basic statutory qualifications and (unless a disability diminishes) never goes away.

If "entitled to [Part A] benefits" instead bore Empire's meaning, Medicare beneficiaries would lose important rights and protections. Perhaps most significantly, a patient could lose his ability to enroll in other Medicare programs whenever he lacked a right to Part A payments for hospital care. As noted earlier, a person's entitlement to Part A benefits is usually the predicate for his enrollment in Part B (covering outpatient care), Part C (providing coverage through privately managed plans), or Part D (offering prescription-drug benefits). See §§1395*o*(a), 1395w–21(a)(3), 1395w–101(a)(3)(A); *supra*, at 2. So if (as Empire urges) a hospitalized patient is not "entitled to [Part A] benefits" on any day he cannot get Part A payments, then he could be locked out of the benefits of Parts B through D at that time. Consider what that might mean in the real world: A Medicare patient in the hospital for longer than 90 days—by definition, a very ill person—could not enroll in Part D's prescription-drug coverage. Congress could not have wanted—and in fact did not provide for—that result.

Empire's interpretation would also make a hash of provisions designed to inform Medicare beneficiaries of their benefits. The statute requires annual notice to individuals "entitled to benefits under part A" concerning all available program benefits, including any "limitations on payment."

§1395b–2(a). Under Empire's reading, that notice requirement would phase in and out depending on whether Medicare Part A was currently paying for the individual's hospital treatment. HHS, for example, would have no obligation to inform a patient of benefits when a private insurer was paying for his hospital care, even if that policy would soon run out and Medicare would assume the coverage. Once again, Congress would not have drafted such an on-again, off-again notice requirement.

So too, Empire's reading of "entitled to [Part A] benefits" would subvert a provision to protect beneficiaries from misleading marketing materials. Under the statute, an insurer offering a Part C (privately managed Medicare) plan may not distribute advertising materials to eligible beneficiaries unless the materials are first cleared by HHS. See §1395w–21(h)(1). Eligible beneficiaries are individuals "entitled to benefits under Part A" and enrolled in Part B. §1395w–21(a)(3). If Empire is right about what the "entitled to" phrase means, an insurer could send whatever it wanted to a patient who at that time lacked a right to Part A payments. But such a person might well be interested in eventually enrolling in a Part C plan—and he is no less vulnerable to deceptive marketing than anyone else.

And the problems with Empire's interpretation do not stop there. The Sixth and D. C. Circuits have cataloged several other statutory provisions that Empire's reading would render unworkable or unthinkable or both. See *Metropolitan Hospital*, 712 F. 3d, at 260; *Northeast Hospital Corp.* v. *Sebelius*, 657 F. 3d 1, 6–11 (CADC 2011). We could spell out each one in painful detail, but we think the above should suffice. Applying Empire's reading of "entitled to [Part A] benefits" across the Medicare statute would diminish the beneficiary protections Congress wrote into law. Those safeguards would apply or not apply, or fluctuate constantly between the two, based on the happenstance of whether Medicare paid for hospital care on a given day.

Once again, that is not the statute Congress wrote.

2

Faced with these many provisions, Empire swerves. Empire effectively (if reluctantly) concedes that its reading of "entitled to [Part A] benefits"—again, to have an "absolute right" to Part A payments—cannot be applied throughout the Medicare statute. Brief for Respondent 30; see *id.*, at 41–42; Tr. of Oral Arg. 37–39. There, over and over—and contra the main thrust of Empire's arguments—the concepts of entitlement and eligibility are the same. So Empire must come up with a way of converting the ordinary meaning of "entitled" in the Medicare law to something different in its fraction provisions. The lever Empire proposes to use for that purpose is the parenthetical phrase "(for such days)." See Tr. of Oral Arg. 38–39 ("[T]he key distinction" is "for such days," which is "language that's not found anywhere else"). Empire argues that when "entitled" is married to "(for such days)"—recall the whole phrase, "patients who (for such days) were entitled to [Part A] benefits"—the idea of entitlement morphs. §1395ww(d)(5)(F)(vi)(I). Now it does not mean meeting Medicare's statutory (age or disability) criteria on the days in question, but instead means actually receiving Medicare payments. (The dissent makes much the same argument.)

But we cannot understand Congress to have changed the statute's consistent meaning of "entitled to benefits" simply by adding "(for such days)." That slight phrase is incapable of bearing so much interpretive weight. If Congress "does not alter the fundamental[s]" of a statutory scheme "in vague terms or ancillary provisions," then it ordinarily does not do so in parentheticals either. *Whitman* v. *American Trucking Assns., Inc.*, 531 U. S. 457, 468 (2001). To the contrary, a parenthetical is "typically used to convey an aside or afterthought." *Boechler* v. *Commissioner*, 596 U. S. ___,

___ (2022) (slip op., at 5) (internal quotation marks omitted). And nothing about the "(for such days)" parenthetical signals anything different. Empire asks us to read it as transforming the uniform statutory meaning of "entitled to benefits" for the fraction provisions alone. But if Congress had wanted to accomplish that unexpected object, it would simply have said so. Or else, to make only paid-for days count, it would have dropped the language of entitlement altogether. What it would not have done is upend the settled meaning of that language, in this one place, through so subtle, indirect, and opaque a mechanism.

The "(for such days)" phrase instead works as HHS says: hand in hand with the ordinary statutory meaning of "entitled to [Part A] benefits." The parenthetical no doubt tells HHS to ask about a patient on a given day. But the query the agency must make is not whether that patient on that day has received Part A payments; the query is, consistent with what "entitled" means all over the statute, whether that patient on that day is qualified to do so. Suppose, for example, that a patient turns 65 halfway through a 30-day hospital stay. HHS will then count only 15 days of his stay when computing the Medicare fraction. Or suppose, similarly, that midway through his stay, a patient begins to qualify as disabled—because, under the statutory definition, he has reached his 25th month of federal disability benefits. Then, too, only the second half of the patient's stay would go into the fraction—because only then has he met the criteria for benefits.

Empire complains that the phrase "(for such days)," viewed in that way, does too "little work." Brief for Respondent 38; Tr. of Oral Arg. 40–41. But it does more than enough. Some 10,000 people turn 65 in this country every day, thus qualifying for Medicare coverage. See American Assn. of Retired Persons, The Aging Readiness & Competitiveness Report: United States 2, https://arc.aarpinternational.org/File%20Library/Full%20Reports/ARC-Report---

United-States.pdf. Many other individuals daily attain their 25th month on federal disability benefits. It is natural for Congress to have thought of those facts when devising the fractions. By the way, said Congress (in what truly is an "aside or afterthought"): If someone turns 65 during the year the fraction covers, make sure to exclude his pre-birthday hospital days. *Boechler*, 596 U. S., at ___ (slip op., at 5) (internal quotation marks omitted). Only count the days after he qualifies for Medicare Part A—when, under the statute's constant meaning, he is "entitled to [Part A] benefits."[4]

B

The structure of the relevant statutory provisions reinforces our conclusion that "entitled to [Part A] benefits" means qualifying for those benefits, and nothing more. As earlier explained, the statute is designed to recompense hospitals for serving low-income patients, who are comparatively more expensive to treat. See *supra*, at 3. The statute determines the appropriate payment (if any) by measuring, through two separate fractions, two separate

[4]The dissent has another complaint: that from 1986 until 2003 HHS read the "for such days" phrase in the Medicare fraction just as Empire does, and that the Department changed its view merely to reduce payments to hospitals. See *post*, at 1–2 (opinion of KAVANAUGH, J.). But that is an incomplete—leading to an inaccurate—picture. From 1986 to 1997, HHS read *both* the Medicare *and* the Medicaid fractions as counting only days actually paid for. The effect on the Medicaid side was to substantially depress payments to hospitals (because many low-income patients were excluded from the numerator, while the denominator remained the same, see *supra*, at 4, and n. 1). Hospitals sued, and four Circuit Courts found that HHS's understanding of the "for such days" language in the Medicaid fraction was wrong. See Brief for United States 12–13 (collecting citations). In response, HHS immediately corrected its approach to the Medicaid fraction—which significantly raised payments to hospitals. Some five years later, HHS issued a rule to bring its reading of the same language in the Medicare fraction into line. The history shows, then, that HHS "changed course" not "to save money" but to comply with the law. *Post*, at 2.

populations: the low-income Medicare population and the low-income non-Medicare population. See *supra*, at 3.[5] (Because the vast majority of Medicare patients are over 65, that roughly translates into the low-income senior population and the low-income non-senior population.) Those populations, taken together, account for all the low-income patients a hospital treats.

HHS's reading of "entitled" comports with the statute's two-population structure. A low-income Medicare patient always counts in the Medicare fraction. That is so regardless of whether the Medicare program is actually paying for a day of his care—because that fact has no relationship to his financial status. The Medicare fraction, as calculated by HHS, thus captures the entire low-income Medicare (*i.e.*, senior) population. And correlatively, the Medicaid fraction captures the entire low-income non-Medicare (*i.e.*, non-senior) population. The binary dividing line HHS uses—do you qualify for Medicare?—mirrors the statute's binary, population-focused framework. All low-income people fit naturally into one or the other box, with the sum of the two leaving no one out.

By contrast, Empire's view fits poorly with the bifurcated, population-based statutory structure. Again, its who-paid-for-a-day-of-care test has no relationship to a patient's financial status. So on Empire's view, a patient could phase in and out of the Medicare fraction even though his income remains the same. Empire responds by asserting that any low-income person excluded from the Medicare fraction (say, because of exhaustion of benefits) would get counted instead in the Medicaid fraction. See Brief for Respondent 15–16, 50–51. But even if that is true—we express our

---

[5] As noted earlier, see *supra*, at 4, n. 1, the two populations (because of their fractions' different denominators) are differently weighted in calculating DSH payments. All else equal, a hospital receives greater compensation for low-income individuals in the Medicare population than for low-income individuals in the non-Medicare population.

doubts below—Empire's scheme would result in patients ping-ponging back and forth between the two fractions based on the happenstance of actual Medicare payments, sometimes during a single hospital stay. That scheme is of course harder to administer than HHS's. And still more, it does not reflect the statute's dichotomy between two discrete low-income populations, each of which counts (but counts differently) toward setting a hospital's DSH rate. See *supra*, at 4, n. 1, 16, n. 5.

In any event, Empire is too quick to claim that those who (on its view) are tossed from the Medicare fraction for non-income-based reasons would still wind up in the Medicaid fraction. Recall here the role Empire says the phrase "(for such days)" plays. See *supra*, at 13–15. According to Empire's ultimate argument, that phrase is what converts the ordinary statutory meaning of "entitled to benefits" (*i.e.*, qualifying for Medicare) to a special meaning (*i.e.*, actually receiving payments). So where the phrase "(for such days)" does not appear, the usual meaning of "entitled" should govern. Now look again at the description of the Medicaid fraction. It counts "patients [i] who (for such days) were eligible for [Medicaid], but [ii] who were not entitled to benefits under part A [of Medicare]." §1395ww(d)(5)(F)(vi)(II). In that description, "for such days" does *not* modify clause [ii]. So the "not entitled" phrase in that clause should mean (consistent with the rest of the statute) not qualifying for Medicare. But those whom Empire's view would oust from the Medicare fraction—say, because of exhaustion—*do* qualify for Medicare. They thus fall outside clause [ii]—and outside the Medicaid fraction. The upshot is that, under Empire's reading, a low-income patient who, say, has exhausted his coverage will not get counted at all. But that person remains just as low income as he ever was, imposing just as high costs on the hospital treating him. His exclusion demonstrates, if anything more needs to, the error of Empire's reading.

Empire's only response is to insist that its interpretation has to be right because it usually (though not always) leads to higher DSH payments for hospitals. See Brief for Respondent 33–35; *supra*, at 6. But the point of the DSH provisions is not to pay hospitals the most money possible; it is instead to compensate hospitals for serving a disproportionate share of low-income patients. And Empire's reading excels only by the former measure, not by the latter one. As just shown, Empire's actual-payment test counts fewer, not more, of the low-income patients the DSH provisions care about. The reason that approach still benefits many hospitals is that it deflates the denominator of the Medicare fraction. Consider a wealthy 70-year-old patient who has exhausted Medicare benefits—or, as is often true, has a private insurance policy. HHS's view would exclude him from the Medicare fraction's numerator (because he is wealthy) but keep him in the denominator (because he is over 65). By contrast, Empire's view would exclude him from both the numerator and the denominator—the latter because he is not actually receiving Medicare payments. That move increases payments to hospitals—but only because it fails to capture high-income Medicare patients, not because it better captures low-income ones. Or said otherwise, it increases payments because it distorts what the Medicare fraction is designed to measure—the share of low-income Medicare patients relative to the total.

III

Text, context, and structure all support calculating the Medicare fraction HHS's way. In that fraction, individuals "entitled to [Medicare Part A] benefits" are all those qualifying for the program, regardless of whether they are receiving Medicare payments for part or all of a hospital stay. That reading gives the "entitled" phrase the same meaning it has throughout the Medicare statute. And it best implements the statute's bifurcated framework by capturing low-

income individuals in each of two distinct populations a hospital serves.

For those reasons, we reverse the judgment of the Court of Appeals and remand the case for further proceedings consistent with this opinion.

It is so ordered.

SUPREME COURT OF THE UNITED STATES

No. 20–1312

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER *v.* EMPIRE HEALTH FOUNDATION, FOR VALLEY HOSPITAL MEDICAL CENTER

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

[June 24, 2022]

JUSTICE KAVANAUGH, with whom THE CHIEF JUSTICE, JUSTICE ALITO, and JUSTICE GORSUCH join, dissenting.

Under the Medicare statute, HHS pays higher reimbursements to hospitals that serve a significant number of low-income patients. The statutory formula for determining exactly how much HHS will pay to those hospitals is mind-numbingly complex. But embedded within the complicated overall formula are various subsidiary calculations, some of which are relatively straightforward.

This case concerns one of those straightforward subsidiary calculations. Consistent with traditional insurance and coordination-of-benefits principles, Medicare by statute cannot pay for a patient's hospital care if, for example, the patient is covered by private insurance, the patient has exhausted her Medicare benefits, or a third-party tortfeasor is liable for the patient's care. The retrospective reimbursement question raised by the statutory provision in this case is this: Was a patient "entitled to" have payment made by Medicare for a particular day in the hospital if the patient by statute could not (and did not) have payment made by Medicare for that day? In my view, the answer to that narrow question is straightforward and commonsensical: No.

Importantly, from the time the statute was enacted in

1986 until 2003, HHS interpreted this statutory provision in the exact same way that I do. See 51 Fed. Reg. 31460–31461 (1986); Brief for Petitioner 32–33. Then in 2004, HHS abruptly changed course. Why? Presumably to save money. HHS was trying hard to find ways to contain Medicare costs in light of increasing Medicare expenditures and the country's fiscal situation. To that end, HHS's new 2004 interpretation of this statutory provision had the downstream effect of significantly reducing HHS's reimbursements to hospitals that serve low-income patients.

Whatever HHS's precise motivations for the 2004 change, we now must focus on the statutory text and HHS's current interpretation of it. To begin, both parties offer a dog's breakfast of arguments about broad statutory purposes, real-world effects, surplusage, structure, consistent usage, inconsistent usage, agency deference, and the like. But this case is resolved by the most fundamental principle of statutory interpretation: Read the statute.

The relevant text of this reimbursement provision refers to "the number of . . . patient days . . . which were made up of patients who (for such days) were entitled to benefits under part A." 42 U. S. C. §1395ww(d)(5)(F)(vi)(I). Importantly, the statute elsewhere says that "[t]he benefits provided" under Medicare Part A consist of a patient's "entitlement to *have payment made* on his behalf . . . (subject to the provisions of this part)." §1395d(a) (emphasis added); see also §426(c) ("entitlement" means "entitlement to *have payment made* under, and subject to the limitations in, part A" (emphasis added)).

Zero in on the phrases "entitlement to have payment made" and "for such days." In my view (and in HHS's view from 1986 to 2003), a patient was entitled to have payment made by Medicare for particular days in the hospital if Medicare was obligated to pay for the patient's care for those days. Stated the other way, a patient was *not* entitled to have payment made by Medicare for particular days in the

hospital if the patient by statute could not (and did not) have payment made by Medicare for those days—for example, because the patient had other insurance, the patient had exhausted his Medicare benefits, or a third-party tortfeasor was paying. Simple enough.

To be sure, patients who satisfy certain criteria (for example, those who are age 65 or older) are generally "entitled" to Medicare hospitalization benefits. No one disputes that point. But this reimbursement provision looks to whether the patient was entitled to *have payment made* by Medicare *for a particular day* in the hospital. And the answer to that question is no if Medicare by statute could not (and did not) pay for that day in the hospital.

Suppose that a college says that your academic record entitles you to a scholarship for next year if your family's income is under $60,000, unless you have received another scholarship. And suppose that your family's income is under $60,000, but you have received another scholarship. Are you still entitled to the first scholarship? Of course not. So too here.

The Court concludes otherwise, mainly by (i) saying that "entitled to benefits" is a term of art in the Medicare statute, (ii) diminishing the value of the statutory phrase "(for such days)," in part because the phrase appears in a parenthetical, and (iii) invoking a parade of horribles about what could happen to other provisions of the Medicare statute if the Court were to read this provision as I would.

With respect, none of that adds up. *First*, although the Medicare statute generally uses "entitled" to refer to those who meet the basic statutory criteria for Medicare benefits, the retrospective reimbursement provision at issue here focuses laser-like on whether the patient was actually entitled to have payment made by Medicare for particular days in the hospital. A patient cannot be simultaneously entitled and disentitled to have payment made by Medicare for a particular day in the hospital.

Second, contrary to the Court's suggestion, we cannot brush aside the statutory phrase "(for such days)" simply because that phrase appears in a parenthetical. See *Duncan* v. *Walker*, 533 U. S. 167, 174 (2001). Parentheticals can be important, as the Constitution itself makes clear. See, *e.g.*, Art. I, §7 (counting days for bill to become law with "(Sundays excepted)"); Art. IV, §4 (affording federal protection to States on application by the Executive but only "(when the Legislature cannot be convened)").

Third, properly interpreting this specific reimbursement provision will not "make a hash" of other provisions or render the Medicare statute "unworkable." *Ante*, at 11–12. We need not speculate about that point: For nearly two decades from the time that the statute was enacted in 1986 through 2003, HHS interpreted this reimbursement provision in the same way that I do. And HHS did so without any noted problems for other provisions in the Medicare statute.

To sum up: A patient was not entitled to have payment made by Medicare "for such days" in the hospital if the patient by statute could not (and thus did not) have payment made by Medicare for those days—for example, because private insurance was already covering the patient's care, or the patient had exhausted his Medicare benefits. Both statutory text and common sense point to that conclusion. HHS's contrary interpretation boils down to the proposition that a patient can be simultaneously entitled and disentitled to have payment made by Medicare for a particular day in the hospital. That interpretation does not work. And HHS's misreading of the statute has significant real-world effects: It financially harms hospitals that serve low-income patients, thereby hamstringing those hospitals' ability to provide needed care to low-income communities.

In my view, HHS's 2004 interpretation is not the best reading of this statutory reimbursement provision. I respectfully dissent.

FY 2023 IPPS Final Rule

September 2022

- *Market Basket Update*: The FY 2023 IPPS final rule included a much improved, but still below inflation, update of 4.3 percent compared to 3.2 percent in the proposed rule. CMS declined to exercise its special exceptions authority either to provide a one-time update to the FY 2023 base rate to account for current underpayment in FY 2022, or to waive the application of a productivity adjustment in FY 2023.

- *Wage Index*: Consistent with the policy first finalized in FY 2020, CMS will again increase the wage index for hospitals with a wage index value below the 25th percentile. In addition, CMS finalized its proposed policy to establish a five percent wage index stop-loss policy, which FAH had urged in its comments. No hospital would receive a wage index less than 95 percent of its wage index value in FY 2022.

- *Outlier Fixed-Loss Threshold:* Based in part on FAH comments, CMS further modified its methodology to determine the FY 2023 threshold. This resulted in a final threshold of $38,859 compared to the proposed $43,214, which itself was lower than the $58,798 threshold that would have applied absent any formula changes.

- *UC-DSH Pool Distribution:* Updated projections from the CMS Office of the Actuary yielded an increase of approximately $330 million in the pool (nearly $6.9 billion) compared to the proposed rule.

- *Data to Set Rates and Weights*: Recognizing that FY 2021 data is still impacted by the COVID-19 Public Health Emergency (PHE), CMS finalized its policy to set weights by averaging two sets of weights using FY 2021 MedPAR claims and FY 2020 cost reports – one with COVID claims and one without COVID claims. CMS also finalized its proposal to apply a stop-loss cap on the reduction of the DRG relative weights at a 10% reduction.

- *Hospital Quality Payment Programs*: As FAH had urged, CMS is finalizing its proposed policies to suppress several measures in the Hospital VBP and HAC Reduction Programs. CMS is implementing a special scoring methodology for FY 2023 that results in each hospital receiving a value-based incentive payment amount that matches their 2 percent reduction to the base operating DRG payment amount. In addition, hospitals participating in the HAC Reduction Program will not be given a measure score, a Total HAC score, nor will hospitals receive a payment penalty.

- *LTCH Payment Update:* CMS expects overall LTCH payments to increase by approximately $71 million (up from $25 million in the proposed rule due to a higher market basket update), and 2.3 percent for cases paid under the standard LTCH payment rate.

Post-Acute Care

September 2022

Inpatient Rehabilitation Facilities (IRFs)

FY 2023 IRF PPS Final Rule

- CMS finalized a net rate update of 3.9 percent based on an IRF market basket increase of 4.2 percent reduced by a 0.3 percent productivity offset. Overall payments are estimated to increase by 3.7 percent, or $275 million, in FY 2023; however, the overall payment increase includes a 0.6 percent decrease in outlier payments in order to retain a 3.0 percent outlier pool.
- CMS did not move forward with any changes to the IRF transfer policy for home health discharges, but a proposal on that issue is likely in next year's proposed rule.
- CMS finalized a new wage index policy that would create a permanent 5 percent cap on annual reductions to a facility's area wage index.

IRF Review Choice Demonstration

- CMS continues to work on development of a new demonstration that would require either 100 percent pre-claim review or 100 percent post-payment review for all IRF patients in Alabama, Pennsylvania, California, and Texas and ultimately for all IRFs with Medicare Administrative Contractor (MAC) regions covering those 4 states. The IRF Review Choice Demonstrations (RCD) proposal has changed little over the past year and the FAH is urging CMS to withdraw and/or modify the proposal that would be overly burdensome and unfair to IRFs and patients or to modify it significantly.
- FAH staff, along with other IRF stakeholders has engaged with CMS, meeting with both political leadership and staff leading the RCD effort. While we have had positive discussions, adoption of a more feasible approach is still uncertain. The program is not likely to begin before 2023. In a recent call with CMS, staff indicated that the program is unlikely to begin before the COVID-19 public health emergency (PHE) expires (January 15), and CMS expects to provide a 90-day advance notice.
- FAH staff also have been engaged with the OIG and other IRF stakeholders in a discussion on medical necessity review and an effort to come to a "meeting of the minds" on key areas of difference on how cases should be assessed for appropriateness. Along those lines the OIG recently announced a nationwide IRF audit aimed in part to "determine whether there are areas where CMS can clarify IRF claims payment criteria. We expect more activity on this to begin in earnest in early Fall 2022.

Long-Term Acute Care Hospitals (LTCH): FY 2023 LTCH PPS Final Rule

- CMS finalized a net rate update of 2.8 percent (LTCH market basket of 4.1 percent reduced by a productivity adjustment of 0.3 percent) and after significant adjustments for

outliers, CMS expects overall LTCH payments to increase by approximately $75 million.

Inpatient Psychiatric Facilities (IPFs): FY 2023 IPF PPS Final Rule

- IPF payments are estimated to increase 2.5 percent or $90 million based on a net rate increase of 3.8 percent from FY 2022 to FY 2023 – based on a 4.1 percent IPF market basket reduced by a 0.3 percent productivity offset – and a decrease of 1.2 percent in outlier payments to retain a 2.0 percent outlier pool.
- CMS also finalized the new wage index policy that would create a permanent 5 percent cap on annual reductions to a facility's area wage index, similar to IRFs.

Unified Post-Acute Care Prospective Payment System (PAC PPS)

- In July, CMS released the long-awaited report to Congress on unified payment for Medicare post-acute care (PAC). Required by the Improving Post-Acute Care Transformation (IMPACT) Act of 2014, the report offers a framework for developing a unified payment approach for Medicare PAC services provided to beneficiaries by skilled nursing facilities (SNFs), IRFs, LTCHs, and home health agencies (HHAs).
- CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) contracted with Research Triangle Institute (RTI) to provide analysis for the report and to convene an external technical expert panel. The report framework applies a uniform approach to case-mix adjustment across Medicare beneficiaries receiving PAC services for different types of PAC providers while accounting for factors independent of patient need that are important drivers of cost across PAC providers.
- Importantly, the report does not include legislative recommendations, and the report states that additional analyses would need to be done prior to testing or universal implementation of a unified PAC payment system.
- FAH has raised significant concerns about the study, including concerns related to COVID-19 disruption to care and significant payment system changes in the HHA and SNF PPS systems. The report acknowledges these data challenges and recommends further research in these and other areas.
- FAH strongly supports legislation introduced and originally cosponsored by Representatives Terri Sewell (D-Al) and Vern Buchanan (R-Fl), respectively, H.R. 2455, *The Resetting the IMPACT Act (TRIA) of 2021*, which would reset and recalibrate the *IMPACT Act* timeline by ensuring that data that predated the COVID-19 PHE as well as reforms to the PAC payment systems would not be used to build the unified PAC PPS prototype.

March 11, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1774-PN; Medicare Program: Announcement of Request for an Exception to the Prohibition on Expansion of Facility Capacity under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition; Notice with request for comment, Federal Register (Vol. 87, No. 27), February 9, 2022

Dear Administrator Brooks-LaSure:

The American Hospital Association (AHA) represents 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and 43,000 health care leaders who belong to our professional membership groups. The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. Together, our members provide patients and communities with access to high-quality, affordable care across settings in both urban and rural areas. They include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services, including in communities that would be impacted by the expansion application of Doctors Hospital at Renaissance (DHR). The AHA and FAH appreciate the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on the above Notice with Request for Comment (Notice) published in the Federal Register (87 Fed. Reg. 7471) on February 9, 2022.

The AHA and FAH urge CMS to deny DHR's request for an exception to the prohibition on expansion of the facility capacity of a physician-owned hospital. CMS is not obligated by statute or regulation to grant an expansion request to any facility that satisfies the "high Medicaid facility" exception criteria, and CMS should deny DHR's request because the

requested expansion is inconsistent with Congress's intent, does not serve a valid public policy purpose, and would set a bad precedent.

Further, the current exception request clearly illustrates how the "high Medicaid facility" exception, as amended in the 2021 hospital outpatient prospective payment system (OPPS) final rule published on December 2, 2020, opens the door for requests that may technically meet, but clearly violate the spirit of the general statutory ban on physician-owned hospitals. ***Accordingly, we also urge CMS to reverse the 2020 amendments to the "high Medicaid facility" exception.***

1. CMS Has Discretion to Deny the Requested Expansion

In Section 1877(i)(3) of the Social Security Act, Congress conferred the Secretary with the *discretion to consider* certain physician-owned hospital requests for facility expansion, despite the statutory prohibition on physician-owned hospitals expanding beyond their licensed capacity as of March 23, 2010. Both the statute and the regulations state that a hospital that meets the criteria for a "high Medicaid facility" may "*apply for*" or "*request*" an exception to the expansion limits.[1] Nowhere does the statute or the regulations state that a facility that meets the "high Medicaid facility" criteria is *entitled* to an exception to the prohibition on facility expansion or that CMS is *obligated* to grant any particular exception. Rather, the statutory and regulatory default is that a physician-owned hospital that expands after March 23, 2010, is no longer entitled to an exception to the prohibition on physician self-referrals and cannot submit Medicare or Medicaid claims for designated health services where a physician owner or investor referred the beneficiary for the services. The only circumstance in which an expansion is permitted is where the Secretary exercises his discretion and grants an expansion exception request to a qualifying facility.

Although the Secretary is required to deny a request that does not comply with the statutory and regulatory requirements, the Secretary may also deny a request based on additional, case-specific considerations, including those raised by commenters. This discretion to consider additional information beyond the three high Medicaid facility criteria is apparent from the community input requirements that are a part of the exception request process. The statute requires that the exception request process include an opportunity for community members "to provide input with respect to" the request.[2] Likewise, under 42 C.F.R. § 411.632(c)(5), community members "may provide input with respect to the hospital's request" for a high Medicaid facility expansion through "written comments."[3] Neither the statute nor the regulation limits public comment to data or information concerning the high Medicaid facility criteria. In fact, when adopting this regulation, the Secretary acknowledged his discretion to consider the full range of potential community input, stating that he was "not restricting the type of community input that may be submitted."[4] This opportunity for community input on all aspects

[1] Social Security Act § 1877(i)(3)(A)(i); 42 C.F.R. § 411.362(c)(1).
[2] Social Security Act § 1877(i)(3)(A)(ii).
[3] This regulation implements the statutory requirement that the Secretary provide community members with an opportunity to provide input with respect to an expansion exception request. Social Security Act § 1877(i)(3)(A)(ii).
[4] 76 Fed. Reg. 74122, 74523 (Nov. 30, 2011).

of the request suggests that the Secretary is not limited to considering the three high Medicaid facility criteria when considering whether he should exercise his discretion to grant or deny an exception request. ***Indeed, the AHA and FAH believe that DHR's request to expand into a wholly new and distant community should be properly denied for the reasons explained further below.***

Moreover, the purpose of the high Medicaid facility exception – preserving the Secretary's discretion to promote access to care for Medicaid recipients by permitting certain expansion exception requests – reinforces our contention that Congress purposefully omitted automatic entitlement for any hospital that meets the criteria for "high Medicaid facility" status. As explained further below, the general acute care hospitals in Cameron County, Texas are adequately providing for the needs of Medicaid beneficiaries in the County; the creation of a distant second campus of DHR in Cameron County is not warranted by beneficiary needs and clearly violates the spirit and intent of the statutory prohibition on physician-owned hospitals under the Stark law.

2. The Request to Expand to a New Community Should Be Denied Based on Community Need and Beneficiary Interests

In its application, DHR is seeking to serve an entirely different community than it does in its main facility. It would accomplish this by building a new inpatient facility approximately 55 miles away from its main hospital campus in a different county. Previously, this extraordinary request for a distant, off-campus provider-owned hospital expansion would have been denied under 42 C.F.R. § 411.362(c)(6)(ii), which prior to 2021 limited expansion requests for high Medicaid facilities to expansions on the hospital's main campus. Although a high Medicaid facility may submit an expansion exception request for an off-campus location under the amended regulation, DHR's request should be denied in light of public policy concerns, community needs, and beneficiary interests.

CMS Should Closely Scrutinize Public Policy Considerations When Evaluating an Off-Campus Expansion Request for a Physician-Owned Hospital. First, DHR's expansion request is troubling considering the extraordinary distance between DHR's proposed Brownsville campus and its main hospital campus in Edinburg. The new facility would not be a typical provider-based location that operates off the main hospital campus but still serves the same or a closely related, nearby community; instead, it would be among the most extreme of off-campus facilities, serving a distinct community over 50 miles away in another county. The AHA and FAH continue to believe that the recent amendments to the high Medicaid facility expansion request requirements are inappropriate for the reasons set forth in their respective letters opposing the 2020 amendments to 42 C.F.R. § 411.362 (*see* AHA Ltr., pp. 35 – 37 (Oct. 5, 2020), attached hereto as Appendix A; FAH Ltr., pp. 23 – 29 (Oct. 5, 2020), attached hereto as Appendix B) and urge CMS to reverse these problematic amendments that open the doors for expansion requests that fail to serve the needs of Medicaid beneficiaries. CMS properly exercised its authority under section 1871 and 1877(i)(3)(A)(i) of the Social Security Act in the 2012 OPPS Final Rule to apply the on-campus limitation to both applicable hospitals and high

Medicaid facilities.[5] Congress, in permitting the Secretary to consider expansion exception requests from high Medicaid facilities, imposed county-specific criteria,[6] reflecting an expectation that the Secretary would limit high Medicaid facility expansions to the same county in which the expanding physician-owned hospital is located. This expectation—apparent in the plain text of the statute—is best served by applying the location limitation for applicable hospital expansions to high Medicaid facility expansions.

Even under the amended regulations, however, CMS is not obligated to grant DHR's request, and the AHA and FAH urge CMS to consider all relevant facts and circumstances -- including the extraordinary distance between DHR's main campus in Edinburg and the proposed expansion site in Brownsville. Based on this and other case-specific factors, such as DHR's Medicaid and uncompensated care numbers and data showing adequate hospital services in Brownsville, the AHA and FAH urge CMS to decline DHR's request for an exception to the prohibition on physician-owned hospital expansions.

In amending the regulation to eliminate the on-campus expansion requirement for high Medicaid facilities, CMS relied on the operation of "distance limitations related to the location of off campus facilities and provider-based departments" to address concerns that high Medicaid facilities would expand into "additional campuses far away from the patients the expansion is intended by statute to serve."[7] CMS cited "section 1833(t)(B)(i) of the Act and § 413.65(e)(3)(v)(F)" in support of the assertion that the distance limitations for off-campus provider-based departments would suffice to protect against expansions to distant communities. However, neither of these provisions operates to impose a distance limitation applicable to DHR. Section 1833(t)(21)(B)(i) of the Social Security Act[8] defines an "off-campus outpatient department of a provider" but does not itself impose any distance limitation for off-campus facilities. And § 413.65(e)(3)(v)(F) does not impose a distance limitation—rather, it requires that a provider-based department of a children's hospital be located *more than* 35 miles from the nearest other neonatal intensive care unit. As a general matter, a provider-based facility must typically be "located within a 35-mile radius of the campus" of the main provider.[9] But the provider-based regulations also permit the establishment of some provider-based facilities in far-flung communities.[10] DHR's request exploits the flexibility of the provider-based regulations to its fullest extent, relying on DHR's contract with Cameron County and its disproportionate share adjustment percentage in an effort to satisfy the alternative standard under 413.65(e)(3)(ii).[11]

[5] 76 Fed. Reg. 74,121, 74,524 (Nov. 30, 2011).
[6] Social Security Act § 1877(i)(3)(F)(i), (ii).
[7] 85 Fed. Reg. 85,866, 86,257 (Dec. 29, 2020).
[8] Due to an apparent typographic error, the preamble did not include the paragraph number in this citation, but as paragraph (21) is the only paragraph of section 1833(t) with a subparagraph (B)(i) referencing an off-campus facility or a provider-based department, the FAH understands that the intent was to cite to section 1833(t)(21)(B)(i).
[9] 42 C.F.R. § 413.65(e)(3)(i).
[10] *E.g.*, 42 C.F.R. § 413.65(e)(3)(ii).
[11] It is also worth noting that Texas law requires that all inpatient building be within a 30-mile radius of the main address of the hospital. Tex. Health & Saf. Code § 241.023(c-1)(2); Tex. Admin. Code, tit. 25, § 133.2(47)(B)(ii). The provider-based rules require that a remote hospital

It is evident that the amendment eliminating the on-campus requirement for high Medicaid facility expansions was made with the assumption that the typical 35-mile "distance limitation" for provider-based departments would be adequate to prevent high Medicaid facilities from expanding to distant locations. Because DHR's current expansion request exceeds these assumed distance limitations, it should be denied. At a minimum, the AHA and FAH urge CMS to closely scrutinize the request in light of larger policy objectives and to decline to permit the requested expansion as unnecessary to serve the needs of Medicaid beneficiaries in Cameron or Hidalgo County.

DHR is Not the Highest Medicaid Provider in Hidalgo County. DHR relies on discharge data to argue that it has the highest percentage of Medicaid admissions in Hidalgo County (where DHR's main campus is located). But data on actual Medicaid days indicate that DHR's inpatient Medicaid utilization is lower than other hospitals in Hidalgo County. Indeed, according to the Texas Medicaid DSH qualification file, DHR's Medicaid days as a percentage of total days was 48.65% in 2020 and 46.874% in 2021.[12] These percentages are lower than those for Mission Regional Medical Center (56.67% in 2021) and Knapp Medical Center (50.65% in 2020 and 55.12% in 2021).[13] Although the high Medicaid facility criteria focus on Medicaid admissions rather than Medicaid days, CMS has discretion to consider this data in determining the overall benefit (or lack thereof) of the proposed expansion.

Patient Access Considerations Do Not Warrant DHR's Expansion into Cameron County. DHR has not identified any reason that an exception to the prohibition on new or expanded physician-owned hospitals is needed in order to address patient access issues in Cameron County. In fact, in its application for a waiver to the 30-mile distance limitation in Texas' hospital licensing law, DHR presented data showing that Cameron County has *more* inpatient acute care beds per capita than Hidalgo County (2.6 beds vs. 2.1 beds per 1,000 people) and that the per capita inpatient bed capacity in Cameron County exceeds the national average of 2.4 beds per 1,000 people (see DHR application, pg. 13 of Appendix C). To the extent that DHR has shown any need for any expansion, it would be a need for expanded capacity at its current location in Hidalgo County. And, in fact, CMS has already granted DHR's request to add 551 operating rooms, procedure rooms, and beds under the "applicable hospital" exception to the expansion limitations for physician-owned hospitals,[14] but DHR has failed to follow through with a robust expansion of its on-campus capacity in Hidalgo County. In obtaining the "applicable bed" expansion exception, DHR presented HCRIS data indicating that DHR has an average bed occupancy rate that is greater than the statewide bed occupancy rate. At present, DHR has 363 acute licensed beds (despite CMS' grant of its "applicable hospital" exception

location be operated under the same license as the main provider where states license remote locations, but DHR is seeking to bypass State licensing requirements through a waiver process.

[12] 2020 DSH Qualification Workbook, released by the Texas Health and Human Services Committee (HHSC) on April 7, 2020; 2021 DSH Qualification Workbook, released by the HHSC on June 2, 2021

[13] *Id.*

[14] 80 Fed. Reg. 55851 (Sep. 17, 2015).

request) but operated at 80.02%, 85.71%, and 83.90% occupancy over the three most recent fiscal years.[15]

Despite the data showing high utilization in Hidalgo County, DHR is seeking to instead expand in a different community that is already well served by existing providers. There are currently two general acute care hospitals in Brownsville: Valley Baptist Medical Center – Brownsville (VBMC with 240 acute licensed beds) and Valley Regional Medical Center (VRMC with 214 acute licensed beds). Over the past three fiscal years, the percentage occupancy at these two facilities has ranged between 46.06% (VBMC in 2019) and 66.02% (VRMC in 2021), indicating that additional capacity is not needed in Brownsville. In addition, as explained below, VRMC has consistently had a higher percentage of Medicaid discharges as compared to DHR, indicating that Medicaid beneficiaries are already well served in Brownsville.

The Proposed Brownsville Campus is Unlikely to Operate as a High Medicaid Facility. Medicaid beneficiaries in Brownsville, Texas are already served by several Cameron County hospitals. In particular, the percent of total VRMC hospital discharges that were Medicaid discharges was 46.188% in 2021, 50.145% in 2020, and 50.522% in 2019. These numbers exceed DHR's Medicaid percentages in these years (41.672%, 37.431%, and 46.176%, respectively). ***The statutory criteria for a high Medicaid facility focus on the percent of Medicaid admissions "in the county in which the hospital is located,"[16] but it is not clear that Congress (or CMS) anticipated the high Medicaid facility expansion exception being used to create a new hospital campus over 50 miles away in another county where existing hospitals already exceed the expanding provider's percent of Medicaid admissions***. CMS should therefore use its discretion to consider the Medicaid discharge percentages in Cameron County in evaluating the public interests at play. Because DHR serves a lower percentage of Medicaid beneficiaries in Hidalgo County compared to VRMC in Cameron County, it appears unlikely that DHR would operate a high Medicaid facility in Cameron County if it expanded there.

Along similar lines, DHR provides relatively low levels of uncompensated care compared to Brownsville and Edinburg hospitals. DHR's uncompensated care cost as a percentage of operating expenses has been consistently less than half of the uncompensated care percentages for the two existing Brownsville hospitals (VBMC and VRMC) and also significantly less than the other large hospital based in Edinburg (South Texas Health System):[17]

Year	DHR	Valley Baptist Medical Center Brownsville	Valley Regional Medical Center	South Texas Health System
2021	4.62%	9.22%	11.80%	14.09%
2020	3.83%	12.69%	13.72%	14.73%
2019	5.43%	13.57%	12.86%	8.67%
2018	3.27%	12.75%	12.01%	11.40%

[15] HCRIS data, available at https://www.cms.gov/Research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/hospital-2010-form.
[16] Social Security Act § 1877(i)(3)(F)(ii).
[17] HCRIS data, available at https://www.cms.gov/Research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/hospital-2010-form.

Careful consideration of this data is appropriate because the statute does not set forth a process for revoking an expansion exception if a physician-owned hospital, after expanding to a new community, exploits the whole-hospital exception to direct cherry-picked physician-investor referrals of lucrative patient populations to its facilities, compromising the payer and case mix at other area general acute care hospitals.

DHR's Proposal to Transfer Patients to its Edinburg Campus Raises Significant Safety Concerns. In its request for a waiver of the 30-mile limitation on new hospital locations under Texas Law, DHR indicated that if a patient requires a transfer, that patient would be transferred to the DHR parent hospital in Edinburg (see page 6 of Appendix C). This would mean that patients requiring transfer would travel over 50 miles rather than receiving care at another Brownsville acute care facility. The proposed patient transfer process creates significant safety concerns that are wholly unnecessary considering the services and facilities in Brownsville and Cameron County. In addition, the high occupancy rate at DHR raises additional concerns as patients will be transferred from an area with more moderate hospital utilization and lower occupancy rates (occupancy rates in Brownsville hospitals have ranged between 46.06% and 66.02% over the past three years) to a high-occupancy facility (over 80% occupancy at DHR from 2019 through 2021).[18]

3. The ACA's Limitations on the Whole Hospital Exception Provide Crucial Programmatic Protections that Warrant Rejecting DHR's Request

Under the ACA amendments to the physician self-referral law, the owners of DHR cannot build a new hospital and then make referrals to that hospital. Instead, DHR's only option to expand physician-ownership into a new market is to cobble together a high Medicaid facility expansion exception with a Texas licensing thereby exploiting the law and regulation as amended in December 2020 by leveraging its grandfathered status under the ACA. There is no indication that Congress intended the high Medicaid facility exception to be used to permit such an expansion of a physician-owned hospital into a new and distinct market. Rather, with the high Medicaid facility and applicable hospital exceptions, Congress simply recognized that expansion exceptions may be necessary to protect access to care among Medicaid and low-income individuals in certain communities. But, here, the expansion request overlooks local needs in DHR's own community and instead exploits local circumstances to expand into a new market.

In short, the extraordinary facts presented by DHR make clear that it is inappropriate for CMS to approve a physician-owned hospital expansion simply because the three high Medicaid facility criteria are met. The creation of a new physician-owned hospital in Brownsville risks distorting the hospital market, skewing hospital payer and case mix, and raising the costs of health care in the area – the very reasons Congress enacted the POH prohibitions in the first place. In fact, the public discourse that ultimately prompted the ACA's prohibition opening and expanding physician-owned hospitals has its roots in Atul Gawande's seminal article, *The Cost*

[18] HCRIS data, available at https://www.cms.gov/Research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/hospital-2010-form.

Conundrum, which highlighted the extraordinary cost of care at DHR.[19] CMS should therefore deny the request, and the AHA and FAH further urge CMS to repeal its December 2020 amendments to 42 C.F.R. § 411.362(c)(1), restoring the on-campus requirement for high Medicaid facility expansions.

The AHA and FAH appreciate the opportunity to submit these comments. If you have any questions, please contact us or have a member of your team contact Joanna Hiatt Kim, AHA Vice President for Payment Policy, at (202) 626-2340 or Steve Speil, FAH Executive Vice President, Policy, at (202) 624-1529.

Sincerely,

Stacey Hughes
Executive Vice President
American Hospital Association

Charles N. Kahn III
President and CEO
Federation of American Hospitals

[19] Atul Gawande, *The Cost Conundrum—What a Texas Town Can Teach Us about Health Care*, NEW YORKER (June 1, 2009), *available at* https://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum.

reason, the FAH believes procedure codes 22551 and 22552 should not be subject to prior authorization.

B. Patient Health and Well-Being Will Be Affected by Delays in Medical Care

CMS indicates that provisional affirmation will be provided within 10 days of a request and 2 days where a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function. The FAH is concerned about the potential for CMS's policy to delay treatment for 10 days where the request may not meet the requirements for expedited review but the patient is still suffering from a painful and debilitating condition such as chronic intractable pain. ***In situations where a delay in receiving medical care could seriously jeopardize the beneficiary's life, health or ability to regain maximum function, any responsible health care provider will furnish the needed services immediately and not wait 2 days for a response from Medicare***. Yet, absent the prior authorization, CMS's proposed policy would deny payment for all services related to the treatment even if the patient had an urgent need for the medical services. While the provider could request a reconsideration or appeal a denial, CMS's proposed policy would force significant administrative burden on a provider in order to receive payment, even in the most urgent of medical situations.

XII. Revisions to Laboratory Date of Service (DOS) Policy (Part XVIII)

Protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) laboratory tests are not considered molecular pathology tests subject to the CMS packaging policy. However, several stakeholders have suggested that they believe the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service. CMS proposes to modify the lab date of service rule to apply the same date of service to these tests as molecular pathology tests and ADLTs. This proposed revision to the laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs to bill Medicare directly for those tests instead of seeking payment from the hospital when the service is not-packaged and the DOS rule is met. The FAH supports this policy.

XIII. Physician-Owned Hospitals (Part XIX)

The FAH strongly opposes CMS's proposal to effectively remove all limits on expansion by physician-owned "high Medicaid facilities," including the frequency with which such a facility can request a capacity expansion; the caps on the number of operating rooms, procedure rooms and beds that can be approved; and the requirement that expansion must only occur on the main campus. We also would strongly oppose any removal or limitation of the opportunity for community input on expansion requests from high Medicaid facilities.

CMS projects in the Proposed Rule that only one physician-owned hospital (POH) per year will request an expansion exception on the grounds that it is a high Medicaid facility. CMS further believes the proposal is unlikely to lead to more frequent expansion exceptions. This suggests that CMS believes the proposal is narrow and likely to have little impact. We disagree.

For multiple reasons, the proposal is much broader than purported in the Proposed Rule and its impact will far surpass only Medicaid patients, while opening the door for significant gaming by POHs and thus undermining Congressional intent to strictly limit POH expansion.

The FAH and the American Hospital Association (AHA) engaged DeBrunner & Associates to analyze the Medicare cost report data for POHs, including high Medicaid facilities. Overall, the analysis shows that there are at least 14 POHs that could qualify as a high Medicaid facility based on the most recent Medicare cost report data (FY 2016-2018) and another six POHs that are on the cusp of qualifying (i.e., they met the high Medicaid requirements in FYs 2017 and 2018 and thus could qualify depending on their FY 2019 data). Still four other POHs met the high Medicaid requirements in FY 2018 and thus could qualify depending on their FYs 2019 and 2020 status.[18] In total, the analysis revealed 24 facilities that either currently – or soon could – qualify as a high Medicaid facility and thus benefit from the broad expansion policies CMS put forth in the Proposed Rule.

The analysis also reveals the low bar needed for some facilities to meet the high Medicaid requirements. For example, one of these "cusp" POHs had the highest Medicaid discharge percentage in the county at a mere 3.3 percent in FY 2018. If it maintained this "high" Medicaid status for only one more year (FY 2019), it would qualify for an expansion exception request. Moreover, its uncompensated care costs as a percentage of its overall operating costs in FY 2018 are minimal at 1.1 percent, and its occupancy rate is under 45 percent. This particular POH clearly is not critical for ensuring access to care for Medicaid patients, yet it could request to expand without limits under CMS's proposal. This is clearly not what Congress had in mind when it established the narrow "high" Medicaid facility exception to its overall policy to strictly limit the expansion of POHs.

The FAH discusses our specific key concerns with the proposal below.

The Proposal Creates Incentives to Game Opportunities to Become High Medicaid Facilities

The proposal creates incentives for facilities to "game the system" by creating opportunities to become a high Medicaid facility, by meeting low thresholds. Under the proposal, there no longer would be a limit on the percentage increase of a high Medicaid facility's baseline number of operating rooms, procedure rooms, and beds. In addition, POHs would no longer be limited to expansion on their main campus and thus could expand beyond to off-campus locations as well.

This will provide POHs with a significant incentive and the ability to game the system. For example, without the main campus limitation, a high Medicaid facility could merge with or purchase a non-POH, which could be operated as a "remote location" of the POH and share its Medicare provider number, thereby greatly increasing the number of operating rooms, procedure rooms, and beds.

[18] DeBrunner & Associates analysis of FFY 2016-2018 Medicare Cost Reports, September 2020. 214 Physician owned hospitals were identified for purposes of this analysis.

Further, if as a result of such a merger the provider would lose its status as a high Medicaid facility due to a dilution of the provider's percentage of Medicaid admissions, the provider would still be able to engage in the expansion because there is no provision in the statute or the regulations that requires a facility to maintain its "high" Medicaid status or that permits a rollback of an approved expansion, once granted. By the same token, in any circumstance, even absent a merger, once the high Medicaid POH secures an expansion, the high Medicaid requirement disappears. ***The facility could become the lowest Medicaid provider in its county, and it would still retain the full complement of expansion beds, operating rooms and procedure rooms***.

Therefore, a POH would have an incentive to become a high Medicaid facility simply to take advantage of the expansion exception, but no incentive to maintain their "high" Medicaid status after receiving the exception. We note that the ability to achieve this status is enhanced in states that have expanded their Medicaid programs under the *Affordable Care Act* (ACA). Illustrating the disincentive to maintain the designation list, the DeBrunner & Associates analysis identified a POH (POH A) that qualified as a high Medicaid facility when its expansion exception request was approved by CMS, but which is no longer the high Medicaid facility in the county.

<u>There is Not a High Bar to Qualifying as a High Medicaid Facility</u>

There is ample opportunity for gaming the system, as discussed above, because in many counties there is not a high bar to qualifying as a high Medicaid facility. ***There is no statutory requirement that a high Medicaid facility in fact serve a high number of Medicaid patients. Instead, a high Medicaid facility is one that simply has a higher percentage of Medicaid admissions than the other hospitals (which may be very few in number) in the same county***. SSA § 1877(i)(3)(F). A 2016 study found that, on average, only 2.2 percent of patients admitted to POHs are Medicaid patients, a percentage that is less than 1/5th of the percentage of Medicaid patient admissions to non-POHs.[19]

More specifically, ***the DeBrunner & Associates analysis shows, for example, one POH that qualifies as a "high" Medicaid facility with a FY 2018 Medicaid discharge percentage of only 1.9 percent*** (POH B). Yet, that 1.9 percent constitutes the highest percentage of Medicaid patients in the county, ***a county with only two facilities***. This suggests that this county treats virtually few, if any Medicaid patients, and that Medicaid patients likely are treated in neighboring counties. The analysis shows that, with respect to POH B, ***hospitals in the neighboring counties treat significantly higher percentages of Medicaid patients. These facilities have FY 2018 Medicaid discharge percentages of approximately 13 percent, 15 percent, and 22 percent, which points to the distinct possibility that POH B treats patients for which it receives more lucrative payment (patient cherry picking), which results in neighboring county hospitals having to provide access to Medicaid patients – exactly the behavior Congress intended to curtail when it enacted strict limits on POHs***.

[19] Dobson & Davanzo, Analysis of FY 2018 MedPAR Data, September 2020.

Moreover, the data shows that POH B, especially in comparison to hospitals in neighboring counties, has significantly lower rates of uncompensated care costs as well as discharges with emergency room services, 2.3 percent and 11.4 percent, respectively.[20] In contrast, the neighboring county hospitals have uncompensated care costs as a percentage of overall operating costs ranging from 5 percent to 11 percent and discharges with emergency room services ranging from 63 percent to 92 percent. As evidenced by the data, permitting POH B an uncapped expansion would not promote access to care for Medicaid patients. And, as discussed above, once a high Medicaid facility's exception request is granted, there is no requirement for the POH to maintain that status, as illustrated by POH A.

The examples above undermine any argument that CMS's proposed policy reversal is intended to support hospitals serving a high number of Medicaid patients. Rather the policy reversal could operate to support POHs that do not serve large numbers of Medicaid patients or those that meet a relatively "high" threshold but do so for a relatively short period of time.

Further, since "high" Medicaid facilities treat all patients, and may in fact treat very few Medicaid patients, as in the POH A example above, the proposal if finalized would allow POHs to expand with regard to all patients, not just Medicaid patients. As such, a POH that doubles its capacity from, for example, 75 to 150 beds, could fill those additional beds and, indeed, all the facility's beds, with non-Medicaid patients. The data show that the existing POHs whose expansion exception requests have been approved by CMS generally doubled in size under the approved request and this could increase exponentially under the proposal since it removes all limits on expansion and does not require that such expansion facilitate or maintain the POH's continued service to Medicaid patients.

There Are No Limits on "High" Medicaid Facility Expansion and Off-Campus Facilities

The FAH has grave concerns that the proposal would remove all limits on the ability of a high Medicaid facility to expand, including permitting unlimited off-campus facilities. ***Once a hospital meets the definition of a high Medicaid facility (even if temporarily) and its exception request is granted, it could expand without any limitation and without any requirements for when that expansion would occur.*** A POH could expand to double or triple or more in size, through both an on-campus expansion or the purchase or building of an off-campus facility (or multiple off-campus facilities). Further, the POH could undertake and complete that expansion sometime in the distant future after it no longer qualifies as a high Medicaid facility.

Further, there are no limits on service line expansion. Therefore, ***a POH could choose to build or purchase an off-campus facility of any size, entirely dedicated to hips and knees or other specific service lines and with no Emergency Department, with devastating consequences for neighboring full-service community hospitals.*** Nothing in the proposal would prevent a proliferation of these new POHs.

[20] DeBrunner & Associates analysis of FFY 2016-2018 Medicare Cost Reports, September 2020.

There Are No Guidelines for CMS to Deny or Amend an Exception Request

The FAH is concerned that if CMS removes all limits on expansion for high Medicaid facilities, the Agency eliminates its discretion to deny requests for expansion, as the proposal will remove any requirements for approving or denying such requests, and the underlying regulations do not provide any guidelines for such actions. This raises the question of whether a denial by CMS could be legally challenged by a POH as "arbitrary and capricious" and is another factor that could incent expansion exception requests, as there may not be any reasonable basis for denials of these requests.

CMS Has Not Presented a Cogent Rationale or Medicare or Medicaid Program Benefit for Reversing Its Longstanding High Medicaid Facility Policy

The Proposed Rule does not articulate a need for the proposed policy reversal nor any benefit to the Medicare or Medicaid program. If finalized, the proposal will eviscerate Congress's intent to place strict limits on the expansion of POHs, with only imagined benefits to the Medicare or Medicaid programs. In fact, ***the proposal is more likely to harm these programs by increasing the number of POHs despite years of independent data showing that self-referrals to physician-owned hospitals result in cherry-picking of the healthiest and wealthiest patients, excessive utilization of care, and patient safety concerns at significant cost to patients and the Medicare program.***

Congress purposefully put tight restrictions on the growth of POHs in the *Affordable Care Act* (ACA), and the exceptions to the limits on expansion of POH operating rooms, procedure rooms and beds were intended to be very clearly and carefully circumscribed. ***CMS has not identified any access to care concerns for Medicaid recipients that have been caused by the present limits on POH expansion nor identified any instances in which POHs would increase the number of Medicaid patients they serve but for the limits on expansion. In short, the proposal contravenes congressional intent and serves no public policy purpose***.

The lone commenter to the CY 2012 OPPS Proposed Rule that addressed the proposal for uniform requirements/limitations in the exception on expansion stated that applying parallel requirements to both "applicable hospitals" and "high Medicaid facilities" would result in an efficient and consistent process. CMS responded "[w]e agree with the commenter regarding our application of parallel requirements." 76 *Fed. Reg.* 74,524 (Nov. 30, 2011). The FAH agrees with the 2012 commenter and CMS's response that the same requirements and limits on expansion should apply to POHs applying for an exception regardless of whether they are applying under the "applicable hospital" exception or the "high Medicaid facility" exception. The FAH also believes the current policy has worked as Congress intended and should be maintained by CMS.

CMS has not offered a rational explanation for the sudden reversal of its longstanding position. To the contrary, CMS states in the Proposed Rule that it continues to believe that the "current regulations, for which the Secretary appropriately used his authority and which treat high Medicaid facilities the same as applicable hospitals, are consistent with the Congress' intent to prohibit expansion of physician-owned hospitals generally." 85 *Fed. Reg*. 49,038 (Aug. 12,

2020). The only rationale proffered in the Proposed Rule for the change in policy is that CMS believes that its current regulations "impose unnecessary burden on high Medicaid facilities." But CMS does not provide any specifics supporting this statement. For example, ***CMS does not point to any particular high Medicaid facility that has been or would be harmed, or describe the nature of the alleged "burden," or how the Medicare program or Medicaid patients would be better served by so radically relaxing restrictions on expansion by high Medicaid facilities***. As discussed previously, CMS has not issued guidelines that even identify "high" Medicaid facilities – just facilities that are higher than other hospitals located in the same county.

While CMS ties its proposal to the *Patients over Paperwork* initiative, this connection is tenuous at best as CMS also states that it does not believe that the proposal would result in any change in burden under the Paperwork Reduction Act. Specifically, without explanation, the Proposed Rule says CMS does not anticipate any change in the annual number of respondents, that more frequent expansion requests would be unlikely, and that it is not changing the information being collected. The data we examined strongly suggests otherwise. As such, there is no clear proposed benefit to CMS's proposed change in policy. While administrative simplification is suggested as the reason for this proposed policy change, the only clear impact of the proposal if finalized will be to undermine Congress's goal of limiting Medicare utilization by POHs.

We also note that CMS projects that only one POH per year will request an expansion exception on the grounds that it is a high Medicaid facility. This raises the question as to whether the proposal is merely meant to benefit a few specific hospitals, which is not a rational basis for establishing such a broad-based policy change.

CMS Should Maintain the Requirement for Community Input

CMS is considering whether it should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities. ***The FAH strongly opposes any removal or limitation of the opportunity for community input on expansion requests from high Medicaid facilities***. Although CMS states in the Proposed Rule that obtaining community input "could" delay or add complexity to the approval of an expansion request, it does not identify any instances in which this has occurred.

We also note that CMS discusses that elimination of the community input requirement could in fact *cause* a delay and/or *increase* complexity because CMS would have to independently verify the data provided by the POH. This counterintuitive logic highlights the very reason why community input is essential – and foundational to the notice and comment process underlying public rulemaking. It is critical for maintaining a transparent process that provides CMS with the necessary data for verifying or disproving a requestor's high Medicaid facility status as well as State licensure for the requested expansion.

Local community hospitals are not only best able to comment on the need for expansion, but also are arguably the only opportunity for CMS to verify that a POH requesting an expansion exception is an eligible applicant. In conducting the analysis referenced herein, DeBrunner & Associates found that a not insignificant percentage of the

available county data was inaccurate (in some cases due to an incorrect spelling of a county name – a seemingly simple error but with enormous consequences for decision-making) and thus it may be difficult to determine whether a POH does in fact have the highest Medicaid admissions percentage in the county. In these cases, it is imperative that CMS maintain the public comment process to hear from other community hospitals and verify the eligibility of POH's applying for this exception and associated expansion.

For the reasons above, the FAH strongly opposes CMS's proposal and urges its withdrawal.

****

The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or Steve Speil, Executive Vice President, at 202- 624-1529.

Sincerely,

TEXAS
Health and Human Services

October 7, 2021

MANISH SINGH, MD, CEO
DHR HEALTH BROWNSVILLE
4750 N EXPRESSWAY 77
BROWNSVILLE, TX 78526

Re: Application to Operate a General Hospital Deficiency Notice

Dear Dr. Singh:

This is to serve as notification that we are in receipt of the Multiple Location Initial General Hospital License Application for DHR Health Brownsville**.** The application and submitted documents have been reviewed. We are unable to process the application until the following documents are corrected /received:

- **Application type –** Please note: If the waiver is not approved, I will not be able to license this location as a multiple location of license #007971 since it is located 47.24 radial miles from the parent hospital and the licensing rules only allow for a 30-mile radius.

- **Ownership Information (Page 1, Section 2) –** According to our records, the entity tied to tax ID 74-2802643 is Day Surgery at Renaissance Ltd. If this has changed, please provide the Certificate of Amendment issued by the Secretary of State.

- **Hospital Services (Page 2, Section 4) –** Please remove "Medical". This service is reserved for Special Hospitals.

- **Accreditation (Page 3, Section 8) -** Please submit the most recent certificate or letter of accreditation from the Joint Commission issued to Doctor's Hospital at Renaissance.

- **Fire Safety Survey (Page 3, Section 11) –** Please submit the approved Fire Safety Survey once received. Reference 25 TAC §133.23(b)(1)(B), "a copy of a hospital fire safety survey indicating approval by the local fire authority in whose jurisdiction the hospital is based."

- **PTP/MOT (Page 4, Section 12) –** Pending approval from Janae Robinson. Janae can be reached by email at janae.robinson03@hhs.texas.gov.

- **Pre-survey Conference (Additional Requirement) –** Please contact the Health Facility Compliance Office in San Antonio at jeanette.salinas@hhs.texas.gov regarding your facility's pre-survey conference. Please reference the hospital licensing rules found at 25 TAC §133.22 (c), "Pre-survey conference. The applicant or the applicant's representative shall attend a pre-survey conference at the office designated by the department." Please send at least one individual who is listed on the application and who will be in charge of day-to-day operations.

- **Final Architectural Inspection (Additional Requirement) –** Submit the Final Architectural Inspection form upon completion of architectural inspection. For questions regarding this requirement, contact the Architectural Review Unit at AskARU@hhs.texas.gov.

Please submit the requested documents or make the required changes on the application along with a date and initial alongside the corrections. *Only submit pages requiring corrections or documents needed, do not resend entire packet.* Amendments can be emailed to Angela Arthur at: angela.arthur@hhs.texas.gov.

Sincerely,

Angela Arthur

Angela Arthur
License & Permit Specialist IV
Regulatory Services Division
Health Facility Licensing

TEXAS Health and Human Services

Form 3229
May 2021-E

Application for a License to Operate a Multiple Location General or Special Hospital

Service Code: 529201039
Dept. ID: ZZ101 Fund: 152

Name of Main Hospital:	Main Hospital License No.:
Doctors Hospital at Renaissance, Ltd.	007971

Multiple Hospital Designation: (●) General ( ) Special

Multiple Hospital Application Type: (●) Initial ( ) Change of Ownership ( ) Relocation

Projected Opening Date or Projected Change of Ownership Effective Date: December 1, 2021

Architectural Project No.: 17065

Hospital within a Hospital? ( ) Yes (●) No

Section 1 – Hospital Information

Name Hospital will be Doing Business As (D/B/A) or Assumed Name:
DHR Health Brownsville

This is the name that will appear on the license and should match advertisements and signage of the hospital.

Street Address:	City:	State:	ZIP Code:	County:
4750 N Expressway 77	Brownsville	TX	78526	Cameron

Mailing Street Address or P.O. Box No. (if different):	City:	State:	ZIP Code:

Area Code and Phone No.:	Area Code and Fax No.:
(956) 362-7469	(956) 362-7371

Section 2 – Ownership Information

Legal Name:
Doctors Hospital at Renaissance, Ltd.

This is the name of the direct owner legally responsible for the day-to-day operation of the hospital, whether by lease or ownership.

Mailing Street Address:	City:	State:	ZIP Code:
5501 S McColl Rd.	Edinburg	TX	78539

EIN No.:	Area Code and Phone No.:	Email Address:
74-2802643	956 362-8677	legalcounsels@dhr-rgv.com

Status:
(●) Profit
( ) Nonprofit

Type of Ownership:

☐ City	☐ Hospital District/Authority
☐ Corporation	☐ Limited Liability Company (LLC)
☐ County	☐ Limited Liability Partnership (LLP)
☐ Hospital	☐ Limited Partnership (LP)
☑ Limited (LTD)	☐ Partnership
☐ Sole Owner/Proprietorship	☐ State
☐ Other: _____	

- Provide a copy of the IRS letter assigning the federal Employer Identification Number (EIN).
- Provide a copy of the Certificate of Filing from the Office of the Secretary of State.
- Attach an organizational chart showing the ownership structure. See Example in the instructions.

Section 3 – Physician Ownership

Does this hospital have physician owners? (●) Yes ( ) No

If yes was marked, also complete Section 16, Physician Ownership Addendum.

Section 4 – Hospital Services

Check all services offered:

- [x] Medical (special hospitals only)
- [x] Surgery (general hospitals only)
- [ ] Obstetrical Care (general hospitals only)
- [x] Clinical Laboratory Services (required contracted or onsite)
- [x] Diagnostic X-ray Services (required)
- [x] Emergency Department
- [ ] Emergency Treatment Room (required if no Emergency Department)
- [ ] Pediatric (if 15 or more beds)
- [ ] Comprehensive Medical Rehabilitation
- [ ] End Stage Renal Disease (ESRD) Acute Services* (in an identifiable part of the hospital)
- [ ] Mental Health Services (in an identifiable part of the hospital)
- [ ] Inpatient Chemical Dependency (in an identifiable part of the hospital)
- [ ] Outpatient Chemical Dependency (in an identifiable part of the hospital)
- [ ] Other Definitive Medical or Surgical Treatment: _____

*Answer the questions below if ESRD stations are provided for treatment within a designated area of the hospital.

1. What patient populations are being served? ○ Pediatric ○ Adult
2. Does the hospital provide peritoneal dialysis? ○ Yes ○ No
3. How many stations does the hospital have (not included in bed count)? _____

Section 5 – All State Waivers

Does this location currently have a state waiver? ○ Yes ◉ No

Does this location currently have a state waiver for the Emergency Department? ○ Yes ◉ No

If yes was marked, provide a copy of the waiver.

Section 6 – Other Services

Select any of the following, if applicable:

- [ ] Long Term Acute Care Hospital
- [ ] Critical Access Hospital
- [ ] Skilled Nursing Unit
- [ ] Children's Hospital
- [x] None

Section 7 – Licensed Beds and Fees

1. How many total licensed beds are at this hospital location (total bed design capacity of this hospital only)? 59

   Note: A change in the bed design requires prior approval and possible fees.

2. Total fee is $39 per bed. Amount paid: $2,301.00

   Make checks payable to Texas Health and Human Services Commission.

2. How many emergency treatment room beds and/or emergency department beds are at this hospital location? 2

   Note: This count is not included in the licensed bed count above and will not affect fees. A minimum of one bed is required.

3. Provide the total number of licensed beds in each unit or area of service at this hospital location: 59

   Medical/Surgical (may include pediatric beds if pediatric bed count is less than 15 beds): 56

ICU/CCU: 3	Postpartum:
Intermediate Care:	Adolescent:
Universal Care:	Pediatric (if 15 or more beds):
Neonatal ICU:	Skilled Nursing:
Continuing Care Nursery:	Comprehensive Medical Rehabilitation:
Antepartum:	Mental Health:
Labor/Delivery/Recovery/Postpartum:	Chemical Dependency:

Section 8 – Hospital Accreditation Only

Check the category that applies and attach a copy of the most recent hospital letter or certificate of accreditation.

- [x] Joint Commission (JC)
- [ ] American Osteopathic Association (AOA)
- [ ] DNV GL
- [ ] Center for Improvement in Healthcare Quality (CIHQ)
- [ ] Not Accredited

Section 9 – Medicare Certification

Is the hospital certified to participate in the Title XVIII Medicare Program? (●) Yes ( ) No

If yes, provide the hospital's CMS Certification number (CCN): 450869

Section 10 – SAFE-ready Facility

Is your facility a SAFE-ready facility? ( ) Yes (●) No

"SAFE-ready facility" means a health care facility designated as a Sexual Assault Forensic Exam-ready facility under Texas Health and Safety Code (HSC) Section 323.0015. A SAFE-ready facility employs or contracts with a sexual assault forensic examiner or uses a telemedicine system of sexual assault forensic examiners to provide consultation to a licensed nurse or physician when conducting a sexual assault forensic medical examination.

Section 11 – Fire Safety Survey

Include a copy of a fire safety survey indicating approval by the local fire authority in whose jurisdiction the facility is based that is dated no earlier than one year prior to the application date, as required by HSC §241.023(d)(1) and 25 Texas Administrative Code §133.22(a)(6). Annual fire safety inspections are required for continued licensure status.

Section 12 – Patient Transfer Policy/Memorandum of Transfer/Patient Transfer Agreement

☑ Submit a copy of the hospital's Memorandum of Transfer and the Patient Transfer Policy developed in accordance with the rules governing patient transfer policies and agreements, signed by both the chairman and secretary of the hospital's governing body attesting to the date of adoption of the policy and the policy's effective date.

☐ Submit copies of all Patient Transfer Agreements between the hospital and another hospital licensed under HSC Chapter 241, developed in accordance with the rules governing hospital patient transfer policies and agreements (unless you have a written waiver granted by HHSC). If you have a written waiver, attach a list of hospitals that your hospital has agreements with and include the effective dates of the agreements. Only submit agreements between hospitals that are licensed under HSC Chapter 241.

☑ Exception to submission of Patient Transfer Agreement – Check this box if you only plan to transfer patients to your parent hospital.

Section 13 – Signature and Attestation

I attest that the owner meets the requirements of 25 Texas Administrative Code, Chapter 133, Hospital Licensing Rules, and that all information contained in this application is true and correct. I attest that all copies submitted with the application are original copies or copies of the original documents. In compliance with HSC §241.022(c)(1) and the Hospital Licensing Rules, I attest that the physicians on the medical staff of this hospital are currently licensed by the Texas Medical Board and are qualified legally, professionally and ethically for the positions to which they are appointed.

Chief Executive Officer (CEO) Signature	Date Signed: 10/04/2021
Manish Singh, MD	Chief Executive Officer
CEO Printed Name	Title
956-362-7151	m.singh@dhr-rgv.com
Area Code and Phone No.	Email Address

Section 14 – Hospital Administrator (Onsite administrator in charge of day-to-day operations)

Aida Coronado Garcia	Senior Vice President, DHR Health Brownsville
Administrator	Title
956-342-1890	a.coronadogarcia@dhr-rgv.com
Area Code and Phone No.	Email Address

Section 15 – Ownership Addendum

Complete if partnership or corporation and attach additional pages, if necessary. ☐ **N/A**

◉ **Owner is Partnership** (List each individual who is a general partner.)

Name: RGV Med, LLC Social Security No.: NA

Name: Social Security No.:

Name: Social Security No.:

Name: Social Security No.:

○ **Owner is Corporation** (List each individual who has an ownership interest of 25% or more in the corporation.)

Section 16 – Physician Ownership Addendum

Complete if hospital has physician owners with each Texas Medical Board license number and attach additional pages, if necessary. ☐ **N/A**

Name: License No.: Owns %

Social Security No.: Address:

Name: License No.: Owns %

Social Security No.: Address:

Name: License No.: Owns %

Social Security No.: Address:

Name: License No.: Owns %

Social Security No.: Address:

Name: License No.: Owns %

Social Security No.: Address:

Chapter 241 Hospital Licensing Waiver Request

Doctors Hospital at Renaissance, Ltd. (DHR Health) (License # 007971) requests waiver of Texas Health and Safety Code, Subchapter B. Licensing of Health Facilities, Chapter 241, Section 241.023(c-1)(2) (Chapter 241 and/or Code) and applicable regulations Chapter 25 Texas Administrative Code (TAC) Section 133.21(c)(4)(A), relating to Section 133.2(47)(B)(ii).

Chapter 241 Section 241.023(c-1) prescribes the conditions under which the Texas Health and Human Services Commission (HHSC) may issue a license for multiple hospitals. DHR Health seeks a waiver of one of these conditions. Specifically, DHR Health seeks a waiver of Code Section 241.023(c-1)(2) which provides that "all buildings in which inpatients receive hospital services are within a 30-mile radius of the main address of the applicant." DHR Health is in compliance with all other conditions under Chapter 241, including the conditions for a multiple hospital license under Section 241.023(c-1).

In accordance with the waiver request of Chapter 241.023(c-1)(2), DHR Health seeks waiver of the applicable regulations, 25 TAC Section 133.21(c)(4)(A), relating to Section 133.2(47)(B)(ii). Section 133.21(c)(4) "Scope of hospital license", provides that multiple hospitals may be licensed under one license provided that several conditions are met, including the condition that "(A) [t]he hospitals must comply with the requirements of multiple hospitals under a single license as specified under § 133.2(41) of this title (relating to Definitions)."[1]

As detailed in DHR Health's Form 3229 Application for a License to Operate a Multiple Location Hospital, DHR Health is adding a new general hospital facility (DHR Health Brownsville) located in Brownsville, TX[2], which is 47.14 miles (as the crow flies) away from DHR Health's main address (primary hospital location).[3] *See* Appendix A. Consequently, as DHR Health Brownsville is located more than 30 miles away from DHR Health's main address, a waiver is required to operate DHR Health Brownsville under DHR Health's existing license.

DHR Health aims to include DHR Health Brownsville under its existing license to avoid any potential federal regulatory issues due to DHR Health's status as a physician-owned hospital. As is provided in more detail below, the granting of the waiver will not adversely affect the health and safety of hospital patients, employees or the general public or the hospital's participation in the federal Medicare program. Moreover, granting the waiver requested would facilitate the creation and operation of the hospital, and would be appropriate when balanced against the best interests of the individuals to be served by the hospital. On the contrary, not granting the waiver could impose an unreasonable hardship on the hospital in providing adequate care for patients by creating potential federal regulatory issues.

[1] Although 25 TAC Section 133.21(c)(4)(A) references Section 133.2(41) as the applicable condition for a multiple hospital license, we believe the proper reference should be to 25 TAC Section 133.2(47) definition of "Premises" as subpart (47) aligns with the statutory conditions in Chapter 241, Section 241.023(c-1) whereas subpart (41), definition of "Pediatric and adolescent hospital' does not. Section 133.2(47)(b)(ii) defines "Premises" and tracks Code Section 241.023(c-1)(2), providing that "Premises" includes multiple buildings if, amongst other conditions, "(ii) all buildings in which inpatients receive hospital services are within a 30-mile radius of the primary hospital location;".

[2] DHR Health Brownsville general hospital facility address: 4705 N. Expressway, Brownsville, TX 78526.

[3] DHR Health main address: 5501 S. McColl Rd., Edinburg, TX 78539.

Waiver Criteria and Justification

(1) Provide evidence to support why the requested waiver will not adversely affect the health and safety of the hospital patients, employees, or the general public;

Granting a waiver of the 30 mile condition for multiple hospitals will not adversely affect the health and safety of the hospital's patients, employees, or the general public for several reasons:

First and foremost, the DHR Health Brownsville will operate in compliance with all applicable federal, state, and local laws, regulations, and ordinances related to hospital health and safety standards, including but not limited to, the Medicare Conditions of Participation, state and local fire code standards, and Texas hospital licensing rules. No waiver of any rules related to the health and safety of patients, staff, or the general public is being sought.

Second, DHR Health operates under the highest quality standards. Our inpatient hospital facilities are accredited by The Joint Commission (TJC), and must meet the most rigorous performance standards. As is discussed below, DHR Health Brownsville will be completely integrated into the DHR Health system, including a requirement for DHR Health Brownsville to receive accreditation by the TJC and being subject to the same quality standards currently governing our inpatient facilities and enforced through our integrated quality assurance team. *See* Appendix B, TJC Accreditation

Third, DHR Health Brownsville will be operated as a general hospital with 39 medical/surgical inpatient beds at single occupancy (59 at double occupancy), and the capabilities and resources to provide necessary care to the general public, including regularly maintaining, at a minimum: clinical laboratory services, diagnostic X-ray services, treatment facilities, including surgery, a 24/7 basic emergency department, intensive care unit with 3 beds, and 7 nursing stations with around-the-clock nursing care.

DHR Health Brownsville will offer the following services:

Medical	Surgical
Family Practice	Urology
Internal Medicine	Gynecological Oncology
Endocrinology	General Surgery
Neurology	Gastroenterology
Radiology	ENT
Pathology	Hand Surgery
Anesthesiology	Bariatric Surgery
Emergency Medicine	Cardiology
	Colorectal Surgery

Fourth, the DHR Health Brownsville facility can provide additional capacity during a public health emergency. The facility is ready-made that will be brought online in short notice and in the case of a COVID-19 surge or future infectious disease outbreak / pandemic, can be quickly converted for higher capacity. The facility can be converted overnight into double occupancy and can operate as a freestanding, isolated, and dedicated infectious disease hospital.

Fifth, the DHR Health Brownsville facility will comply with all applicable multiple hospital requirements with the exception of being located within 30 miles of the main address. DHR Health Brownsville will be fully integrated into the DHR Health organization and governance structure, unless otherwise required by law or regulation. DHR Health currently operates four inpatient facilities under this model (general acute care hospital, rehabilitation hospital, women's hospital, and behavioral hospital). DHR Health Brownsville will be integrated into the unified DHR Health system and operated in the same manner as all four of our current inpatient facilities.

Texas Health and Safety Code §241.023(c-1) / 25 TAC § 133.2(47):

(1) all buildings in which inpatients receive hospital services and inpatient services of each of the hospitals to be included in the license are subject to the control and direction of the same governing body;

- DHR Health Brownsville, including all buildings in which inpatients are to receive hospital services and inpatient services is completely owned and operated by DHR Health and is subject to the control and direction of DHR Health's governing body, the Board of Managers. *See* Appendix C, Deed of Trust; Appendix D, DHR Health Organizational Chart.

(2) all buildings in which inpatients receive hospital services are within a 30-mile radius of the main address of the applicant;

- *A waiver of this provision is being sought.*

(3) there is integration of the organized medical staff of each of the hospitals to be included in the license;

- There will only be one unified medical staff for DHR Health, which includes DHR Health Brownsville. *See* Appendix E, DHR Health Medical Staff Bylaws.

(4) there is a single chief executive officer for all of the hospitals who reports directly to the governing body and through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of the hospital;

- There is a single chief executive officer for all of DHR Health. The Senior Vice President for DHR Health Brownsville will serve as the facility's top administrator and will report directly to DHR Health's Chief Executive Officer, who in turn reports directly to DHR Health's governing body - the Board of Managers.
- All administrative authority flows through DHR Health's Chief Executive Officer who exercises control and surveillance over all administrative activities of the hospital. Support and administrative services such as, but not limited to, legal, accounting, human resources, payroll, revenue cycle, and information technology will be provided by DHR Health's existing centralized infrastructure and departments. *See* Appendix D, DHR Health Organizational Chart.

(5) there is a single chief medical officer for all of the hospitals who reports directly to the governing body and who is responsible for all medical staff activities of the hospital;

- The DHR Health Brownsville Chief Medical Officer will report directly to the DHR Health (system) Chief Medical Officer who is responsible for all medical staff activities of DHR Health and who reports directly to DHR Health's governing body - the Board of Managers. *See* Appendix D, DHR Health Organizational Chart.

(6) each building of a hospital to be included in the license that is geographically separate from other buildings of the same hospital contains at least one nursing unit for inpatients, unless providing only diagnostic or laboratory services, or a combination of diagnostic or laboratory services, in the building for hospital inpatients; and

- DHR Health Brownsville will have 7 nursing stations: 4 on the first floor (Emergency Dept. 1; Post-Op 2; and Pre-Op 1); and 1 nursing station on the second floor and 2 on the third floor.

(7) each hospital that is to be included in the license complies with the emergency services standards:

(A) for a general hospital, if the hospital provides surgery or obstetrical care or both; or

- DHR Health Brownsville is a general hospital that will provide surgery services but not obstetrical services. DHR Health Brownsville complies with all emergency service standards in compliance with 25 TAC § 133.41(e).

(B) for a special hospital, if the hospital does not provide surgery or obstetrical care.

- DHR Health Brownsville is a general hospital facility.

DHR Health Brownsville will comply all multiple hospital requirements in 25 TAC § 133.21(c)(4), including providing emergency services in compliance with 25 TAC §133.41(e), and meeting the requirements for new construction in 25 TAC § 133.162, and necessary documentation.

Finally, granting the waiver will increase access for Brownsville residents to the most advanced health care services available in the Rio Grande Valley. Patients at the DHR Health Brownsville will be provided with excellent care provided under the highest standards for quality. However, should a patient require a higher level of care than can be provided at DHR Health Brownsville, through patient transfer, the patient will have direct access to DHR Health's vast offerings of advanced services.

With over 70 specialties and sub-specialties and 600+ physicians on our medical staff required to take emergency call, DHR Health has the most extensive around-the-clock on-call coverage of any hospital in the Rio Grande Valley. DHR Health has continually invested in expanding the availability of advanced treatments and technologies. For example, DHR Health provides:

- The region's first and only Level I Comprehensive Trauma facility with the highest level of orthopedic trauma coverage with the Valley's only orthopedic traumatologist;
- the most comprehensive neurology services, including neuro-intervention, 3 full-time neuro-surgeons, a dedicated neurological Intensive Care Unit (ICU), and the *first* and *only* Certified Comprehensive Stroke Center by The Joint Commission in the RGV;
- the only kidney transplant program in the Rio Grande Valley;
- the area's only structural heart program; and
- the most extensive coverage of any hospital in the region for Ear, Nose and Throat (ENT), Oral-Maxi facial (OMF), and ophthalmology services, to name a few.

DHR Health's main general acute care hospital is a designated Level I Comprehensive Trauma Facility and our health system serves as the flagship teaching hospital for the University of Texas Rio Grande Valley School of Medicine's with 155 accredited training positions in general surgery, family medicine, internal medicine, obstetrics and gynecology, cardiology, gastroenterology, sports medicine, urology, and hospice and palliative care. These are critical services for a high-level trauma center and teaching hospital and their availability substantially increases the level of life-saving and care for the residents of the Rio Grande Valley. With the opening of the DHR Health Brownsville, the residents of Cameron County will have increased access to the Rio Grande Valley's most advanced health care services.

Consequently, the granting of the waiver to allow the DHR Health Brownsville to operate under DHR Health's existing license would not in any way adversely affect the health and safety of hospital patients, employees, or the general public.

(2) Indicate how it was determined that granting of the waiver would not adversely impact the hospital's participation in the federal Medicare program or accreditation by a Centers for Medicare and Medicaid Services-approved organization;

Granting the requested waiver will not adversely impact the hospital's participation in the federal Medicare program or accreditation by The Joint Commission (TJC), the Medicare approved accreditation organization used by DHR Health. Conversely, the granting of the waiver will facilitate the enrollment of the DHR Health Brownsville in Medicare under DHR Health's existing Medicare provider agreement. Operating DHR Health Brownsville under DHR Health's existing license will provide clarity and avoid any potential issues related to the Medicare provider-based regulations and DHR Health's status as a physician-owned hospital.

As a physician-owned hospital, DHR Health is restricted in its ability to expand by the physician self-referral law (Stark).[4] In order to participate in the Medicare program, the Stark law requires physician-owned hospitals to have had a CMS provider agreement as of December 31, 2015 and prohibits existing physician-owned hospitals from acquiring a new provider agreement.[5] Additionally, the Stark law limits the number of operating rooms, procedure rooms, and beds that a physician-owned hospital can operate to the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010,[6] with some exceptions.[7] DHR Health was granted an exception to expand in 2015.[8]

To comply with the Medicare provider-based regulations, DHR Health Brownsville will be enrolled in the Medicare program under DHR Health's existing Medicare provider agreement as a "remote location of a hospital".[9] For the purposes of clarity and avoiding any potential issues, DHR seeks to license DHR Health Brownsville under the same license as DHR Health's inpatient facilities in Edinburg, TX.

(3) Describe how not granting the waiver would impose an unreasonable hardship on the hospital in providing adequate care for patients;

Not granting the 30-mile waiver would impose an unreasonable hardship on the hospital because granting the waiver would avoid potential federal regulatory issues, and granting the waiver while not impacting or implicating the safety of patients, employees or the public.

(4) Describe how the waiver would facilitate the creation or operation of the hospital; and

Granting of the waiver would allow DHR Health to proceed forward with the creation and operation of DHR Health Brownsville by removing regulatory barriers that would not impact the quality of care delivered or the safety of patients, staff, and the general public.

[4] Section 1877 of the Social Security Act, 42 U.S.C. §1395nn.
[5] 42 U.S.C. §1395nn(i)(1)(A).
[6] 42 U.S.C. §1395nn(i)(1)(B).
[7] 42 U.S.C. §1395nn(i)(3).
[8] *See* https://www.federalregister.gov/documents/2015/09/17/2015-23363/medicare-program-approval-of-request-for-an-exception-to-the-prohibition-on-expansion-of-facility.
[9] 42 C.F.R. §413.65(a): "*Remote location of a hospital* means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section….".

(5) Explain how the waiver would be appropriate when balanced against the best interests of the individuals served or to be served by the hospital.

The granting of the 30-mile waiver would be appropriate because it would be in the best interests of the individuals to be served at DHR Health Brownsville by increasing access to care and advanced health care services in the Brownsville, Cameron County, TX area. Additionally, as is expanded on above, granting the waiver would not adversely affect the health and safety of the hospital's patients, employees, or the general public in any manner.

The City of Brownsville, Cameron County, Texas is situated on the U.S.-Mexico southern border in the Rio Grande Valley of Texas. Cameron County is one of the four southern-most counties in Texas along with Hidalgo, Starr, and Willacy. Cameron County has a population of about 425,000.[10] The City of Brownsville, with 183,000 residents, is the largest city in Cameron County.

Applying the 'inpatient acute bed per capita" ratio, a widely-used metric to measure and compare the adequacy of inpatient hospital capacity across regions demonstrates that the Rio Grande Valley, including the City of Brownsville is under-bedded. The average number of inpatient acute beds for the West South Central Region of the country, which includes Texas, Louisiana, Oklahoma, and Arkansas, is 3.48[11]. The Rio Grande Valley, however, falls below the regional ratio.

Rio Grande Valley	Inpatient Acute Care Bed Per Capita	% Below West South Region[12]
City of Brownsville[13]	2.5	-29%
Cameron County[14]	2.6	-26%
Hidalgo County[15]	2.1	-38%

The national average number of acute beds per 1,000 people is 2.4.[16] However, because of disparities in socio-economic and health factors, a more accurate assessment requires a comparison between similarly situated regions. The South West Central Region is comparable to the Rio Grande Valley in important

[10] U.S. Census Cameron County, Texas Quick Facts: https://www.census.gov/quickfacts/cameroncountytexas
[11] Beckers Hospital Review 308 Stats on Acute Care Beds Hospital Referral Centers. https://www.beckershospitalreview.com/patient-flow/308-stats-on-acute-care-beds-by-hospital-referral-region.html
[12] *Id.*
[13] Brownsville has two general acute hospitals, Valley Baptist Medical Center – Brownsville (240 acute licensed beds), and Valley Regional Medical Center (214 acute licensed beds) [DSHS Hospital Directory 03/31.2021] for a population of 183,000 in the City of Brownsville and the many surrounding communities including San Benito, South Padre Island, Los Fresnos, Port Isabel and many others.
[14] Cameron County has four general acute hospitals, Valley Baptist Medical Center – Harlingen (534 acute licensed beds), Harlingen Medical Center (112 acute licensed beds), Valley Baptist Medical Center – Brownsville (240 acute licensed beds), and Valley Regional Medical Center (214 acute licensed beds) [DSHS Hospital Directory 03/31.2021] for a population of 425,000 based on latest US Census estimates.
[15] Hidalgo County has seven inpatient general acute hospitals – DHR Health (363 acute licensed beds), South Texas Health System's hospitals: Edinburg Regional/McAllen Medical/McAllen Heart Hospital/Cornerstone (687 acute licensed beds), Rio Grande Regional (320 acute licensed beds), Knapp Medical Center (220 acute licensed beds), and Mission Regional (254 acute licensed beds) [DSHS Hospital Directory 03/31.2021] for a population of 869,000 based on latest US Census estimates.
[16] *Supra* n. 11.

ways. Texas, Louisiana, Oklahoma, and Arkansas all rank within the top ten states with high rates of diabetes and obesity.[17] Additionally, the other states rank in the top ten states in terms of poverty levels, however, no state-wide poverty level reaches the heights experienced in the Rio Grande Valley.[18] Consequently, given the high rates of chronic disease and poverty levels, it is not surprising that the South Central Region would have a higher need for inpatient acute beds per capita (i.e. the higher rates of poverty and disease, the more need for hospital beds).

The two remaining counties in the Rio Grande Valley are rural, lack access to care, and are low in population. Starr County has approximately 65,000 persons and a small, basic general acute public hospital – Starr County Memorial Hospital (SCMH). DHR Health is affiliated with SCMH and provides emergency department, hospitalist, and general surgery coverage at the hospital to ensure it is able to maintain a higher level of care. Higher acuity patients in Starr County are generally seen in Hidalgo County area hospitals, including DHR Health. However, DHR Health is working with SCMH to increase specialized care in Starr County to reduce the need for residents to travel to Hidalgo County for care. Starr County residents now have access to specialties such as endocrinology, urology, cardiology and outpatient general surgery and orthopedics as a result of the affiliation with DHR Health. Willacy County, in the Northeastern part of the Rio Grande Valley is home to approximately 23,000 persons and has no hospitals. Generally, Willacy County patients are seen in Cameron County hospitals.

The Rio Grande Valley, and Brownsville in particular, has a shortage of inpatient acute beds due to a variety of factors, including, but not limited to:

1. Health Factors
    a. Epidemic of diabetes (30%, with another 32% pre-diabetic), combined with high rates of obesity (51%) and related health issues, including cardiovascular, liver, peripheral artery and chronic renal disease, and retinopathy, and behavioral issues.
2. Access to Health Care Factors
    a. High Poverty Rate (40%)
    b. Highest Uninsured Rate in the Country (29% - 33%)
    c. Health Professional Shortages (1,700+ physician shortage, and nurse shortages)
3. Growing Population and Needs

The population of Brownsville, and the Rio Grande Valley in general, is sicker, more impoverished, and faces significant obstacles to access care. The high rates of poverty and chronic diseases translate into a situation where a large proportion of the population needs access to preventative medical care and disease management yet cannot afford health insurance or out-of-pocket costs.

Additionally, many residents of Cameron County lack accessible transportation options. The area also faces health professional shortages, further limiting access. DHR Health is the primary teaching site for the University of Texas Rio Grande Valley School Of Medicine, and as their natural partner, we want to continue to increase access to health care by expanding residency programs to the Brownsville area. These factors result in many patients foregoing preventative care or disease management and seeking care while in crisis via hospital emergency rooms, which increases the overall cost of treatment as well as the demand and need for inpatient acute beds

[17] https://www.stateofobesity.org/diabetes/
[18] https://www.usnews.com/news/best-states/slideshows/states-with-the-highest-poverty-rates-in-the-us?onepage

Cameron County is growing and is **expected to add an additional 40,000 residents** within the next five years, the majority of which will be in Brownsville. Additionally, two new major projects currently in development for Brownsville will generate thousands of new jobs, billions of dollars in economic impact and substantially increase the Brownsville area's population.

Consequently, the City of Brownsville is in need of additional inpatient acute care beds due to an epidemic of chronic disease, and a growing and impoverished population that lacks sufficient access to preventative medical care to manage their disease. Data indicates that both the city and region are falling behind similarly situated regions in terms of acute inpatient beds per capita. Granting the waiver will allow DHR Health to proceed forward and add additional bed capacity in Brownsville and increase access to care in a much underserved area.

Congress of the United States
House of Representatives
Washington, D.C. 20515

July 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Physician-Owned Hospital Regulation Concerns

Dear Administrator Brooks-LaSure:

We write to reiterate our concerns relating to the regulations amended in the Calendar Year (CY) 2021 Hospital Outpatient Prospective Payment System (HOPPS) rule that modified needed regulations relating to Physician Owned Hospital (POH) expansions. On October 21, 2020, we wrote to the Centers for Medicare & Medicaid Services (CMS) opposing the CY 2021 HOPPS proposal to increase opportunities for further expansions of POHs, which we believe flouted Congressional intent to limit expansions of POHs except in certain circumstances.[1] Unfortunately, CMS finalized its proposal and added to the circumstances for which a POH could apply for an expansion. We urge CMS to follow Congressional intent reconsider the recent changes to the expansion prohibition for POHs.

As discussed in our 2020 letter (enclosed), the challenges with POHs have been long documented by the Department of Health and Human Services (HHS) Office of Inspector General (OIG)[2] and the Medicare Payment Advisory Commission (MedPAC).[3] POHs were found to cherry-pick healthier more-lucrative patients, serve fewer Medicaid beneficiaries, increase costs, and negatively impact quality of care. As such, Congress statutorily required a moratorium on new POHs and limited their ability to expand.

[1] Letter from Richard E. Neal, Chair, Committee on Ways and Means & Frank Pallone, Chair, Committee on Energy and Commerce, to Seema Verma, Administrator, Ctrs. For Medicare & Medicaid Servs. (Oct. 21, 2020), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/POH_Letter%20to%20CMS_10%2021%2020_FINAL_signed.pdf.
[2] Office of Inspector General, *Physician Owned Specialty Hospitals' Ability to Manage Medical Emergencies,* U.S. DEPT. OF HEALTH & HUMAN SERVS. (Jan. 2008), https://oig.hhs.gov/oei/reports/oei-02-06-00310.pdf.
[3] *Report to the Congress: Physician-Owned Specialty Hospitals,* MEDICARE PAYMENT ADVISORY COMMISSION (Mar. 2005), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar05_SpecHospitals.pdf.

Section 1877 of the Social Security Act prohibits the expansion of POHs, stating that "the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after the date of the enactment of… [the Affordable Care Act] is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of such date."[4] While the law allows for hospitals to apply for exceptions, we are concerned that the rule lowered the standard to be considered a high-Medicaid facility and removed limitations on the size and frequency of expansions.

Congress intended to prohibit POH expansion except in limited circumstances and the current policy that allows for further expansions deviates from Congressional intent. We urge you to reconsider the amendments to POH regulations as finalized in December 2020.

Sincerely,

Richard E. Neal
Chair
House Committee on Ways and Means

Frank Pallone
Chair
Committee on Energy and Commerce

[4] Social Security Act § 1877 Limitation on Certain Physician Referrals.

Congress of the United States
House of Representatives
Washington, D.C. 20515

October 21, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, DC 20201

Re: Notice of Proposed Rule Making Entitled, "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals" 85 Fed. Reg. 48772 (August 12, 2020)

Dear Administrator Verma:

We write to express our strong concerns regarding the proposal to modify the regulatory framework currently limiting the expansion of Physician Owned Hospitals (POHs) and ask that you not include this proposal in the final rule. As you know, Congress placed a moratorium on the expansion of POHs as a result of concerns with these facilities cherry-picking patients, self-referring, increasing costs and utilization, and adversely affecting quality of care. Such concerns have previously been highlighted by the Medicare Payment Advisory Commission (MedPAC) and the Office of the Inspector General (OIG).[1,2] Under current law, a POH must meet certain reasonable tests to expand its capacity. The Centers for Medicare & Medicaid Services' (CMS) proposal would roll back the agency's current policy by eliminating requirements on the frequency and size of expansion for certain POHs; and it would effectively eviscerate the statutory moratorium on expansion. We urge you to reconsider this proposal because of its potential to exacerbate existing inequities and further erode the health care safety net in underserved communities.

[1]Medicare Payment Advisory Commission. *Physician-Owned Specialty Hospitals* (March 2005). (www.medpac.gov/docs/default-source/reports/Mar05_SpecHospitals.pdf?sfvrsn=0)
[2] US Department of Health and Human Services, Office of Inspector General. Physician Owned Specialty Hospitals' Ability to Manage Medical Emergencies. Washington, DC: US Department of Health and Human Services (2008).

No justified reason for the change. CMS proposes this change in policy as a part of its "Patients Over Paperwork" initiative. While it asserts that current regulations "impose unnecessary burden on high Medicaid facilities," CMS also states that it continues to believe that current regulations "are consistent with the Congress' intent to prohibit expansion of physician-owned hospitals generally." In addition, the Proposed Rule neither points to any particular high Medicaid facility that has been or would be harmed under current law, nor does it describe the nature of the alleged "burden." Most importantly, it also fails to explain how this change would better serve Medicare or Medicaid beneficiaries.

Misleading analysis of who is affected. While CMS claims that only one facility per year will request the proposed expansion exception, another analysis estimates that approximately 24 facilities currently or could soon qualify as high Medicaid facilities. CMS should provide a complete analysis of the number of POHs that currently qualify or may soon qualify for this exception as well as the Medicaid discharge percentages of these facilities. Such analysis is needed to determine the impact of this proposal.

Proposed test for expansion eviscerates the statutory moratorium and provides opportunity for gaming. According to the proposal, once a hospital meets the definition of a high Medicaid facility, there will be no limits on size, scope, or duration of its expansion. Facilities could exponentially increase beds and services offered, undermining the patient caseload and mix of community facilities, skimming off the profitable cases, and leaving those deemed to be less financially desirable for other providers in the community. POHs would no longer be limited to the confines of their main campus and, thus, could expand to off-campus locations as well. While CMS proposes this POH exception for high Medicaid facilities, this proposal could impact all facilities in a community. The proposal does not link the time during which the exception is granted and the time of expansion, meaning that a POH could begin and complete its expansion after it no longer qualifies as a high Medicaid facility. Whether a facility qualifies as high Medicaid is relative, and some facilities that might qualify have quite low overall Medicaid numbers. Additionally, any facility that expands can do so without any requirement to maintain its high Medicaid status. Perversely, this proposal could jeopardize sustained operations of facilities that actually make caring for Medicaid patients and the uninsured their mission in the very communities that depend on them the most.

Proposed elimination of community input is concerning. Finally, CMS states in the Proposed Rule that obtaining community input on expansion "could delay or add complexity" to the approval of an expansion request and therefore proposes eliminating the opportunity for community input. This proposed elimination of community input in the POH expansion process undermines Congressional intent and would prevent important voices from participating in the process. CMS does not identify any instances in which the requirement to seek community input has prolonged the application process. Patients and communities deserve a voice in the design of their local health care system, and we strongly oppose any removal or limitation of the community input requirement.

Simply put, CMS' proposal to allow POHs to expand without guardrails is detrimental to the health of the very communities they serve, and contrary to Congressional intent. We urge you to reconsider this ill-advised proposal.

Thank you for your timely attention to this important matter.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce

Select Financial and Operating Characteristics of Physician Owned Hospitals and Non-Physician Owned Hospitals

Dobson | DaVanzo

Dobson | DaVanzo

Al Dobson, Ph.D.
Kennan Murray, M.P.H.
Randall Haught
Sung Kim

March 30, 2016

Dobson | DaVanzo recently examined select operating and financial characteristics of hospitals in categories defined by hospital ownership[1]. This fact sheet provides descriptive statistics for physician owned hospitals (POH) and non-physician owned hospitals, as shown in Exhibit 1 and Figures 1 through 7. Exhibit 1 provides these statistics in tabular form, while Figures 1 through 7 present the data graphically.

In this fact sheet, POH are defined as hospitals on the Physician Hospitals of America member hospital list as of March 30, 2016. Non-POH are defined as acute care hospitals that fall under the inpatient hospital prospective payment system (IPPS) defined under Section 1886(d) of the Social Security Act. We identified 68 POH and 3,116 non-POH to be included in the table using the FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File and FY 2014 Medicare Cost Reports.

The data were drawn from the FY 2014 Medicare Cost Reports, FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File, and 2014 CMS 100% Standard Analytic File Limited Data Set (LDS) for inpatient and outpatient services. Specific data sources for each variable are provided in the Appendix.

The statistics included in Exhibit 1 and Figures 1 through 7 represent select hospital financial and operating characteristics. They illustrate the differences between POH and non-POH on multiple dimensions.

Exhibit 1: Summary Statistics for Physician Owned Hospitals (POH) and All Other Medicare IPPS Hospitals (Non-POH)[2] from the 2014 Medicare Cost Reports, 2014 CMS 100% Standard Analytic File Limited Data Set, and 2016 Hospital IPPS Final Rule and Correction Notice Public Use File

	POH	Non-POH
Number of Hospitals	68	3,116
Hospital Operating Characteristics		
Medicaid Discharges as a Percent of Total	2.2%	12.4%
Percentage of Hospitals in Hospital Group with Medicare Maximum Readmission Penalty of 3%	10.3%	0.9%
Percentage of Medicare Inpatient Claims with Emergency Department Services	21.1%	72.4%
Percentage of Medicare Inpatient Claims for Patients with Dual Eligibility	12.2%	27.6%
Mean Number of CC/MCCs[3] per Medicare Claim	1.3	2.4
Hospital Financial Characteristics		
Total All-Payer Margin (Average)	21.0%	8.0%
Uncompensated Care Costs as Percent of Total Hospital Expense	1.6%	3.9%

[1] This study was commissioned by the Federation of American Hospitals and the American Hospital Association.

[2] Physician owned hospitals were identified using the Physician Hospital of America member hospital list as of March 30, 2016. We note that four hospitals on this list were not included in the analysis because Medicare provider numbers could not be found. Non-physician owned hospitals were identified using the FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File and FY 2014 Medicare Cost Reports.

[3] CC is defined as complicating or comorbid condition. MCC is defined as a major complicating or comorbid condition.

Figure 1. Medicaid Discharges as Percent of Total Discharges for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

Figure 2. Percentage of Hospitals with Medicare Maximum Readmission Penalty of 3% for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

Figure 3. Percentage of Medicare Inpatient Claims with Emergency Department Services for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

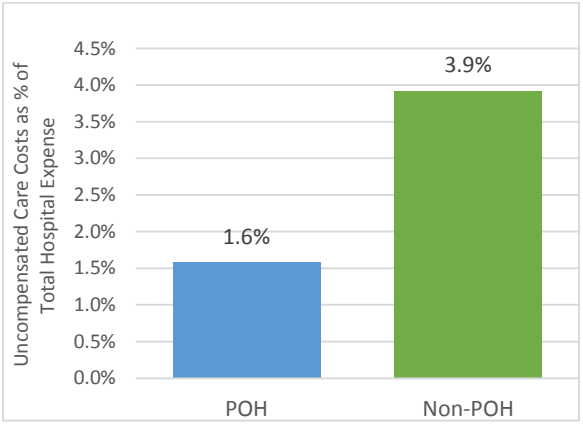
Figure 4. Percentage of Medicare Inpatient Claims for Patients with Dual Eligibility for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

Note: Data were drawn from the FY 2014 Medicare Cost Reports, 2014 CMS 100% Standard Analytic File Limited Data Set for inpatient and outpatient services, and FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File. Physician owned hospitals were identified using the Physician Hospitals of America member hospital list as of March 30, 2016. Non-physician owned hospitals were identified using the FY2016 IPPS Final Rule and Correction Notice Impact Public Use File and FY2014 Medicare Cost Reports.

Figure 5. Mean Number of CC/MCCs per Medicare Claim for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

Figure 6. Average All-Payer Margin for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals

Figure 7. Uncompensated Care Costs[4] as Percent of Total Hospital Expense for Physician Owned and Non-Physician Owned Medicare IPPS Hospitals



Note: Data were drawn from the FY 2014 Medicare Cost Reports, 2014 CMS 100% Standard Analytic File Limited Data Set for inpatient and outpatient services, and FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File. Physician owned hospitals were identified using the Physician Hospitals of America member hospital list as of March 30, 2016. Non-physician owned hospitals were identified using the FY2016 IPPS Final Rule and Correction Notice Impact Public Use File and FY2014 Medicare Cost Reports.

[4] Uncompensated care costs are defined as Line 30 from the S-10, which includes the cost of charity care plus the cost of non-Medicare and non-reimbursable Medicare bad debt expense.

Appendix: Data Sources Used to Calculate Summary Statistics

Source: FY 2014 Medicare Cost Reports			
Data Point	Worksheet	Line	Column
Medicaid Discharges as a Percent of Total	S-3, part I	14	14
Total discharges	S-3, part I	14	15
Net patient revenue	G-3	3	1
Other revenue	G-3	25	1
Total revenue	Sum of Net patient and Other revenue		
Operating expense	G-3	4	1
Other expense	G-3	28	1
Total expense	Sum of Operating and Other expense		
Uncompensated care	S-10	30	1

Source: 2014 CMS 100% Standard Analytic File Limited Data Set		
Data Point	File	Variable(s)
Percentage of Medicare Inpatient Claims with Emergency Department Services	FY2014 Inpatient Claims File, FY2014 Inpatient Revenue File. ER claims were defined as having charges in revenue centers (0450-0459 or 0981).	REV_CNTR, REV_CNTR_TOT_CHRG_AMT
Mean Number of CC/MCCs per Medicare Claim	FY2014 Inpatient Claims File, FY2014 CC File, FY2014 MCC File	ICD_DGNS_CD1 - ICD_DGNS_CD25

Source: 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File	
Data Point	Variable(s)
Medicare readmission penalty	Readmission Adjustment Factor

Medicaid

September 2022

As of April 2022, 88.3 million people were enrolled in Medicaid and CHIP. From February 2020 to April 2022, Medicaid enrollment increased by 17.0 million enrollees (a 23.9% increase), with enrollment increases seen in every state, after many Americans lost their jobs and livelihoods due to COVID-19 economic shutdowns.

Regulatory Update

CMS Proposes Rule to Streamline Medicaid and CHIP Eligibility and Enrollment

- In August 2022, CMS issued a proposed rule to streamline Medicaid and CHIP eligibility and enrollment. The proposal aims to make it easier for millions of people to enroll in and maintain Medicaid and CHIP coverage. The proposed rule would simplify the enrollment process and maintain continuity of coverage for eligible beneficiaries. CMS estimates that this proposed rule would remove barriers to enrollment and increase the number of eligible individuals who obtain coverage and are continuously enrolled in Medicaid and CHIP.

Biden Administration Directives to States on Continuous Enrollment Requirements

- In November 2021, CMS released strategic guidance to states to help maintain coverage of eligible individuals at the end of the continuous enrollment requirements, enacted under the *Families First Coronavirus Response Act* (FFCRA) through the duration of the COVID-19 public health emergency (PHE). The strategic guidance provides states with actionable steps to form proactive plans to restore normal operations and at the same time help maintain continuous coverage for eligible individuals enrolled in Medicaid, CHIP, and the Basic Health Plan (BHP).
- In March 2022, CMS provided additional guidance on ways to unwind state programs that will need to be tracked at the individual state level.

Medicaid Eligibility for 12-months Postpartum

- As of August 25, 2022, 24 states and the District of Columbia have implemented the extension of postpartum Medicaid and CHIP coverage to 12-months after pregnancy through the American Rescue Plan. CMS has approved another 10 states' extensions, and both Texas and Wyoming have proposed limited coverage extensions.

Department of Homeland Security Public Charge Final Rule

- On September 8, 2022, the Department of Homeland Security (DHS) issued a final rule to exclude enrollment in Medicaid and other public benefit programs from the criteria used to make determinations on public charge inadmissibility. The proposed rule reverses the 2019 public charge rule that denied legal immigrants permanent resident status if they received or were expected to receive Medicaid among other public benefits.

- In April 2022, FAH submitted a letter applauding the DHS for the proposal and cited past public comments stating, "policies that discourage eligible residents from seeking medical benefits can hurt health outcomes and distort health spending."

Medicaid Work Requirements

- The Biden Administration completed its process to withdraw Medicaid work requirement waivers approved by the Trump Administration. Last year CMS sent letters notifying Arizona, Arkansas, Georgia, Indiana, Michigan, New Hampshire, Ohio, South Carolina, Utah, and Wisconsin of its final decision to withdraw work requirement waiver authorities in these states. In August 2022, a federal judge reinstated Georgia's work requirement after CMS withdrew the state's Section 1115 approval in December 2021. The Administration has 60 days to appeal the decision.

State Action on Medicaid Expansions

- To date, 39 states have adopted Medicaid expansion under the Affordable Care Act. Other states are considering such expansion:
    - In June, the North Carolina Senate passed a Medicaid expansion bill. If the state House fails to approve Medicaid expansion before the end of September, North Carolina could lose more than $1 billion in federal payments.
    - Mississippi's Medicaid expansion approval has been halted following a Mississippi Supreme Court decision that the citizen-sponsored ballot initiative process is invalid. The effort to place the expansion initiative on the November 2022 ballot was led by the Mississippi Hospital Association.
    - In November 2022, a constitutional amendment to expand Medicaid will be on the ballot in South Dakota.

Current and Future Payments

Phase 4 and ARP Rural Distributions - Payment Status

Phase 4 Payments to Date

- Funding distributed: Approximately $15.4 billion
- Providers paid: More than 90,000
- Applications processed: 99%
- Public dataset of providers who received a payment from the Provider Relief Fund (including Phases 1-3 and Targeted Distributions) and attested to the terms and conditions. Phase 4 payments will be reflected in this dataset.
- State-by-state breakdown of Phase 4 payments to date

ARP Rural Payments to Date

- Funding distributed: More than $8.3 billion
- Providers paid: More than 47,000
- Applications processed: 100%
- Public dataset of recipient names, locations (city, state, ZIP code), and payment amounts
- State-by-state breakdown of ARP Rural payments to date

Note: Providers should be aware that payment notifications are sent from the email address UHG_HRSA@ProviderEmail.uhc.com. Providers are advised to add this address to their "Safe Sender" list and check their "Spam" and "Junk Mail" folders regularly to ensure that they do not miss payment notifications or related correspondence.

Phase 4 and ARP Rural Distributions

On December 16, 2021, HRSA began distributing Phase 4 General Distribution payments. While the vast majority of applications have now been processed, the remaining applications require additional review as part of the risk mitigation and cost containment safeguards outlined in the Phase 4 methodology. All payments are accompanied by email notifications to the providers whose applications have been processed.

On November 23, 2021, HRSA began distributing ARP Rural payments. Applicants receiving payments have received both an email notification and a paper letter with additional detail on their aggregate payment, including individual payment amount(s) attributable to any eligible subsidiary billing TINs included in their application.

Applicants that HRSA has determined will not receive a payment will receive email notifications that include the primary reason for their payment determination. Providers who have not yet received any communication regarding their Phase 4 and/or ARP Rural payment determination will be notified as soon as HRSA completes the review and processing of their application.

Within 90 days of receiving a payment, recipients must sign an attestation confirming receipt of the funds and agreeing to the Terms and Conditions of payment by re-entering the Provider Relief Fund Application and Attestation Portal. Should a recipient choose to reject the funds, they must still complete the attestation to indicate this and then return the funds within 15 calendar days.

For more information on how Phase 4 and ARP Rural payments are calculated, please consult the payment methodology webpage. Providers with questions about the Phase 4 and ARP Rural application process or who need payment support should contact the Provider Support Line at 866-569-3522 (for TTY dial 711).

HRSA COVID-19 Uninsured Program Claims Submission Deadline FAQs

Date Last Updated: April 2022

Why has the HRSA COVID-19 Uninsured Program stopped accepting claims?

The HRSA COVID-19 Uninsured Program (UIP) stopped accepting claims for testing and treatment at 11:59 p.m. on March 22, 2022, and claims for vaccine administration at 11:59 p.m. on April 5, 2022 due to a lack of sufficient funds.

Any testing and treatment claims submitted in the Portal after March 22, 2022, will not be adjudicated for payment.

Any vaccine administration claims submitted in the Portal after April 5, 2022, will not be adjudicated for payment.

When was the final deadline to submit claims for reimbursement?

The deadlines to submit claims for each category of service are as follows:

- **Testing claims:** March 22, 2022, at 11:59 p.m. ET
- **Treatment claims:** March 22, 2022, at 11:59 p.m. ET
- **Vaccine administration claims:** April 5, 2022, at 11:59 p.m. ET

Any testing and treatment claims submitted in the Portal after March 22, 2022, will not be adjudicated for payment.

Any vaccine administration claims submitted in the Portal after April 5, 2022, will not be adjudicated for payment.

Will eligible claims submitted by the deadline be reimbursed?

Claims submitted by the deadline for each category of service will be adjudicated and paid subject to their eligibility and the availability of funds.

What other resources are available to providers and/or uninsured individuals after the Uninsured Program winds down?

Alternative resources for uninsured individuals who need COVID-19 services or other health care coverage include:

- Medicaid enrollment
- Healthcare marketplace enrollment
- COVIDtests.gov
- HRSA.gov – Find a Health Center

Note: per the Centers for Disease Control and Prevention's Requirements for COVID-19 Vaccination Program Providers, providers must continue to administer COVID-19 vaccines at no out-of-pocket cost to recipients.

I submitted claims before the submission deadline was announced on March 15, 2022. Will those claims be paid?

Claims submitted by the deadline for each category of service will be adjudicated and paid subject to their eligibility and the availability of funds.

What will happen if I submit a testing or treatment claim after March 22, 2022?

Testing and treatment claims submitted after the deadline will NOT be adjudicated. Regardless of whether the system shows your claim as having being received, no testing or treatment claim submitted after March 22, 2022, will be processed.

Will eligible claims submitted by the deadline be processed and reimbursed within the typical 30 business days?

HRSA anticipates that claims submitted by the deadline may take longer than the typical 30 business day timeframe to process as HRSA works to adjudicate and pay claims subject to their eligibility and the availability of funds.

How should health care organizations bill for the COVID-19 related testing and treatment services they provide to uninsured individuals?

HRSA is unable to provide general legal advice regarding a provider's billing practices for testing and treatment services for the uninsured beyond the scope of the HRSA COVID-19 Uninsured Program.

How does exhaustion of funding for the Uninsured Program and Coverage Assistance Fund affect providers participating in the CDC COVID-19 Vaccination Program?

On April 5, 2022, CDC issued the following statement:

Due to the lack of supplemental funding from Congress, HRSA stopped accepting claims for reimbursement of costs associated with administering COVID-19 vaccines to uninsured and underinsured individuals as of 11:59 PM ET on April 5, 2022. CDC strongly encourages providers to stay in the CDC COVID-19 Vaccination Program and CDC expects participating providers will continue to administer these lifesaving vaccines at no cost to patients to ensure equitable access for all individuals. Where CDC becomes aware of a provider engaging in any

Charles N. Kahn III
President and CEO

July 22, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Subject: Proposed Changes to CMS 2552-10 Hospital and Health Care Complex Cost Report (OMB Control Number 0938–0050)

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, D.C and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to comment on proposed revisions to the Hospital and Health Care Complex Cost Report, Form CMS-2552-10 (OMB Control Number 0938– 0050), following CMS' Notice, published in the Federal Register on June 22, 2022 (87 Fed. Reg. 37,339).

I. Worksheet S-2, Part I, Lines 24 and 25 and Exhibit 3A (DSH Eligible Medicaid Days)

CMS instructs hospitals to support the Medicaid days on Worksheet S-2, Part I, line 24 or line 25 by completing new Exhibit 3A. The FAH urges CMS to simplify the reporting of Medicaid days by consolidating the six columns in lines 24 and 25 into a single column for all Medicaid days and only require the completion of a single copy of Exhibit 3A for all Medicaid days reported. Although lines 24 and 25 have been included for some time, the FAH questions the necessity of separately reporting on specific categories of Medicaid days in six columns (Medicaid FFS In-State Paid Days, Medicaid FFS In-State eligible unpaid days, Medicaid Out of State days paid, Medicaid Out of State ineligible days unpaid, Medicaid HMO days, and Medicaid other). Refining the Medicaid days data into the six categories for reporting purposes does not further accurate

payment and imposes a significant and unnecessary administrative burden on providers. This administrative burden would be compounded by new Exhibit 3A because many providers do not store claims data broken out by the six categories in columns 1 through 6 of lines 24 and 25.

The FAH, therefore, requests that CMS eliminate the separate columns for lines 24 and 25 to streamline reporting of Medicaid days and to instruct providers to only complete one version of new Exhibit 3A. If CMS maintains the separate columns in lines 24 and 25, the FAH requests that CMS permit providers to complete a single Exhibit 3A that crosswalks each entry to the six columns in lines 24 and 25. The FAH also asks that CMS clarify that column 5 (Medicaid HMO days) includes both in-state and out-of-state Medicaid HMO days and includes both paid and HMO-eligible but unpaid Medicaid HMO days.

Additionally, the FAH makes the following recommendations regarding new Exhibit 3A:

- **Patient Name (Columns 1-2).** Exhibit 3A requires hospitals to separately report the patient's last name in column 1 and first name in column 2. Some providers, however, maintain claims data showing the patient's full name in a single field. Although CMS' response to stakeholder comments that it declined to combine these columns in order to promote consistency among various proposed exhibits, the FAH asks CMS to clarify whether a provider can provide a listing of Medicaid eligible days that alters the presentation and order of data by combining the patient name into a single field. Having to break the field into two columns would be an administrative burden for these providers.

- **Medicaid Recipient ID Number (Column 7).** The instructions for new Exhibit 3A ask for the Medicaid recipient identification number in column 5. However, hospitals may not have Medicaid identification numbers for Medicaid recipients. For example, Medicaid recipients covered by Medicaid managed care organizations (MCOs) may not have an identification number because MCOs frequently use their own HIC or insurance identification number. ***The FAH therefore asks CMS to clarify that a hospital may report any alternative identification number used by the Medicaid MCO in the absence of a Medicaid beneficiary identification number.*** In addition, the FAH is concerned that hospitals in some states may be unable to fully complete Exhibit 3A because some state Medicaid plans do not return recipients' Medicaid identification numbers to providers, and this data will not be available to providers in the event that a recipient does not provide their Medicaid identification number. Because eligibility matches can be (and, in past audits, have been) completed using social security numbers and birth dates—***the FAH requests that CMS permit the reporting of alternative data (including social security numbers or birth dates) in column 5 where the Medicaid recipient identification number is not available***. In the alternative, the FAH requests that CMS require state Medicaid plans to provide Medicaid identification numbers to providers.

- **State Plan Eligibility Code (Column 8).** The instructions for column 8 require hospitals to enter the applicable state plan eligibility code number (if available) and to report additional eligibility codes in column 18, but this information is

burdensome to supply and provides no apparent value. In fact, because eligibility codes are variable between states, this data would not even be standardized across providers. ***Therefore, the FAH urges CMS to delete column 8 from Exhibit 3A as unnecessarily burdensome.***

- **Newborn Baby Days (Column 12).** Many babies have complications with birth that result in a stay with a concurrent and non-concurrent portion. The instructions specify that, for a newborn baby born to a Medicaid eligible mother, the number of newborn baby days occurring prior to the mother's date of discharge (the concurrent portion of the stay) is reported in column 12, and that the newborn baby days occurring after the mother's discharge (the non-concurrent portion of the stay) is reported on a separate line in column 10. The FAH is concerned that reporting the concurrent and non-concurrent days separately in two lines would create a significant administrative burden for providers and increases the risk of errors (*e.g.*, duplication of days or total eligible days exceeding the total length of stay). Rather, the FAH urges CMS to instruct providers to report the entire stay of the newborn baby (both the concurrent and non-concurrent portions) in one number in column 12 and to create a separate column to identify the newborn baby days from the non-concurrent portion of the stay. Determining and reporting the total newborn baby days and the number of non-concurrent newborn baby days in a single column provides the same information, but in a manner that reduces unnecessary burden and decreases the risk of errors.

- **Primary Payer (Column 13) and Secondary Payer (Column 14).** The instructions for columns 13 and 14 require hospitals to enter the name of the patient's primary and secondary insurer or other payer. This data is not necessary to confirm Medicaid eligible days, and the ***FAH recommends that CMS reduce the regulatory burden associated with Exhibit 3A by removing these unnecessary columns.*** If CMS does not remove these columns, the FAH seeks clarification as to whether these columns include information for payers that failed to make payment for the stay.

II. Worksheet S-2, Part I, Lines 88-89 (TEFRA Adjustment Date)

CMS proposes to add lines 88 and 89, including column 2 to line 89, which requests the effective date for the provider's permanent adjustment to the target amount per discharge under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). ***The FAH requests that CMS delete column 2 from new line 89*** because some hospitals may not know the specific date on which the permanent adjustment was granted and CMS already has this information. The proposed instructions for line 89 specify that the requested date is for the cost reporting beginning date for which the permanent adjustment was effective. In many cases, the permanent adjustments to the TEFRA targets were granted more than a decade ago. Those individuals familiar with the circumstances of how and when the hospital received the adjustment have left the organization. Meanwhile, because CMS has this information, the inclusion of column 2, line 89 is unnecessary. ***In the alternative, CMS should require that the MAC provide the information requested in line 89 to any requesting provider.***

III. Worksheet S-2, Part I, Line 123 (Purchased Administrative Services)

The FAH urges CMS to remove proposed line 123 from Worksheet S-2, Part I because this addition to the cost report would impose a significant and unnecessary administrative burden on providers without providing data necessary for determining the amount of payments due the provider. As modified, line 123 would require providers to report whether the majority of professional services expenses were purchased from an unrelated organization located in a core-based statistical area (CBSA) outside of the main hospital CBSA. Hospitals widely use purchased legal, accounting, tax preparation, bookkeeping, payroll, and management consulting services and do not track the percentage of services that are purchased from unrelated organizations, let alone whether the unrelated organization is in the main hospital's CBSA. It is also unclear when an unrelated organization would be considered to be located in the main hospital CBSA for purposes of proposed line 123—in many instances, organizations providing these services may have a local office in the main hospital's CBSA but, in light of the complexity of the tax, accounting, and legal rules applicable to providers, will leverage staff resources outside the CBSA to provide the requisite level of expertise on individual projects.

Overall, the costs imposed by this data element (even with the modification to report whether the proportion is more or less than half instead of the exact percentage) would be vastly disproportionate to the value of the data collected. As such, the FAH strongly opposes the addition of line 123 and urges CMS to remove it from Worksheet S-2.

IV. Worksheet S-2, Part II, Exhibit 2A (Listing of Medicare Bad Debts)

A. Flexibility, Beneficiary Name (Columns 1 & 2) and Medicaid number (Column 7)

The FAH requests the CMS permit providers flexibility to alter the presentation and order of data reported in Exhibit 2A and to include additional information and data elements where appropriate. Updating provider templates to present these data elements in the exact order and with identical wording would be administratively burdensome and impose unnecessary costs on providers. For example, some providers normally have recoveries listed in a separate tab, and if they are required to conform to the format of Exhibit 2A, columns 18 and 19 on the new template may have missing information if years have passed since the provider claimed the initial bad debt. In addition, updating current templates that are not separated by inpatient and outpatient would be burdensome, and the FAH requests confirmation as to whether providers have the ability to report Medicare bad debts without separate listings for inpatient and outpatient services.

Along these lines, the FAH notes that Exhibit 2A does not include columns for reporting non-allowable portions, which need to be taken into consideration in order to compute the amount of the patient responsibility. The Exhibit does not include columns for non-covered items and services, such as self-administered drugs and professional fees. Additional patient payments may be proportionally applied to these items, but without this information, and this data would aid in substantiating the allowable bad debt amount in these situations. The flexibility to modify the form and fields of Exhibit 2A, as described above, would enable providers to report this information where appropriate.

For the same reasons explained above with respect to Exhibit 3A, ***the FAH requests CMS clarification that a provider may combine the patient name into a single field and furnish the alternative identification number used by the Medicaid MCO in the absence of a Medicaid beneficiary identification number.*** Likewise, the FAH requests that CMS make a corresponding change to the instructions to Exhibit 2, column 4 so that alternative identifiers may be used where no Medicaid identification number is available.

B. Collection Effort Ceased Date (Column 16)

Column 16 on new Exhibit 2A requires reporting of the "date all collection efforts ceased, both internal and external, including efforts to collect from Medicaid and/or from a state for its cost sharing liability." ***The FAH urges CMS to remove this column as unnecessary.*** In many instances, this date is the same date that will be reported in column 15 (return date from collection agency) and/or column 17 (Medicare write off date), making column 16 largely redundant. In addition, because providers do not currently report on the Medicaid denial date, reporting in column 16 will necessitate another burdensome process change to gather and provide this information.

C. Medicare Bad Debt Write-Off Date (Column 17)

It is the FAH's understanding that the write-off date cannot be earlier than the latest date reported in columns 14, 15, or 16, but the FAH requests that CMS clarify in the instructions that a provider is not otherwise limited in the write-off date (*i.e.*, the Medicare bad debt write-off date may be later than the dates reporting in columns 14, 15, and 16). ***In addition, the FAH requests that CMS address differences in the write-off date and write-off effective date for correct MAC misunderstandings of hospital operations and accounting.*** In some cases, a provider might have a Medicare year end of December 31 with a post-close period through January 4. Bad debts written off in this post-close period would still have an expense effective date of December 31, which is the actual write off date recorded on the general ledger for the provider cost reporting period in question, and the bad debt in these situations should still be allowed in the period that the expense is realized.

D. Current Year Payments Received (Columns 22 & 23)

Exhibit 2A includes new data fields on the amount and source of any deductible or coinsurance payments received from or on behalf of the Medicare beneficiary during the cost reporting period, before the account was written off. ***The FAH requests the elimination of these columns because payments related to the Medicare beneficiary deductible and coinsurance balance will often occur in prior year(s) and the separate reporting of prior and current year payments adds complexity and administrative burden without providing commensurate value.***[1] Instead, the FAH recommends replacing this column with a field to report the unpaid deductible and coinsurance amounts at the time of the Medicare write-off date reported in column 24. During an audit, the MAC would still be able to properly validate the unpaid deductible and

[1] In addition, the FAH requests a corresponding change to strike "less any payments in columns 18 and 22" from the instructions for Allowable Bad Debts reported in column 24.

coinsurance balance against the detailed payment history as part of the normal audit review process for bad debt amounts.

II. Worksheet S-10

A. Introduction

The FAH supports CMS' addition to the first paragraph of the instructions for Worksheet S-10 of a sentence clarifying that "CMS does not mandate the eligibility criteria that a hospital uses under its financial assistance policy."

B. Medical Necessity (definition of charity care and uninsured discounts, line 20, line 25.01, and Exhibit 3B columns 6, 14 and 18)

The revised definition of "Charity Care and Uninsured Discounts" includes a reference to medical necessity that invites confusion and potential arbitrary disallowances, and similar references are included in the instructions for lines 20 and 25.01 as well as columns 6, 14, and 18 of Exhibit B. ***The FAH requests that CMS strike the addition of "medically necessary" from the definition and other instructions***. Under the revised definition, charity care and uninsured discounts must result from a hospital's policy to provide all or a portion of "medically necessary health care services" free of charge to patients who meet the hospitals charity care policy or financial assistance policy, and the notion of medical necessity is incorporated in other instructions. As a general matter, ***Medicare cost report auditors are not clinicians and will not know the underlying clinical details of a case, and the FAH is concerned that these new references to medical necessity may give rise to inappropriate reviews of medical necessity, diverting both hospital and auditor resources without improving the accuracy of the data reported in Worksheet S-10.***

C. "If Such Inclusion is Specified" (lines 20 & 25, and Exhibit 3B)

The revisions to the instructions for Worksheet S-10 also includes the qualification that charges can only be included in particular fields "if such inclusion is specified in the hospital's charity care policy or FAP and the patient meets the hospital's policy criteria." ***The FAH requests that CMS remove this ambiguous language from the instructions for lines 20 and 25 and Exhibit 3B to reduce the risk of arbitrary disallowances and unnecessary administrative burdens.*** As written, this language could prompt some auditors to erroneously interpret and extend this language to require unreasonably specific and granular provisions in charity care and financial assistance policies. An overly stringent interpretation of this term could result in the particularized description of a wide variety of clinical and coverage scenarios in hospital policies to ensure that each patient who meets the financial criteria to receive charity care or financial assistance can be included in the charity care charges and uninsured discounts reported in Worksheet S-10. The resulting costs and administrative burdens would not further the accuracy or reliability of Worksheet S-10 data, and the FAH therefore urges CMS to remove this language. The propriety of including amounts in line 20 should turn on whether the patient has an outstanding balance related to services rendered and meets the financial criteria set forth in the hospital's charity care or financial assistance policy.

D. Reporting simplification through the use of insured and uninsured Columns (lines 20 to 23)

At present, column 1 of line 20 is used to report uninsured individuals and column 2 of line 20 covers (1) deductible, coinsurance, and copayment amounts for insured patients, (2) non-covered charges for days exceeding a length of stay (LOS) limit under Medicaid or another indigent care program, and (3) charges other than deductibles, copayment, and coinsurance amounts that represent the insured patient's liability. ***The FAH believes that reporting in line 20 could be simplified by moving the second and third categories of charges to column 1 and making corresponding changes to lines 21 through 23, which would simplify the preparation of the cost report and reduce the likelihood of error. This would also eliminate the need for line 25.01.*** Under this approach, column 2 would be limited to deductible, copayment, and coinsurance amounts for insured patients that are written off to charity care. Meanwhile, column 1 would cover gross charges written off to charity care for uninsured individuals, insured individuals with charges for non-covered services or days that exceed a LOS limit, and gross charges other than deductible, copayment, or coinsurance amounts. This change would be consistent with the instructions to new Exhibit 3B, which requires separate listings of charity care amounts for uninsured and insured patients.

E. Exhibit 3B (Charity Care Listing)

1. Simplification and Consistency with Audit Schedules

As a threshold matter, the FAH is concerned that Exhibit 3B differs from the audit schedules that have been used in audits of charity care amounts to date. ***In order to achieve administrative simplification and reduce unnecessary costs associated with cost reporting and charity care audits, the FAH urges CMS to mandate that auditors use the final version of Exhibits 3B and 3C as the audit document for reported charity care and bad debt.*** Imposing this requirement on auditors would facilitate consistent auditing practices while economizing both CMS and provider audit resources. In addition, to facilitate smooth audits, the FAH also requests that the instructions for Exhibit 3B be modified to offer providers the ability to update this schedule to reflect subsequent changes in a patient's insurance status prior to an audit. Any charity care listing will reflect the patient account's status at the time the cost report is prepared, and as this information may change prior to audit, providers should be permitted to update Exhibit 3B at audit.

2. Multiple CCNs

The proposed instructions for Exhibit 3B (as well as those for Exhibit 3C) would require a separate listing for each CCN in the hospital healthcare complex, while Worksheet S-10 would require reporting data for all CCNs in the hospital health care complex in Part I and limiting the data to inpatient and outpatient services billable under the hospital CCN in Part II. In order to promote consistency and enable the direct crosswalking of data from these exhibits and Worksheet S-10, the FAH urges CMS to instead instruct providers to provide two listings of the exhibits that mirror Parts I and II of Worksheet S-10. In other words, the FAH urges that CMS instruct hospitals to submit two listings of patients for Exhibit 3B: the first listing would include data for all CCNs in the hospital health care complex (corresponding to Part I of Worksheet S-10) and the

second listing would be limited to data for inpatient and outpatient services billable under the hospital CCN (corresponding to Part II of Worksheet S-10).

3. Flexibility, Beneficiary Name (Columns 1 & 2)

Presenting charity care data using the form and structure of new Exhibit 3B would impose significant and unnecessary administrative burdens on providers unless providers have flexibility to alter the presentation and order of data reported in Exhibit 3B. ***The FAH therefore requests that CMS clarify that providers have the flexibility to modify or alter the presentation and order of data in this exhibit (as well as Exhibits 3A to Part I of Worksheet S-2 and Exhibit 2A to Part II of Worksheet S-2).***

Likewise, for the same reasons explained above with respect to Exhibit 3A to Worksheet S-2, Part I and Exhibit 2A to Worksheet S-2, Part II, ***the FAH requests that CMS clarify that a provider may combine the patient name into a single field (columns 1 & 2).***

4. Insurance Status (Column 6)

The form requires the provider to indicate the insurance status in one of three categories. Insured patients are broken out into two categories ("insured" and "insured but not covered"), but on Worksheet S-10, line 20, there is only a single column for entering data for insured patients (with no differentiation based on coverage). The FAH requests that CMS instead limit the categories of insurance status in column 6 to uninsured and insured patients, mirroring the columns in line 20 of Worksheet S-10 and reducing unnecessary provider reporting burdens. Otherwise, it is unclear how a hospital would report data for an insured patient that had both deductible and coinsurance and non-covered charges.

5. Write Off Date (Column 21)

In proposed Exhibit 3B, a provider would report "the date the charity care amount or uninsured discount was written off" in column 21. Because a patient may have multiple write off dates, the FAH requests that CMS clarify in the instructions that, in the event of multiple write off dates, the latest date in the cost reporting period should be reported in column 21.

F. Exhibit 3C (Listing of Total Bad Debts)

Multiple CCNs. The proposed instructions for Exhibit 3C (as well as those for Exhibit 3B) would require completing a separate listing for the hospital and each component of the hospital complex (*i.e.*, each CCN), while Worksheet S-10 would require reporting data for all CCNs in the hospital health care complex in Part I and limiting the data to inpatient and outpatient services billable under the hospital CCN in Part II. In order to promote consistency and enable the direct crosswalking of data from these exhibits and Worksheet S-10, the FAH urges CMS to instead instruct providers to provide two listings of the exhibits that mirror Parts I and II of Worksheet S-10. In other words, the FAH urges that CMS instruct hospitals to submit two listings of patients for Exhibit 3C: the first listing would include data for all CCNs in the hospital health care complex (corresponding to Part I of Worksheet S-10) and the second listing would be limited

to data for inpatient and outpatient services billable under the hospital CCN (corresponding to Part II of Worksheet S-10).

Primary and Secondary Payor (Columns 7 & 8). The FAH urges CMS to revise the instructions for columns 7 and 8 (primary and secondary payer) to clarify that these columns are optional to report because this data may be unavailable for older accounts that are written off and claimed on Worksheet S-10, line 26 as bad debt years later.

Reporting Recoveries. The FAH also requests instructions for reporting recoveries in new Exhibit 3C. Patient information for recovery accounts (negative bad debt) may be difficult for many providers to extract given the way that these post-close transactions are posted. Although auditors have accepted the recovery amount data without patient detail, it appears that Exhibit 3C would not permit listing of recovery amounts without this patient-level detail.

Total Patient Payments (Column 12). The FAH requests that CMS include specific instructions that would apply where a patient has multiple accounts (dates of service) with outstanding balances and submits payment without indicating the account to which the payment should be applied. The FAH further recommends that CMS clarify that the provider may apply any such funds received to the oldest date(s) of service first, consistent with the recommendations in the Health Care Financial Management Association's *Best Practices for Resolution of Medical Accounts Receivable.*

Patient Charity Care Amount (Column 14). The FAH requests additional instructions for this data element, confirming that this field includes both charity care and uninsured discounts as reported in Worksheet S-10, line 20.

Write-Off Date (Column 16). The FAH appreciates CMS' confirmation in response to comments that the accounts receivable write-off date for the proposed Exhibit 3C is "the date that the provider writes off the account in the hospital's financial accounting system (and financial statements)." The FAH further requests, however, that CMS address MAC misunderstandings of hospital operations and accounting with respect to the write-off date and write-off effective date. In some cases, a provider might have a Medicare year end of December 31 with a post-close period through January 4. Bad debts written off in this post-close period would still have an expense effective date of December 31, which is the actual write off date recorded on the general ledger for the provider cost reporting period in question and reported in column 16, and the bad debt in these situations should still be allowed in the period that the expense is realized.

Patient Bad Debt Write Off Amount (Column 17). The FAH is concerned that the formula set forth in column 17 will not consistently calculate an accurate bad debt amount, particularly in the case of Medicare cross-over bad debt for dual eligible beneficiaries. The FAH therefore asks that CMS revise the instructions to column 17 to direct hospitals to report the patient bad debt write off amount rather than calculating an amount using the specified formula. This approach would accommodate bad debt reversals and discrepancies in data collected in columns 12 through 15, improving the accuracy of the amounts reported in column 17.

III. Worksheet E-5 (Outlier Reconciliation at Tentative Settlement)

New Worksheet E-5 will be used by contractors to report outlier reconciliation amounts during the cost report tentative settlement. ***The FAH supports the addition of Worksheet E-5 and requests that CMS urge all MACs to apply the outlier reconciliation adjustment at the time of cost report tentative settlement and to notify CMS of interim reconciliation.*** This process will enable a prompt outlier reconciliation adjustment, which should operate to eliminate interest accruals on outlier reconciliations. At present, providers have confronted interest accumulations even when payment of provider-estimated outlier reconciliation amounts was made with submission of the cost report, and the FAH strongly supports establishing a process for permitting prompt outlier reconciliation adjustments in a manner that eliminates unnecessary interest accruals.

* * *

The FAH appreciates the opportunity to comment on the proposed changes to CMS-2552-10, Hospital and Health Care Complex Cost Report. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,