LEGAL & OPERATIONAL POLICY COMMITTEE
Tuesday, September 27, 2022
3:30 – 5:00 pm (ET)
Conservatory Ballroom A
Phone: 301-715-8592 / Meeting ID: 847-7534-1847 / Passcode: 493699

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Senior Vice President, Policy Communications, Subject Matter

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e. Baby Formula
f. SEC Climate Change Disclosure Proposed Rule

IX. FALSE CLAIMS ACT AMENDMENTS

X. LABOR / WORKFORCE ISSUES **TAB 9, p. 107**

XI. NEW BUSINESS

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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.

Lindsay Kryzak

Senior Vice President, Policy Communications at Subject Matter (biography from Subject Matter website)

Lindsay develops and executes strategic communication plans supporting clients' goals while leveraging legislative and regulatory policy expertise in infrastructure, privacy and technology. Prior to Subject Matter, she directed the Federal Trade Commission's Office of Public Affairs and served as the agency's chief spokesperson. Lindsay also ran corporate communications for The Port Authority of New York and New Jersey and spent a decade working for Senate Majority Leader Charles E. Schumer (D-NY). In Schumer's office, she led digital media strategy for the leader and democratic caucus, worked on political campaigns with Schumer and the Democratic Senatorial Campaign Committee, and served as speechwriter.

Fun Facts

- Rescue dog evangelist.
- Infrastructure nerd.
- Expert on New York State's 933 towns.
- Holds a record for consecutive questions asked.

Hospital Antitrust Issues

September 2022

- **Federal & State Antitrust Legislation**. On June 14, 2022, the United States Senate unanimously passed the *State Antitrust Enforcement Venue Act of 2021*, which grants state attorneys general the power to choose their venue. The bill awaits a House vote. Meanwhile, the *American Innovation and Choice Online Act* stalled in the Senate and likely will not be put to a vote before the midterms. The bill is geared toward big tech and would prohibit certain large online platforms from engaging in specified acts, including giving preference to their own products on the platform, unfairly limiting the availability on the platform of competing products from another business, or discriminating in the application or enforcement of the platform's terms of service among similarly situated users.
    - Also of note is that New York's *Twenty-First Century Anti-trust Act*, which includes sweeping antitrust provisions, passed the state senate but has not passed the General Assembly.
- ***United States v. UnitedHealth Group Inc***. On September 19, the district court rejected DOJ's challenge to block UnitedHealth Group's proposed merger with Change Healthcare. However, the court ordered divestiture of ClaimsXten to TPG Capital, the remedy the defendants originally offered.
- **Certificates of Public Advantage**. On August 15, 2022, the FTC issued a policy paper detailing its concerns with Certificates of Public Advantage (COPAs). Consistent with its past positions, the FTC expressed skepticism over the purported benefits of COPAs and signaled it may be more aggressive in engaging with state lawmakers to discourage the passage and approval of future COPAs.
- **Criminal No-Poach**. The government is close to securing its first win in its recent string of criminal no-poach employment cases. A defendant in *United States v. Hee* filed a notice that it intended to change its plea to guilty, and a combined hearing on the change of plea and sentencing is scheduled for January 6, 2023.
- **Recent Challenges to Proposed Hospital Mergers**. After the FTC filed complaints, RWJ Barnabas Health abandoned its proposed acquisition of Saint Peter's Health Care System in New Jersey on June 14, 2022. Similarly, after objection by New Hampshire's Attorney General, Dartmouth Health and GraniteOne Health abandoned their proposed merger on May 13, 2022.
- **CarePoint Health Antitrust Litigation**. CarePoint filed two separate suits against RWJ Barnabas Health alleging anticompetitive behavior. First, on August 8, 2022, CarePoint sued Jersey City Medical Center, which is owned by RWJ, in state court for allegedly steering ambulance patients with private insurance to RWJ facilities and away from CarePoint facilities. Second, on September 6, 2022, CarePoint sued RWJ in federal district court for violations of federal and state antitrust laws arising out of an alleged conspiracy to monopolize general acute care hospital services in northern New Jersey.
- **Horizontal Merger Guidelines**. There is no update as to when the FTC and DOJ will release the revised Horizontal Merger Guidelines per their request for information on merger enforcement in January.

FOLEY

FOLEY & LARDNER LLP
ATTORNEYS AT LAW

MEMORANDUM

CLIENT-MATTER NUMBER
127671-0165

TO: Katie Tenoever, Esq.
Senior Vice President and General Counsel
Federation of American Hospitals

FROM: Lori Rubin, Esq.
Diane Hazel, Esq.
William McCaughey, Esq.

DATE: September 16, 2022

RE: Hospital Antitrust Update

This Memorandum presents developments and updates to antitrust activity and enforcement in the health care industry since our last Hospital Antitrust Update in June 2022.

1. Federal and State Antitrust Legislation Update

On June 14, 2022, the United States Senate unanimously passed *the State Antitrust Enforcement Venue Act of 2021*.[1] The bill places state attorneys general on par with federal antitrust enforcers, granting them the power to choose the venue for suits involving federal antitrust claims. The bill now requires a vote on the House floor and currently has bi-partisan support.

Senators Amy Klobuchar (D-Minn) and Chuck Grassley's (R-Iowa) *American Innovation and Choice Online Act*—a major bill targeting big tech that is believed to have the greatest chance of passage, compared to other proposed legislation targeting big tech—has stalled in the Senate. Although Senator Chuck Schumer (D-NY) voiced support for the bill, he did not introduce the bill to the Senate floor before the August recess.[2]

On May 25, 2022, the New York state senate passed the *Twenty-First Century Anti-trust Act* (S933C).[3] The bill contains sweeping provisions, including a New York state analogue of Section 2 of the Sherman Act (monopolization); a prohibition on monopsonization (which occurs when a firm is the sole purchaser of a good or service); the implementation of a premerger notification regime; a prohibition on unilateral abuse of dominance, more akin to the European standard; and an increase in the penalties and remedies available to the state and private plaintiffs. The New York General Assembly has not taken up the bill. In addition to New York, other states

[1] State Antitrust Enforcement Venue Act of 2021, S. 1787, 117th Cong § 2. (2022).
[2] Brendan Bordelon & Josh Sisco, *Schumer's office says he plans to hold vote on tech antitrust bill*, Politico (Aug. 4, 2022), https://www.politico.com/news/2022/08/04/schumer-tech-antitrust-bill-00049890.
[3] Twenty-First Century Anti-Trust Act, S993C, Cal. No. 131 (N.Y. Jan. 6, 2021).

recently have passed or considered legislation implementing or expanding merger control. Oregon passed legislation[4] that went into effect earlier this year, requiring notification of certain types of transactions involving health professionals, hospitals, or insurers. At the end of 2021, Nevada passed legislation[5] requiring merger notification of hospital and physician practice mergers. Florida unsuccessfully attempted to introduce merger notification legislation[6] in its most recent legislative session.

2. United States v. UnitedHealth Group Inc., Case No. 1:22-cv-00481 (D.D.C.)

The Court considering the U.S. Department of Justice's challenge to block UnitedHealth Group's proposed $13.8 billion merger with Change Healthcare issued its order on September 19, denying the government's request to enjoin the merger. Change Healthcare provides technology to health payors to handle payments and edit claims. During closing arguments on September 8, 2022, the Court repeatedly questioned the government's theory that the merger would create a monopoly for health insurance claims processing technology. Although the defendants already had offered to divest Change Healthcare's ClaimsXten, DOJ argued that the transaction would still harm competition because ClaimsXten would not compete with the same vigor, as Change Healthcare would no longer support it.

The government primarily focused on a vertical theory—*i.e.*, that UnitedHealth would have "access to vast amounts of competitively sensitive data about United's rivals—data that reveals how their plans are designed and how they calculate payments to providers, for example." [7] DOJ argued Change would have incentives to slow innovation and the development of new products or features. In response, defendants argued that firewalls and other safeguards would prevent any abuse of rival insurer data. The Court issued a brief order on September 19, and the full opinion is currently under seal until the parties have the opportunity to review. Although the Court rejected DOJ's challenge, it ordered the divestiture of ClaimsXten to TPG Capital—the remedy the defendants originally offered.

3. Certificates of Public Advantages (COPAs)

On August 15, 2022, the FTC—in a bi-partisan, 5-0 vote—issued a policy paper[8] detailing its concerns with Certificates of Public Advantage (COPAs). COPAs are state laws that allow a health care provider to enter into cooperative arrangements, including mergers, which may otherwise be subject to antitrust review or challenge. A state may approve a COPA after it determines the proposed collaboration likely has benefits that outweigh any disadvantages. In exchange for immunity under the "state action doctrine," states often impose various restrictions or conditions on the provider, such as price controls or state oversight. Consistent with its past

[4] Or. Rev. Stat. § 415.501.
[5] S.B. 329 § 1(1), 81st (2021) Sess. (Nev. 2021); Assemb.B. 47 § 6.5(1), 81st (2021) Sess. (Nev. 2021).
[6] S.B. 1112 § 1, 2022 Sess. (Fla. 2022); H.B. 705 § 1, 2022 Sess., (Fla. 2022).
[7] Complaint, *United States v. UnitedHealth Group Inc.*, No. 1:22-cv-00481 (D.D.C).
[8] FTC Policy Perspectives on Certificates of Public Advantage, Federal Trade Commission, (Aug. 15, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/COPA_Policy_Paper.pdf; https://www.foley.com/en/insights/publications/2022/08/ftc-public-advantage-health-care-transactions.

positions, the FTC expressed skepticism over the purported benefits of COPAs and signaled it may be more aggressive in engaging with state lawmakers to discourage the passage of future COPAs.

4. Criminal No-Poach: United States v. Hee, Case No. 2:21-cr-00098 (D. Nev.)

On September 2, 2022, VDA OC LLC (VDA), a defendant in *United States v. Hee*, filed notice[9] in the Nevada District Court that it intended to change its plea to guilty over allegations that it violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by agreeing with a competitor to not hire nurses from each other and to cap the wages paid to nurses. During a September 8, 2022 hearing, the parties argued over whether the elements of a Section 1 claim required a defendant to "substantially" impact interstate commerce. VDA ultimately did not reach a plea agreement with DOJ, and a combined hearing on VDA's guilty plea and sentencing will occur on January 6, 2023.

5. Recent Challenges to Proposed Hospital Mergers

The FTC filed a complaint on June 2, 2022,[10] challenging RWJ Barnabas Health's (RWJ) proposed acquisition of New Jersey based healthcare provider Saint Peter's Healthcare System (Saint Peter's). According to the FTC, RWJ is one of the largest healthcare systems in New Jersey and competes with Saint Peter's in Middlesex County. The FTC's complaint alleged that the transaction would give RWJ an approximately 50% share for general acute care services in Middlesex County. RWJ and Saint Peter's subsequently abandoned the deal on June 14, 2022.

Last, on May 13, 2022, New Hampshire Attorney General John Formella objected[11] to a proposed merger of Dartmouth Health (Dartmouth) and GraniteOne Health (GraniteOne). In New Hampshire, health care charitable trusts, including nonprofit hospitals, must file notice of certain acquisitions with the Director of Charitable Trusts of the Attorney General's Office. According to Attorney General Formella, "[T]his transaction seeking to combine two of our top four largest systems is unacceptable without appropriate protections for consumers in place." Dartmouth and GraniteOne abandoned the proposed transaction on the day of the Attorney General's report.

6. CarePoint Health Management Associates, LLC v. Jersey City Medical Center, Case No. 002599-22 (N.J. Super. Ct. Law Div.) and CarePoint Health Management Associates, LLC v. RWJ Barnabas Health, Inc., Case No. 2:22-cv-05421 (D.N.J.)

On August 8, 2022, New Jersey based provider CarePoint Health (CarePoint) sued[12] a rival provider, Jersey City Medical Center (JCMC), which is owned and operated by RWJ Barnabas Health, Inc. (RWJ), in New Jersey state court. CarePoint claims JCMC violated a settlement agreement by steering ambulance patients with private insurance to its own hospital while delivering uninsured or underinsured ambulance patients to CarePoint. CarePoint and JCMC

[9] Notice of Intent to Plead Guilty, *United States v. Hee*, Case No. 2:21-cr-00098 (D. Nev.).
[10] Complaint, *In the Matter of RWJ Barnabas Health, Inc. and Saint Peter's Healthcare System, Inc.*, No. 9409 (June 2, 2022).
[11] Report of New Hampshire Department of Justice, Charitable Trusts Unit (May 13, 2022), https://www.doj.nh.gov/charitable-trusts/documents/graniteone-dartmouth-health-report.pdf.
[12] Complaint, *CarePoint Health Management Associates, LLC v. Jersey City Medical Center*, Case No. 002599-22 (N.J. Super. Ct. Law Div.).

entered a settlement in 2016, stemming from prior litigation, which required JCMC to deliver ambulance patients to the closest appropriate medical facility, based on an agreed upon grid system. CarePoint contends that since 2019, JCMC failed to follow this grid system and redirected privately-insured patients to JCMC. CarePoint alleged breach of contract and monopolization and attempted monopolization under New Jersey's antitrust laws.

CarePoint then filed a separate complaint[13] against RWJ in New Jersey federal district court on September 6, 2022. CarePoint argues RWJ violated federal and state antitrust laws by engaging in a years-long conspiracy with others to monopolize general acute care services in northern New Jersey. CarePoint alleges a variety of anticompetitive actions by RWJ, including that RWJ and its conspirators "asserted undue influence" on New Jersey government officials to hinder CarePoint from receiving state funds and that RWJ engaged in a sham transaction with CarePoint by signing a Letter of Intent for the acquisition of two CarePoint hospitals, when its real intent was to gain competitive intelligence.

7. Horizontal Merger Guidelines

There is no update on the release of revised Horizontal Merger Guidelines. The DOJ and FTC are in the process of reviewing comments and, according to Assistant Attorney General Jonathan Kanter, are actively working "to prepare a draft of the guidelines for public comment."[14]

[13] Complaint, *CarePoint Health Management Associates LLC, v. RWJ Barnabas Health, Inc.*, Case No. 2:22-cv-05421 (D.N.J.).

[14] Jonathan Kanter, Assistant Attorney General, Keynote Speech at Georgetown Antitrust Law Symposium (Sept. 13, 2022), https://www.justice.gov/opa/speech/assistant-attorney-general-jonathan-kanter-delivers-keynote-speech-georgetown-antitrust.

Charles N. Kahn III
President and CEO

April 19, 2022

The Honorable Lina Khan
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The Honorable Jonathan Kanter
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Re: Request for Information on Merger Enforcement (FTC-2022-0003)

Dear Chairwoman Khan and Assistant Attorney General Kanter:

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. The 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.

We appreciate the opportunity to provide the Federal Trade Commission and Antitrust Division of the Department of Justice (the Agencies) with our views in response to their June 18, 2022, Request for Information on Merger Enforcement (RFI).

I. RETAINING CONTINUITY IN MERGER GUIDELINES

Our members appreciate and rely on consistent and transparent guidelines in analyzing merger and acquisition activity. The Agencies' Horizontal Merger Guidelines (Guidelines) have been instrumental in providing insight into the Agencies' analytical techniques, practices, and enforcement policy, and our members have relied upon the consistency with which the Agencies have applied the Guidelines to mergers. This consistency leads to better decision-making, reduced costs, and more efficient merger review processes. Significant revisions to the Guidelines would risk eroding these efficiencies by introducing uncertainty. ***In short, the Guidelines work, and the FAH urges the Agencies to leave the Guidelines substantively intact, making only surgical amendments that are necessary and targeted to particular circumstances.***

We understand that the Agencies have concerns that certain industries are becoming more concentrated and less competitive. Accordingly, the Agencies are interested in updating the merger guidelines to "reflect the realities of the modern economy."[1] Although some sectors have evolved over the past decade, modern market dynamics have remained relatively stable for other significant industries. In particular, the competitive playing field for hospital and health system services has not changed fundamentally since the Agencies last revised the Guidelines in 2010: hospitals and other health facilities continue to focus their operations on providing services needed in their local communities. Therefore, we believe an extensive re-work of the Guidelines would be unnecessary, introduce unwarranted inefficiencies, and create significant and unproductive uncertainty.

To the extent other industries may have changed drastically since 2010, we urge the Agencies to limit any substantial changes in their guidance to those particular industries. The Agencies can provide targeted, industry-specific guidance in joint statements regarding merger enforcement in such industries. For instance, the Agencies' joint 1996 Statements of Antitrust Enforcement Policy in Health Care (1996 Statements) could serve as a template for potential future joint statements regarding these industries and other appropriate sectors.

The FAH nonetheless supports targeted changes to modernize enforcement of the antitrust laws regarding mergers in response to the Agencies' RFI. As identified in Parts III through V below, the FAH has identified certain areas where revisions to the Guidelines may be appropriate to addressing hospital and health system mergers but urges the Agencies to limit revisions in other areas (*e.g.*, the market definition guidance in section 4 of the Guidelines) in order to minimize uncertainty and volatility.

Finally, we note that the 1996 Statements provide very helpful guidance and clarifications to healthcare organizations seeking to engage in procompetitive joint activities in the health care area, including hospital mergers, and recognize that "[m]ost hospital mergers and acquisitions do not present competitive concerns." They also provide guidance on mergers that fall within certain "safety zones" and will not be challenged, absent extraordinary circumstances. As such, any updated merger Guidelines should incorporate the hospital merger safety zones established in the 1996 Statements and provide greater transparency by addressing the types of extraordinary circumstances under which hospital mergers that fall into these zones might be challenged.

II. MARKET DEFINITIONS CONTINUE TO BE KEY

The FAH believes that defining product and geographic markets is vitally important to evaluating transactions, particularly in the hospital and health care system industry. The Agencies' RFI asks whether it is "necessary to precisely define the market in every case?"[2] We believe the answer is an emphatic "yes." Thus, we do not believe the Agencies should modify

[1] Remarks of Chair Lina M. Khan Regarding the Request for Information on Merger Enforcement Docket No. FTC-2022-0003 (Jan. 18, 2022), https://www.ftc.gov/system/files/documents/public_statements/1599783/statement_of_chair_lina_m_khan_regarding_the_request_for_information_on_merger_enforcement_final.pdf.
[2] FTC-2022-0003 p.5.

their guidance regarding defining product and geographic markets in any significant way. Having specific principles and methods to define product and geographic markets is critical for both market participants, including hospitals and health systems, as well as the Agencies. Hospital and health system services in particular remain inextricably linked to their local communities in meaningful ways because comprehensive patient care requires the option for a patient to be physically present at a facility and each facility location is licensed and regulated at the State and/or local level. Clear market definition rules reflect this connection to the local community, bring greater certainty to the evaluation of potential transactions, and help avoid wasting resources on mergers that the Agencies are likely to challenge. Moreover, specific market definitions improve the efficiency of transaction decision-making and the Agencies' review of the transactions.

Eliminating the need to define specific markets would upend years of established judicial precedent and introduce substantial confusion and uncertainty to the marketplace. The determination of precise product and geographic markets remain especially apt to the assessment of hospital and health system mergers because they are subject to significant regulation such as state licensing provisions that impose geographic and scope limitations on hospitals and health systems. Ignoring the realities of the marketplace and the markets in which participants operate could lead to inconsistent outcomes and increased costs.

III. ACCOUNTING FOR HEALTHCARE'S TWO-STAGE COMPETITION MODEL IN DIVERSION RATIOS

The FAH urges that any revisions to the Guidelines include guidance on how the Agencies will treat asymmetric diversion ratios between merging parties in the hospital and health system industry. The Guidelines state, "Diversion ratios between products sold by one merging firm and products sold by the other merging firm can be very informative for assessing unilateral price effects, with higher diversion ratios indicating a greater likelihood of such effects."[3] The current diversion ratio guidance, however, does not account for the unique two-stage competition model that is present in the hospital and health system industry.

The two-stage competition model for hospitals and health systems means insurers and other third-party payers, rather than patients, are responsible for negotiating prices. Accordingly, hospitals and health systems do not have direct control over the prices typically paid for their in-network services. Diversion ratios measure *consumer* choice and preference, but in the two-stage competition model any analysis of diversion ratios should take into account whether a particular health system is a substitute from the perspective of an *insurer or other third-party payer*. Given the importance that the Agencies sometimes place on diversion ratios, consideration should be given to industries, such as hospitals and health systems, where the diversion ratio does not accurately capture relevant preferences in a two-stage competition model—in this case the preferences of insurers and other third-party payers. To alleviate this concern, the Agencies should refine the Guidelines to expressly recognize circumstances, such hospital and health systems, where the diversion ratio may not be as reliable.

[3] Guidelines § 6.1.

More specifically, because economic analyses such as diversion ratios and upward pricing pressure have become frequently important factors in merger investigations in the hospital and health system context, the Guidelines should establish safe harbors that can be used to effectively screen for concentrations that are highly unlikely to raise concerns of anticompetitive harm—this will promote efficiency in analyzing potential mergers and save resources across the system and all stakeholders, including the Agencies.

IV. ADDRESSING QUALITY IMPROVEMENTS AND OTHER PRO-COMPETITIVE EFFICIENCIES

The Guidelines should recognize and credit improvements in quality as a result of a merger. The Agencies' current Guidelines focus largely on financial or price efficiencies, mentioning improvements in quality only in passing.[4] However, hospital and health system mergers may produce significant improvements in quality of care. We believe the Agencies' current Guidelines undervalue these quality efficiencies and urge the Agencies to revise the Guidelines to appropriately account for quality-based efficiencies, particularly in hospital and health system mergers.

The FAH further requests that the Agencies provide greater transparency into how they quantify and substantiate pro-competitive efficiencies, including quality. Greater transparency will benefit all market participants by providing improved accuracy in their merger decision-making. For example, the FAH urges the Agencies to confirm that they will credit an efficiency as merger-specific despite the existence of a theoretical-but-impractical alternative to attaining such efficiency. In addition, the FAH urges the Agencies to include specific examples of the efficiencies that are most likely to be credited to merging parties in any revised Guidelines. In the hospital and health system context, potential examples of pro-competitive efficiencies could include, but are not limited to, improvements in population health management, readmission rates, mortality rates, patient outcomes, operational costs, or physician retention rates. And if the Agencies adopt specific examples of efficiencies, we suggest that any such exemplars should not be presented as an exhaustive list; rather, the Guidelines should retain their flexibility to account for a difference of circumstances amongst mergers.

Finally, the Agencies should ensure that updated Guidelines apply more flexible standards of efficiencies in the context of smaller independent or rural hospitals merging into integrated hospital systems with more sophisticated models of care delivery. As the 1996 Statements recognize, "many general acute care hospitals, especially with fewer than 100 licensed beds and an average daily census of fewer than 40 patients are unlikely to achieve the efficiencies that larger hospitals enjoy"; thus, there is greater potential for efficiencies to be realized through a merger with a larger hospital or health system.

[4] Guidelines § 10 ("[A] primary benefit of mergers to the economy is their potential to generate significant efficiencies and thus enhance the merged firm's ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products.").

V. FAILING AND FLAILING FIRMS: RECOGNIZING THE PUBLIC'S INTEREST IN MAINTAINING HOSPITAL AND HEALTH SYSTEM SERVICES

We believe the Agencies should adopt broader standards under Section 11 of the Guidelines to recognize "flailing" firms when the flailing firm serves the public interest and the weakened nature of the flailing firm would have adverse impacts on the public. Section 11 of the Guidelines recognizes that a merger "is not likely to enhance market power if imminent failure . . . of one of the merging firms would cause the assets of that firm to exit the relevant market."[5] Importantly, Section 11 does not address the *flailing* firm. A weakened hospital or health system may be unable to invest in needed capital improvements, the recruitment and retention of professionals and staff, or the continued operation of unprofitable but needed service lines, which can reduce access to care and cause significant harm to the community. When a flailing hospital or health system cannot maintain robust and varied service lines, effectively recruit and retain health professionals, and continue investing in needed facilities and technologies, a potential merger may be in the public interest. As discussed above, a potential merger can increase a community's access to high quality care in significant ways. It is not in the public interest to wait until a community's hospital qualifies as a failing firm before parties can avail themselves of the benefits of Section 11 of the Guidelines. Once a hospital is lost or a particular service line is eliminated (*e.g.*, an emergency department), it becomes much more costly and burdensome to replace that hospital or service line. Such closures often result in an enduring barrier to care access in the community. Accordingly, the Agencies should expand Section 11 to include flailing firms where the public has an interest in the survival of the flailing firm, including an interest in access to community health care services.

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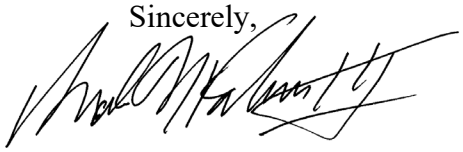
The FAH appreciates the opportunity to provide the Agencies with our views in response to their request for public comment on how the Agencies can modernize enforcement of the antitrust laws regarding mergers. We believe that the current Guidelines provide principled and transparent guidelines, which do not require significant overhaul.

As detailed above, certain revisions to the Guidelines may be beneficial to: (i) better capture the realities of the hospital and health system two-stage competition model, (ii) better recognize and credit quality and access to care improvements as a result of a merger, and (iii) expand Section 11 to include certain flailing firms. Otherwise, the FAH believes that a tailored approach, such as issuing industry specific guidelines, will provide the greatest benefit to consumers, while maintaining the consistent and transparent guidelines upon which marketplace participants may rely.

If you have any questions, please contact me at 202-624-1534, or any member of my staff at 202-624-1500.

Sincerely,



[5] Guidelines § 11.

TAB 3

Medicare Advantage / Managed Care

September 2022

- The FAH is engaged in a multi-faceted effort to highlight Medicare Advantage (MA) and managed care plan abuses and unfair payment and coverage practices. We continue to raise the issue with multiple policymakers and HHS and CMS leadership in every way we can.
- Our multipronged strategic effort to address MA and managed care abuses includes:
    - Creating metrics of accountability including the submission of a quality measure on Medicare Advantage denials.
    - Pushing for transparency, accountability, and increased oversight over MA plans and their practices.
    - Partnering on research with AHA to inform our advocacy efforts.
    - Educating and engaging policy stakeholders on MA abuses through earned and paid media campaigns.

Legislative Efforts

- On September 14, 2022, H.R. 3173, the *Improving Seniors' Timely Access to Care Act of 2022*, passed in the House. The bipartisan bill establishes several prohibitions, requirements, and streamlined standards relating to prior authorization processes under MA plans.
- The bill aims to:
    - Reduce delays in the prior authorization process by requiring insurers to make it electronic and by tasking HHS with creating a process that enables real-time decisions for routine items.
    - Directs plans to report prior authorization approval rates to CMS, and orders HHS to establish requirements that encourage plans to follow "evidence-based medical guidelines."
- The FAH participated in a large coalition of entities in support of the bill and its House passage. A Senate companion bill, S. 3018, has 43 cosponsors, and the goal is to move it for a Senate vote during the lame duck session of Congress at the end of this year.

HHS' OIG Report on MA Plan Abuses

- In April 2022, the HHS Office of the Inspector General (OIG) released a report finding that MA organizations (MAOs) are often shortchanging patients by denying millions of requests each year for medically necessary care. The report notes that "CMS annual audits of MAOs have highlighted widespread and persistent problems related to inappropriate denials of services and payment."
- In May 2022, the FAH wrote to CMS Administrator Chiquita Brooks-LaSure urging prompt implementation of the OIG's recommendations and further action to protect beneficiaries and address program abuses. The letter notes that the OIG's findings reflect a broader pattern of MAO practices that inappropriately deny, limit, modify, or delay the delivery of or access to services and care for MA beneficiaries.

- In August, CMS released a Request for Information (RFI) on MAO practices and access issues. The FAH submitted comments again urging CMS to make needed changes and to research the potential health disparities in care that may be resulting from MAO practices.

CMS Outreach and Regulatory Efforts

- As part of FAH efforts to hold MA plans accountable, the FAH submitted to CMS a prototype MA quality measure that would publish a plan's Level 1 denial upheld rate for inclusion in an MA plan's star rating. The measure would disincentivize the denial of services or payments that could not be easily supported upon provider or patient appeal.
- The FAH is currently in the early stages of the measurement development process and is engaging in outreach with potential partners to field test and certify the validity of the measure.

Federation of American Hospitals®

Charles N. Kahn III
President and CEO

August 31, 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: Request for Information on Medicare Advantage (CMS–4203–NC)

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.

We are writing in response to the Centers for Medicare & Medicaid Services' (CMS) request for information (RFI) on the Medicare Advantage (MA) program. The FAH has previously expressed concerns about the need for CMS to take steps to protect Medicare beneficiaries that receive access to Medicare coverage through MA and address program abuses by Medicare Advantage organizations (MAOs). This RFI is an important step, and we urge CMS to quickly layout plans to address major shortcomings in MAO oversight and ensure that beneficiaries in the program have improved access to care.

The Office of the Inspector General (OIG) in its recent report, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About

Beneficiary Access to Medically Necessary Care" (hereinafter, "OIG Report")[1] outlined how MAOs systemically apply problematic operating policies, procedures and protocols that inappropriately deny and delay care that Medicare beneficiaries are entitled to receive. We urge CMS to exercise its broad oversight authority over MAOs to ensure beneficiaries maintain adequate and improved access to their entitled benefits in the medically appropriate healthcare service setting.

As part of this RFI on ways to strengthen the MA program, CMS is seeking input for improvements in five key areas that align with CMS' vision:

- Advance Health Equity
- Expand Access: Coverage and Care
- Drive Innovation to Promote Person-Centered Care
- Support Affordability and Sustainability
- Engage Partners

This letter addresses these five areas and offers recommendations to improve access and care for MA enrollees. We applaud CMS' effort as the agency begins to scrutinize actions by MAOs to ensure MA enrollees are receiving appropriate care.

Section 1: Advance Health Equity

There is growing evidence that MA enrollees experience significant disparities in access to high-quality and necessary care compared to traditional Medicare fee-for-service (FFS) beneficiaries. These disparities in access and quality are amplified due to the differences in the demographic distributions between the MA and FFS programs. The MA program has a significant population of racial and/or ethnic minority and dual eligible enrollees. Racial and ethnic minority beneficiaries make up a much higher proportion of the MA program than FFS. In 2019, the percentage of racial and ethnic minorities enrolled in MA was 32 percent, compared to 21 percent in traditional Medicare.[2] This means that when MA plans limit enrollee access to high-quality care, these practices could increase disparities in care.

Disparities in access to care under the MA program include networks with limited access to high-quality hospitals, receiving lower-quality end-of-life care and lower-quality nursing home care, and greater dissatisfaction with out-of-pocket costs compared to beneficiaries in FFS. Overall, MA enrollees are more likely than traditional Medicare enrollees to be admitted to average-quality hospitals than high- or low- quality hospitals, suggesting that MA plans may be

[1] Christi A. Grimm, U.S. Department of Health and Human Services Office of the Inspector General ("OIG"), OEI-09-18-00260, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

[2] Murphy-Barron, et al. (2020). Comparing the Demographics of Enrollees in Medicare Advantage and Fee-For-Service Medicare. Milliman Report. https://bettermedicarealliance.org/publication/comparing-the-demographics-of-enrollees-in-medicare-advantage-and-fee-for-service-medicare/.

steering their enrollees to specific hospitals for nonemergent hospitalizations.[3] When looking at end-of-life care received by both MA and FFS beneficiaries, family and friends of beneficiaries enrolled in MA at the time of death or prior to hospice were more likely to report that care was not excellent and that they were not kept informed compared to traditional FFS.[4] MA enrollees also reported greater dissatisfaction with out-of-pocket expenses at 25.51 percentage points higher than traditional Medicare enrollees.[5] Most notably, an OIG report recently found that MAOs denied or delayed care and payments that met applicable coverage and billing rules under FFS.[6] The report found that 13 percent of MA prior authorization requests met Medicare coverage rules and 18 percent of denied requests met coverage and billing rules. These findings offer overwhelming evidence that the direct and indirect actions MA plans take to cut costs and restrict networks, and the resulting disparities in MA beneficiary access to necessary care, may have inequitable impact due to the larger proportion of minority and dually eligible MA enrollees.

As the MA program continues to grow, racial and ethnic minorities, as well as other disadvantaged populations, are entering the program at significantly higher rates than their Caucasian counterparts.[7] While there are many beneficial aspects intrinsic to the MA program, more data must be collected to determine the extent to which its pitfalls may be disproportionately affecting minorities and disadvantaged populations. If significantly more racial/minorities and/or dually eligible beneficiaries continue to enroll in the MA program at higher rates than Caucasian and non-dual eligible enrollees, they will continue to experience delayed care or be denied medically necessary care that they would otherwise receive under FFS. Therefore, the direct or indirect actions that MA plans are taking to delay and/or limit enrollee access to necessary care cannot go unaddressed.

MA plans often offer attractive benefits to disadvantaged Medicare beneficiaries who struggle to afford supplemental services such as Medicare Part D, dental, club memberships, or other similar benefits. Some MA plans also offer wraparound services that address social determinants of health by providing benefits such as meals for patients after a hospital stay. Plans should be commended for these types of policies. However, severely-ill or injured patients who need access to medical and hospital services may find these additional benefits do not outweigh the access problems they encounter due to limited provider networks and overly aggressive utilization control practices.

[3] Meyers, D. J., Trivedi, A. N., Mor, V., & Rahman, M. (2020). Comparison of the Quality of Hospitals That Admit Medicare Advantage Patients vs Traditional Medicare Patients. JAMA network open, 3(1). https://doi.org/10.1001/jamanetworkopen.2019.19310.

[4] Ankuda, C. K., Kelley, A. S., Morrison, R. S., Freedman, V. A., & Teno, J. M. (2020). Family and Friend Perceptions of Quality of End-of-Life Care in Medicare Advantage vs Traditional Medicare. JAMA network open, 3(10). https://doi.org/10.1001/jamanetworkopen.2020.20345.

[5] Park, Sungchul. (2022). Effect of Medicare Advantage on health care use and care dissatisfaction in mental illness. Health Services Research, 57(4). https://doi.org/10.1111/1475-6773.13945.

[6] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp

[7] Meyers, D. J., Mor, V., Rahman, M., & Trivedi, A. N. (2021). Growth In Medicare Advantage Greatest Among Black And Hispanic Enrollees. Health affairs (Project Hope), 40(6), 945–950. https://doi.org/10.1377/hlthaff.2021.00118

As part of CMS' efforts to provide guidance to MAOs regarding the appropriate use of MAO clinical criteria for medical necessity reviews and utilization management, **the FAH urges CMS to clarify that MAOs, their downstream risk providers and their contracted hospitalists must provide their beneficiaries with inpatient coverage and providers with inpatient reimbursement when (1) appropriate under Medicare's Two-Midnight Rule; and (2) beneficiaries undergo procedures on the inpatient-only (IPO) list.** These two Medicare FFS clinical standards should be applied consistently to all MA enrollees since the Medicare Advantage program and the Medicare FFS program serve the same demographic population and these beneficiaries are entitled to the same benefits as required by 42 C.F.R. § 422.100. Requiring MA plans to use these policies will protect patients enrolled in MA and afford them the same protections that FFS beneficiaries are guaranteed. Again, while *all* MA enrollees are put at greater risk by these MA policies that inappropriately push patients out of hospitals (or inadequately reimburse hospitals for providing the appropriate level of care), due to the demographic differences between MA and FFS populations, these policies may inadvertently create disparities in care for the MA program's most at risk beneficiaries.

Excessive use of unique prior authorization criteria and limited networks also are likely creating disparities and may be even more challenging to identify because when MAOs deny care, there are no encounter data or claims to highlight the trends. Our members have noted that disabled patients that need inpatient medical rehabilitation facility (IRF) services, as well as inpatient mental health and substance abuse services, are at particular risk.

CMS is also seeking information on MA plans' use of algorithms to identify enrollees with special care needs or vulnerabilities. We are not aware of special programs such as these. However, the FAH has significant concerns about MA plans that rely heavily on algorithms that lead to prior authorization and claims payment denials – often after the care has been provided. The use of these algorithms likely has the opposite impact that CMS would hope to achieve in addressing care disparities. To the extent these algorithms are based on historic biases, appropriate patient care could be in jeopardy. We have heard concerns especially related to IRF care and inpatient care for substance abuse. **We urge CMS to require that utilization management tools and the logic for proprietary algorithms be made public to patients and providers.**

The growing research on potential disparities in care and access to care for the sick and more diverse populations covered under MA highlight the need for more oversight and exploration on direct and indirect MA policies and practices that may be creating disparities in care – especially when compared to beneficiaries in traditional FFS. **The FAH urges CMS to expand data collection, public reporting, and research on care disparities that may be affecting diverse populations, either directly or indirectly, due to MAO policies and practices.**

Section 2: Expand Access: Coverage and Care

CMS is seeking comments on ways to strengthen beneficiary access to health services for enrollees in MA. The RFI's "Expanding Access: Coverage and Care" section seeks input on ways to improve the tools and information for beneficiaries to choose an MA plan that best

meets their anticipated needs; increase mental and substance use access; the role of telehealth in improving MA enrollee access to care; the best ways to ensure network adequacy and communicate network changes; and the impact of utilization management programs used and ways to ensure that the programs do not prevent or delay appropriate care. These are important issues for CMS to consider and we appreciate CMS' focus and attention to engage with patient and provider stakeholders to improve enrollee access to high quality and timely care.

Aggressive utilization control practices are a problem that the FAH and other stakeholders have raised with CMS for several years. But it is not just patients and providers raising concerns. The OIG Report[8] highlighted that MAOs systemically apply problematic operating policies, procedures and protocols that limit care for MA enrollees.

The OIG Report also identifies a pattern by which MAOs apply utilization controls to improperly withhold coverage or care from MA enrollees, as previously discussed. Specifically:

- *Improper prior authorization denials*. The OIG found that thirteen percent (13%) of prior authorization requests denied by MAOs would have been approved for beneficiaries under original Medicare.

- *Improper denials for lack of documentation*. The OIG found that in many cases, beneficiary medical records were sufficient to support the medical necessity of the services provided.

- *Improper payment request denials*. The OIG found that eighteen percent (18%) of payment requests denied by MAOs actually met Medicare coverage rules and MAO billing rules.

These OIG findings reflect a broader pattern of MAO practices that inappropriately deny, limit, modify or delay the delivery of or access to services and care for MA beneficiaries. FAH members have regularly observed that MAOs abuse prior authorization requirements, maintain inadequate provider networks, use extended observation care, retroactively reclassify patient status (*i.e.*, inpatient versus observation), improperly down code claims, and deploy inappropriate pre- and post-payment denial policies, and even deny claims for previously authorized services. These activities are often carried out by way of MAOs' downstream at-risk physicians and contracted hospitalists. All of these activities limit MA beneficiaries' access to the care to which they are entitled under the Social Security Act.[9]

Giving beneficiaries a better picture of the utilization control practices used by MA plans, along with other plan details, during the enrollment process could go a long way to educating enrollees of the potential access challenges they may face – especially if they have a known

[8] Christi A. Grimm, U.S. Department of Health and Human Services Office of the Inspector General ("OIG"), OEI-09-18-00260, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

[9] For further detail, see Federation of American Hospitals, "Re: Needed Improvements to Medicare Advantage Organization Practices," September 1, 2021 (the "September 1 Letter"), attached hereto.

medical condition. **The FAH recommends that MA marketing materials outlining plan benefits include a list of services that require prior authorization or pre-certification, the rate at which those services are approved, and the average length of time for approvals.** This important information could provide invaluable details to enrollees and their families as they weigh their coverage options in MA plans and traditional FFS. This information is also a good counterbalance to oversimplified messages about "free" MA services excluded from FFS coverage (such as gym memberships or other supplemental services) that appear generous but that are often obsolete when a patient is very ill and needs extensive health care services.

From a network adequacy perspective, MA enrollee access to services and care is often more limited than it would appear in an MAO's Health Service Delivery ("HSD") submission or provider directory that a beneficiary reviewed and relied upon during their open enrollment decision making process to choose an MAO. MAOs often use downstream organizations which direct care to a far narrower provider network, rendering network access to certain providers illusory. Downstream organizations are often affiliated with their own contracted or employed physician or provider groups and their sub-capitation arrangements create a financial incentive to direct care to a particular provider or group, creating a de facto provider network at the downstream organization level that is far more limited than the MAO's advertised network. **The FAH continues to recommend that CMS take action to foster MAO network transparency to protect MA enrollees' access to care by implementing audit protocols to identify and review the adequacy of downstream organizations' provider networks and taking appropriate network enforcement actions for noncompliance with network adequacy standards. In addition, the FAH urges CMS to incorporate network adequacy into the Star Ratings Program.**

Network adequacy is particularly a problem in post-acute care. MA enrollees routinely experience inappropriate delays in discharge from the inpatient hospital setting due to MAOs' lack of (1) an adequate post-acute network and (2) post-acute providers in MAOs' networks willing to accept beneficiary discharges. When a patient is ready for transfer from an acute-care setting to a post-acute environment (including Long Term Care Hospitals (LTCHs), IRFs, and skilled nursing facilities ("SNFs")), the most appropriate course is the prompt and safe transfer of the beneficiary so s/he may begin to receive post-acute care (e.g., rehabilitation) in the most suitable environment. MAOs, however, often are financially incentivized to prolong beneficiaries' hospital stays (often paid at a case rate such as the MS-DRG system) rather than incurring the additional cost of post-acute provider stays, and may delay discharges based on the lack of available or willing post-acute providers. In addition, MAO's post-acute networks often do not include an adequate number of post-acute facilities to ensure that the appropriate facility is available and post-acute care is not delayed or disrupted. This has been a particularly acute problem during the COVID-19 public health emergency (PHE) when hospitals often have been desperate to discharge patients quickly to open up beds for waiting COVID-19 patients. **The FAH recommends that CMS require MAOs to demonstrate meaningful network access, including by raising the minimum number of in-network post-acute facilities, establishing a minimum facility-to-beneficiary ratio for in-network IRFs and LTCHs, and monitoring delays in MA beneficiary inpatient hospital discharges due to the lack of capacity among in-network post-acute facilities.**

The OIG Report highlighted the many harmful practices that arise from MAOs' adoption of prior authorization and use of inappropriate clinical criteria, and the FAH urges CMS to protect beneficiaries by ensuring MAOs adhere to critical Medicare coverage rules, as discussed above. For example, instead of consistently and transparently authorizing and paying for inpatient services when an MAO beneficiary receives hospital services that span two or more midnights from the first day of patient presentation to the hospital (Two-Midnight Rule), many MAOs use a variety of standards (including unique standards they develop and promulgate on their own) to determine whether a particular hospital stay meets their criteria for an inpatient admission. MAOs deny authorizations for inpatient admissions ordered by physicians and reclassify them as outpatient observation stays with troubling frequency, often using non-transparent, remote means of assessing medical necessity and overriding the treating medical professional's clinical decision. In addition, our members report that MAOs create financial incentives for contracted physicians to change the admission status before discharge and reduce the MAO's payment obligation to hospitals for services and care. Furthermore, members have reported MAO denials of inpatient coverage for procedures included on the Medicare IPO list, which is the single definitive source of guidance as to which procedures must for patient safety reasons be performed in an inpatient setting to be covered by Medicare. These practices are not appropriate utilization review activities; instead, they dilute the benefits provided to MA beneficiaries and undermine the benchmarking process used to fund MA coverage and ensure actuarial equivalence. ***The FAH, therefore, reiterates our recommendation that CMS require MAOs and their contracted physicians—including their employed group physicians, downstream at-risk physicians and their hospitalists—follow the Two-Midnight Rule in determining patient status and the medical necessity of an inpatient admission and provide inpatient coverage and payment for each procedure on Medicare's IPO list.*** The consistent application of these requirements across the Medicare program would protect patients and promote transparency in and fiscal oversight of the MA program.

MAO clinical criteria and review practices may particularly burden beneficiary access to specific types of care, and the FAH supports the OIG's recommendation that CMS undertake targeted audits of particular service types that have a history of inappropriate denials. For example, some MAO plans use proprietary, non-CMS-endorsed standards to determine coverage for IRF services. These standards may direct beneficiaries to less intensive care settings, delaying or denying MA beneficiary access to the intensive, comprehensive, IRF-level care indicated by their condition and reducing access to their entitled benefits. The use of these proprietary standards creates confusion and administrative challenges for beneficiaries and providers and results in an inappropriate misalignment between the treatment of Medicare beneficiaries under the FFS program and those in an MA plan. The OIG's report identified a number of cases in which the MAO improperly denied a request for prior authorization of IRF services. ***The FAH therefore urges CMS to (i) issue new guidance to ensure MAOs do not use more restrictive clinical criteria or request unnecessary documentation, and (ii) undertake targeted audits focusing on IRF and other specific service types that have a history of inappropriate denials.***

In order to protect MA beneficiaries, the FAH urges CMS to exercise its broad MAO oversight authority and ensure beneficiary access to their entitled benefits by addressing MAO authorization and payment denials of care that meets Medicare coverage rules. As the OIG observed:

> ***Denied requests that meet Medicare coverage rules may prevent or delay beneficiaries from receiving medically necessary care and can burden providers.*** *Even when denials are reversed, avoidable delays and extra steps create friction in the program and may create an administrative burden for beneficiaries, providers, and MAOs. Further, beneficiaries enrolled in Medicare Advantage may not be aware that there may be greater barriers to accessing certain types of health care services in Medicare Advantage than in original Medicare.*[10]

Finally, MA providers' appeal rights are typically governed by their agreements with MAOs. MAOs' appeals processes are complex, cumbersome, not standard across plans, often not automated, and require significant administrative resources and staffing for health care providers. Additionally, MAO patient portals or websites should include "point and click" options for patients to appeal prior authorization denials for services and items. Ensuring that patients and providers have an easy way to quickly appeal denials of service will improve patient access and minimize excessively strict approval criteria.

Section 3: Drive Innovation to Promote Person-Centered Care

While MAOs and providers do engage in innovative risk-based payment and delivery models, these relationships can be more challenging to establish with multiple MA plans in various markets, with smaller patient populations, and greater reliance on FFS rates as a starting point for payment. However, models that build off CMMI models and programs, where infrastructure can be expanded to MA populations offer some options and flexibility. Some plans are more sophisticated in their ability to develop and maintain innovative programs, and hospitals look for opportunities to work with plans to improve patient care, program efficiencies, and care quality.

Section 4: Support Affordability and Sustainability

The FAH understands MAOs currently include MA encounter data from denied (in part or in full), pended, and underpaid claims in their risk adjustment data submissions to CMS, resulting in increased risk adjustment payments that do not reflect the costs incurred by the MAO. This behavior is inconsistent with the purposes of the Part C Risk Adjustment Program and inflates Medicare spending without any corresponding beneficiary benefit. **The FAH urges CMS to limit MA encounter data for the Risk Adjustment Program to data derived from fully paid claims or, in the case of a provider that accepts capitation, provider encounter data.**

Further, MAOs often hire private contractors on a contingency fee basis to conduct a variety of audits on a pre-payment or post-payment claims basis. These audit types include (1) charge audits, where the contractors inappropriately remove Medicare covered charges from claims; (2) MS-DRG audits, where the contractors use proprietary software to downgrade the

[10] OIG Letter at 20 (emphasis added).

underlying diagnoses necessary to support a DRG by inappropriately removing or re-bundling billed ICD-10 codes; and (3) medical record audits, where the contractors question the accuracy of physician documentation regarding the beneficiary's health and associated comorbidities that support the underlying diagnosis and medical necessity. These audits often are undertaken without any clinical basis and regularly fail to include an adequate explanation for the contractor's conclusions. Through this process, remote third-party contractors overrule the professional opinion of the treating professionals, despite often lacking the relevant clinical training or expertise. MAOs' delegation to these contractors frequently creates confusion due to poor communication between MAOs and their contractors. These issues are exacerbated due to convoluted appeal processes. While the FAH acknowledges that MAOs are obligated to conduct reasonable audits, we are concerned that contingency fee audits conducted by MAOs' contractors are improperly motivated by financial incentives, fueling a "bounty hunter" mentality, and inappropriately burdening providers caring for MA beneficiaries. CMS acted several years ago to curb these types of unfair practices under the Medicare FFS recovery audit contractor (RAC) program and should exercise similar oversight of these practices under the MA program.

Section 5: Engage Partners

CMS is requesting comments on ways to improve the gap in information for patients, plans and providers. Quality information is a critical component in selecting a provider or hospital and is also important when beneficiaries are selecting an MA plan. In addition to our recommendations on policy improvements to protect patients in MA, **we urge CMS to consider further refinements to its MAO oversight by developing new quality metrics for MAO operations that could be included in the Star Ratings Program**. New quality measures should be developed to rate and report on patient access problems related to appeals and denial overturn rates for prior authorization, appeals and overturn rates for payment denials, network adequacy, and service delays. The FAH is currently developing a new MA quality measure concept on Level 1 Appeals to highlight overturn rates for health plans. This measure would supplement the current measures evaluating Level 2 Appeals. We believe such measures would promote competition on these critical access-oriented dimensions of MA plan quality, rewarding and incentivizing better MAO behavior and providing beneficiaries with critical information on the potential for excessive plan denials for service.

CMS has the statutory authority to address these and other abusive MAO practices as part of its broad oversight authority over MAOs. If CMS were to implement some of our recommended changes through regulation, we believe it would facilitate improved engagement between plans and providers. And, as explained further below, such oversight would not implicate the non-interference clause contained in section 1854(a)(6)(B)(iii) of the Social Security Act or compromise its goals.

The Social Security Act provides CMS wide latitude to address MAO behavior, and the non-interference prohibitions expressly enumerated in the statute would *not* preclude CMS from taking action regarding MAOs' inappropriate use of clinical criteria to deny or alter care delivery settings, improper actions limiting provider networks, or other abusive measures that inappropriately limit beneficiary access to care and burden providers.

The non-interference clause contains two discrete, narrowly-drawn prohibitions. First, CMS cannot mandate an MAO contract with a specific provider. Second, CMS cannot mandate that an MAO implement a particular price structure within a provider contract. The text of the non-interference clause reads as follows:

> *In order to promote competition under this part and part D and in carrying out such parts, the Secretary may not [1] require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this subchapter or [2] require a particular price structure for payment under such a contract to the extent consistent with the Secretary's authority under this part.*[11]

Beyond these two express prohibitions, CMS retains its broad regulatory authority – and responsibility – to ensure beneficiaries receive the Medicare benefits to which they are entitled.

The plain text of the non-interference clause has not been expanded by regulation or judicial precedent. To date, we have only identified limited CMS discussion of section 1854(a)(6)(B)(iii) in the context of mandated payment model adjustments for MAOs, which would plainly violate the statute's directive that CMS not "require a particular price structure for payment under" a provider agreement.[12] Along similar lines, CMS recently concluded that a commenter's suggestion that CMS require "payment by the MA organization of certain amounts to a contracted provider" is "within the scope of" actions precluded by the non-interference clause.[13]

The larger context of the MA statutory scheme and legislative history confirm the non-interference clause is a narrowly tailored, targeted provision designed to foster competition rather than to place MAO conduct beyond CMS' regulatory reach. Ever since the Medicare and Medicaid programs were enacted in 1965, CMS has been charged with providing a broad swath of Americans with access to essential quality and affordable health care. The MA program incorporates private, CMS-contracted plans in the Medicare program with the objective of expanding beneficiary choice while leveraging plan competition to improve quality and reduce program costs. The MA non-interference clause and the Part D non-interference clause, are designed to preserve that competition by preventing CMS from setting MA rates or mandating

[11] Social Security Act § 1854(a)(6)(B)(iii).

[12] *See* CMS, "Report to Congress: Alternative Payment Models & Medicare Advantage" (July 16, 2019), https://www.cms.gov/medicare/medicare-advantage/plan-payment/downloads/report-to-congress-apms-and-medicare-advantage.pdf; *See also* Centers for Medicare & Medicaid Services (CMS), "Additional Information Regarding the Mandatory Payment Reductions in the Medicare Advantage, Part D, and Other Programs" (May 1, 2013), https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/PaymentReductions.pdf

[13] Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards, 87 Fed. Reg. 22,290, 22,380 (April 14, 2022).

contracting with any particular provider.[14] The legislative history reflects a particular desire to preserve price-based competition among MA plans by prohibiting CMS from setting rates.[15]

Expanded CMS oversight over the abusive MAO practices described in our September 1, 2021 Letter and in this letter would not implicate the non-interference clause or compromise its goals. Indeed, the law is clear that Medicare beneficiaries who enroll in MA plans are entitled to the same benefits, at a minimum, that they would receive if they were enrolled in original Medicare.[16] To that end, CMS retains the authority to ensure MAOs satisfy minimum benefit requirements. By implementing the recommendations we have offered, CMS would ensure MAOs comply with their basic statutory obligation to provide beneficiaries access to timely, adequate, and appropriate care. Such a regulatory response would *promote* meaningful competition between MAOs on the dimensions of quality, value and care delivery while also protecting beneficiaries and promoting improved partnership with providers.

* * *

The FAH appreciates the opportunity to offer these insights. We are committed to working with you to ensure America's seniors in MA plans have improved access and better care. If you have any questions or would like to discuss further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

[14] In 2003, section 1854(a)(6)(B)(iii) was amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, § 222, 117 Stat 2066, to extend its requirements to Medicare Prescription Drug Plans, and a corresponding provision was included in the Part D statute at 1860D-11(i).

[15] *See* 149 Cong. Rec. S15670-03, S15691, describing legislators' goals in incorporating the non-interference clause with respect to Part D plans: *"*They said: We believe in competition. . . . Let the private sector negotiate their incentives for the insurers to get lower costs out of the pharmaceuticals. . . . Let that mechanism work. Don't have the head of CMS, the Medicare Director in Washington, DC, dictate prices for everybody. *Let us not set those prices in the Senate.* Let us let the marketplace work to squeeze cost and get efficiency out of the system" (emphasis added).

See also 149 Cong. Rec. S15670-03, S15761, "The competition in this bill achieves significant 'bang for the buck' because it relies on drug plans to negotiate discounts. CBO says the private insurance model has a cost management factor of 25 percent-the effect of price discounts, rebates, utilization controls, and other tools that a PDP might use to control spending. By relying on the bargaining power of drug plans, this bill will drive down the costs of prescription drugs."

See also Congressional Budget Office, Letter to the Honorable William H. Frist, MD (January 23, 2004), https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/49xx/doc4986/fristletter.pdf, "CBO estimates that substantial savings will be obtained by the private plans and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree."

[16] *See* S.S.A. §1852(1)(A), "[E]ach Medicare+Choice plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this title and part A of title XI, benefits under the original [M]edicare fee-for-service program option".

Federation of American Hospitals®

Charles N. Kahn III
President and CEO

May 19, 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

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.

We are writing to express our strong support for the Centers for Medicare & Medicaid Services ("CMS") taking steps to protect beneficiaries and address program abuses by Medicare Advantage organizations ("MAOs"). We appreciate CMS' concurrence with the recommendations made by the Office of the Inspector General ("OIG") in its recent report, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (hereinafter, "OIG Report").[1] MAOs systemically apply problematic operating policies, procedures and protocols in addition to the problematic MAO practices identified in the OIG Report. We therefore urge CMS to exercise its broad oversight authority over MAOs to ensure beneficiaries maintain adequate access to their entitled benefits in the medically appropriate healthcare service setting.

[1] Christi A. Grimm, U.S. Department of Health and Human Services Office of the Inspector General ("OIG"), OEI-09-18-00260, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

As part of CMS' efforts to provide guidance to MAOs regarding the appropriate use of MAO clinical criteria for medical necessity reviews, the FAH urges CMS to clarify that MAOs, their downstream risk providers and their contracted hospitalists must provide their beneficiaries with inpatient coverage and providers with inpatient reimbursement: (1) when appropriate under Medicare's Two-Midnight Rule, and (2) when beneficiaries undergo procedures on the inpatient-only (IPO) list. These two Medicare fee-for-service clinical standards should be applied consistently to all Medicare Advantage (MA) beneficiaries since the MA program and the Medicare fee-for-service program serve the same demographic population and each of these beneficiaries are entitled to the same benefits as required by 42 C.F.R. § 422.100. In addition, the FAH urges CMS to address MAO practices that particularly burden beneficiary access to specific types of care or facility types (especially inpatient rehabilitation facilities ("IRFs") and long term care hospitals ("LTCHs") because, as the OIG notes, MAOs may have an incentive to deny such care over cost concerns) by: (1) issuing new guidance to ensure MAOs do not disproportionately burden beneficiary access to particular provider types or care through the use of more restrictive clinical criteria or requests for unnecessary documentation, and (2) undertaking targeted audits focusing on IRF and other specific service types that have a history of inappropriate denials. Finally, the FAH urges CMS to examine and address MAO abuses more broadly to promote MA beneficiary access to timely and appropriate care.

I. Inappropriate MAO Utilization Controls Limit and Delay Beneficiary Access to Care

The OIG Report identifies a pattern by which MAOs apply utilization controls to improperly withhold coverage or care from MA beneficiaries. Specifically:

- *Improper prior authorization denials*. The OIG found that thirteen percent (13%) of prior authorization requests denied by MAOs would have been approved for beneficiaries under original Medicare.

- *Improper denials for lack of documentation*. The OIG found that in many cases, beneficiary medical records were sufficient to support the medical necessity of the services provided.

- *Improper payment request denials*. The OIG found that eighteen percent (18%) of payment requests denied by MAOs actually met Medicare coverage rules and MAO billing rules.

These OIG findings reflect a broader pattern of MAO practices that inappropriately deny, limit, modify or delay the delivery of or access to services and care for MA beneficiaries. FAH members have regularly observed that MAOs abuse prior authorization requirements, maintain inadequate provider networks, use extended observation care, retroactively reclassify patient status (*i.e.*, inpatient versus observation), improperly down code claims, and deploy inappropriate pre- and post-payment denial policies, and even denying claims for previously approved services. These activities are often carried out by way of MAOs'

downstream at-risk physicians and contracted hospitalists. All of these activities limit MA beneficiaries' access to the care to which they are entitled under the Social Security Act.[2]

Many of these harmful practices arise from MAOs' adoption of inappropriate clinical criteria, and the FAH urges CMS to protect beneficiaries by ensuring MAOs adhere to critical Medicare coverage rules. For example, instead of consistently and transparently applying CMS' Two-Midnight Rule, many MAOs use a variety of standards (including unique standards they develop and promulgate on their own) to determine whether a particular hospital stay meets their criteria for an inpatient admission. MAOs deny authorizations for inpatient admissions ordered by physicians and reclassify them as outpatient observation stays with troubling frequency, often using non-transparent, remote means of assessing medical necessity and overriding the treating medical professional's clinical decision. In addition, our members report that MAOs create financial incentives for contracted physicians to change the admission status before discharge and reduce the MAO's payment obligation to hospitals for services and care. Furthermore, members have reported MAO denials of inpatient coverage for procedures included on the Medicare IPO list, which is the single definitive source of guidance as to which procedures must be performed, for patient safety reasons, in an inpatient setting to be covered by Medicare. These practices are not appropriate utilization review activities; instead, they dilute the benefits provided to MA beneficiaries and undermine the benchmarking process used to fund MA coverage and ensure actuarial equivalence. ***The FAH, therefore, continues to recommend that CMS require MAOs and their contracted physicians—including their employed group physicians, downstream at-risk physicians and their hospitalists—follow the Two-Midnight Rule in determining patient status and the medical necessity of an inpatient admission and provide inpatient coverage and payment for each procedure on Medicare's IPO list.*** The consistent application of these requirements across the Medicare program would promote transparency in and fiscal oversight of the MA program.

MAO clinical criteria and review practices may particularly burden beneficiary access to specific types of care, and the FAH supports the OIG's recommendation that CMS undertake targeted audits of particular service types that have a history of inappropriate denials. For example, some MAO plans use proprietary, non-CMS-endorsed standards to determine coverage for IRF services. These standards may direct beneficiaries to less intensive care settings, delaying or denying MA beneficiary access to the intensive, comprehensive, IRF-level care indicated by their condition and reducing access to their entitled benefits. The use of these proprietary standards creates confusion and administrative challenges for beneficiaries and providers and results in an inappropriate misalignment between the treatment of Medicare beneficiaries under the fee-for-service program and those in an MA plan. The OIG's report identified a number of cases in which the MAO improperly denied a request for prior authorization of IRF services. ***The FAH therefore urges CMS to (1) issue new guidance to ensure MAOs do not use more restrictive clinical criteria or request unnecessary documentation, and (2) undertake targeted audits focusing on IRF and other specific service types that have a history of inappropriate denials.***

[2] For further detail, see Federation of American Hospitals, "Re: Needed Improvements to Medicare Advantage Organization Practices," September 1, 2021 (the "September 1 Letter"), attached hereto.

In order to protect MA beneficiaries, the FAH urges CMS to exercise its broad MAO oversight authority and ensure beneficiary access to their entitled benefits by addressing MAO authorization and payment denials of care that meets Medicare coverage rules. As the OIG observed:

> **Denied requests that meet Medicare coverage rules may prevent or delay beneficiaries from receiving medically necessary care and can burden providers.** Even when denials are reversed, avoidable delays and extra steps create friction in the program and may create an administrative burden for beneficiaries, providers, and MAOs. Further, beneficiaries enrolled in Medicare Advantage may not be aware that there may be greater barriers to accessing certain types of health care services in Medicare Advantage than in original Medicare.[3]

The FAH appreciates CMS' concurrence with the OIG's recommendations, including the recommendations to issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews and to update CMS' audit protocols to address the issues identified by the OIG.

II. CMS Should Take Steps to Address Broader MAO Abuses and Protect Beneficiaries

In addition to addressing the OIG findings concerning MAOs' inappropriate prior authorization denials, denials for lack of documentation, and payment denials, the FAH urges CMS to exercise its broad oversight authority to curtail a number of other MAO abuses. By way of example, the FAH previously identified in its September 1 Letter the following MAO activities that inappropriately burden providers and may adversely impact beneficiaries:

- **Network Adequacy:** MA beneficiary access to services and care is often more limited than it would appear in an MAO's Health Service Delivery ("HSD") submission or provider directory that a beneficiary reviewed and relied upon during their open enrollment decision making process to choose an MAO. MAOs often use downstream organizations which direct care to a far narrower provider network, rendering network access to certain providers illusory. Downstream organizations are often affiliated with their own contracted or employed physician or provider groups and their sub-capitation arrangements create a financial incentive to direct care to a particular provider or group, creating a *de facto* provider network at the downstream organization level that is far more limited than the MAO's advertised network. The FAH continues to recommend CMS take action to foster MAO network transparency to protect MA beneficiary's access to care by implementing audit protocols to identify and review the adequacy of downstream organizations' provider networks and taking appropriate network enforcement actions for noncompliance with network adequacy standards. In addition, the FAH urges CMS to incorporate network adequacy in the Star Ratings Program.

[3] OIG Letter at 20 (emphasis added).

- **Access to Post-Acute Care:** MA beneficiaries routinely experience inappropriate delays in discharge from the inpatient hospital setting due to MAOs': (1) lack of an adequate post-acute network, (2) lack of post-acute providers in MAOs' networks willing to accept beneficiary discharges, and (3) MAOs' utilization review activities, which include prior authorization to the post-acute setting. When a patient is ready for transfer from an acute-care setting to a post-acute environment (including LTCHs, IRFs, and skilled nursing facilities ("SNFs")), the most appropriate course is the prompt and safe transfer of the beneficiary so s/he may begin to receive post-acute care (e.g., rehabilitation) in the most suitable environment. MAOs, however, often are financially incentivized to prolong beneficiaries' hospital stays (often paid at a case rate such as the MS-DRG system) rather than incurring the additional cost of post-acute provider stays, and may delay discharges based on the lack of available or willing post-acute providers or utilization review activities. In addition, MAO's post-acute networks often do not include an adequate number of post-acute facilities to ensure that the appropriate facility is available and post-acute care is not delayed or disrupted. The FAH recommends CMS require MAOs to demonstrate meaningful network access, including by raising the minimum number of in-network post-acute facilities, establishing a minimum facility-to-beneficiary ratio for in-network IRFs and LTCHs, and monitoring delays in MA beneficiary inpatient hospital discharges due to the lack of capacity among in-network post-acute facilities. In addition, CMS should audit MAO practices associated with approving timely discharges to an appropriate post-acute setting. In contrast to FAH member experiences with MAOs, FAH members generally do not routinely experience these post-acute care issues in the Medicare fee-for-service beneficiary population.

- **Risk Adjustment Claim Encounter Submissions:** The FAH understands MAOs currently include MA encounter data from denied (in part or in full), pended, and underpaid claims in their risk adjustment data submissions to CMS, resulting in increased risk adjustment payments that do not reflect the costs incurred by the MAO. This behavior is inconsistent with the purposes of the Part C Risk Adjustment Program and inflates Medicare spending without any corresponding beneficiary benefit. The FAH urges CMS to limit MA encounter data for the Risk Adjustment Program to data derived from fully paid claims or, in the case of a provider that accepts capitation, provider encounter data.

- **Use of Third-Party Contractors to Perform Audits:** MAOs often hire private contractors on a contingency fee basis to conduct a variety of audits on a pre-payment or post-payment claims basis. These audit types include: (1) charge audits, where the contractors inappropriately remove Medicare covered charges from claims; (2) MS-DRG audits, where the contractors use proprietary software to downgrade the underlying diagnoses necessary to support a DRG by inappropriately removing or rebundling billed ICD-10 codes; and (3) medical record audits, where the contractors question the accuracy of physician documentation regarding the beneficiary's health and associated comorbidities that support the underlying diagnosis and medical necessity. These audits are undertaken without any clinical basis and regularly fail to include an adequate explanation for the contractor's conclusions. Through this process, remote third-party contractors overrule the professional opinion of the treating professionals, despite often lacking the relevant clinical training or expertise. MAOs' delegation to these contractors

frequently creates confusion due to poor communication between MAOs and their contractors. These issues are exacerbated due to convoluted appeal processes, as discussed below. While the FAH acknowledges that MAOs are obligated to conduct reasonable audits, we are concerned that contingency fee audits conducted by MAOs' contractors are improperly motivated by financial incentives, fueling a "bounty hunter" mentality, and inappropriately burdening providers caring for MA beneficiaries. CMS acted several years ago to curb these types of unfair practices under the Medicare fee-for-service recovery audit contractor ("RAC") program and should exercise similar oversight of these practices under the MA program.

- **Appeal Rights:** MA providers' appeal rights are typically governed by their agreements with MAOs. The MAOs' appeals processes are complex, cumbersome, not standard across plans, often not automated, and require significant administrative resources and staffing for health care providers.

- **Improving Transparency and Quality Incentives for MA Stars Ratings Program:** In addition to our recommendations on policy improvements to protect patients in MA, we urge CMS to consider further refinements to its MAO oversight by developing new quality metrics for MAO operations that could be included in the Star Ratings Program. New quality measures should be developed to rate and report on patient access problems related to appeals and denial overturn rates for prior authorization, appeals and overturn rates for payment denials, network adequacy, and service delays. The FAH is currently developing a new MA quality measure concept on Level 1 Appeals to highlight overturn rates for health plans. This measure would supplement the current measure evaluating Level 2 Appeals. We believe such measures would promote competition on these critical access-oriented dimensions of MA plan quality, rewarding and incentivizing better MAO behavior and providing Medicare beneficiaries with critical information on the potential for excessive plan denials for service. We hope to share more on this work with you and your staff soon.

CMS has the statutory authority to address these and other abusive MAO practices as part of its broad oversight authority over MAOs. And, as explained further in the next section, such oversight would not implicate the non-interference clause contained in section 1854(a)(6)(B)(iii) of the Social Security Act or compromise its goals.

III. The Non-Interference Clause Should Be Construed Narrowly

The Social Security Act provides CMS wide latitude to address MAO behavior, and the non-interference prohibitions expressly enumerated in the statute would *not* preclude CMS from taking action regarding MAOs' inappropriate use of clinical criteria to deny or alter care delivery settings, improper actions limiting provider networks, or other abusive measures that inappropriately limit beneficiary access to care and burden providers.

The non-interference clause contains two discrete, narrowly-drawn prohibitions. First, CMS cannot mandate an MAO contract with a specific provider. Second, CMS cannot mandate that an MAO implement a particular price structure within a provider contract. The text of the non-interference clause reads as follows:

> In order to promote competition under this part and part D and in carrying out such parts, the Secretary may not [1] require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this subchapter or [2] require a particular price structure for payment under such a contract to the extent consistent with the Secretary's authority under this part.[4]

Beyond these two express prohibitions, CMS retains its broad regulatory authority – and responsibility – to ensure beneficiaries receive the Medicare benefits to which they are entitled.

The plain text of the non-interference clause has not been expanded by regulation or judicial precedent. To date, we have only identified limited CMS discussion of section 1854(a)(6)(B)(iii) in the context of mandated payment model adjustments for MAOs, which would plainly violate the statute's directive that CMS not "require a particular price structure for payment under" a provider agreement.[5] Along similar lines, CMS recently concluded that a commenter's suggestion that CMS require "payment by the MA organization of certain amounts to a contracted provider" is "within the scope of" actions precluded by the non-interference clause.[6]

The larger context of the MA statutory scheme and legislative history confirm the non-interference clause is a narrowly tailored, targeted provision designed to foster competition rather than to place MAO conduct beyond CMS' regulatory reach. Ever since the Medicare and Medicaid programs were enacted in 1965, CMS has been charged with providing a broad swath of Americans with access to essential quality and affordable health care. The MA program incorporates private, CMS-contracted plans in the Medicare program with the objective of expanding beneficiary choice while leveraging plan competition to improve quality and reduce program costs. The MA non-interference clause and the Part D non-interference clause, are designed to preserve that competition by preventing CMS from setting MA rates or mandating contracting with any particular provider.[7] The legislative history reflects a particular desire to preserve price-based competition among MA plans by prohibiting CMS from setting rates.[8]

[4] Social Security Act § 1854(a)(6)(B)(iii).

[5] *See* CMS, "Report to Congress: Alternative Payment Models & Medicare Advantage" (July 16, 2019), https://www.cms.gov/medicare/medicare-advantage/plan-payment/downloads/report-to-congress-apms-and-medicare-advantage.pdf; *See also* Centers for Medicare & Medicaid Services (CMS), "Additional Information Regarding the Mandatory Payment Reductions in the Medicare Advantage, Part D, and Other Programs" (May 1, 2013), https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/PaymentReductions.pdf

[6] Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards, 87 Fed. Reg. 22,290, 22,380 (April 14, 2022).

[7] In 2003, section 1854(a)(6)(B)(iii) was amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, § 222, 117 Stat 2066, to extend its requirements to Medicare Prescription Drug Plans, and a corresponding provision was included in the Part D statute at 1860D-11(i).

[8] *See* 149 Cong. Rec. S15670-03, S15691, describing legislators' goals in incorporating the non-interference clause with respect to Part D plans: "They said: We believe in competition. . . . Let the private sector negotiate their incentives for the insurers to get lower costs out of the pharmaceuticals. . . . Let that mechanism work. Don't have the head of CMS, the Medicare Director in Washington, DC, dictate prices for everybody. *Let us*

Expanded CMS oversight over the abusive MAO practices described in our September 1 Letter and above would not implicate the non-interference clause or compromise its goals. Indeed, the law is clear that Medicare beneficiaries who enroll in MA plans are entitled to the same benefits, at a minimum, that they would receive if they were enrolled in original Medicare.[9] To that end, CMS retains the authority to ensure MAOs satisfy minimum benefit requirements. By implementing the recommendations we have offered, CMS would ensure MAOs comply with their basic statutory obligation to provide beneficiaries access to timely, adequate, and appropriate care. Such a regulatory response would *promote* meaningful competition between MAOs on the dimensions of quality, value and care delivery while also protecting beneficiaries and providers.

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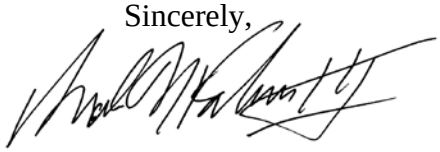
The FAH appreciates the opportunity to offer these insights. We are committed to working with you to ensure America's seniors in MA plans have improved access and better care. If you have any questions or would like to discuss further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,



CC: The Hon. Christi A. Grimm, Inspector General, Department of Health and Human Services
Jonathan Blum, Principal Deputy Administrator and COO, CMS
Dr. Meena Seshamani, MD, PhD, Deputy Administrator and Director, Center for Medicare

Attachment

not set those prices in the Senate. Let us let the marketplace work to squeeze cost and get efficiency out of the system" (emphasis added).

See also 149 Cong. Rec. S15670-03, S15761, "The competition in this bill achieves significant 'bang for the buck' because it relies on drug plans to negotiate discounts. CBO says the private insurance model has a cost management factor of 25 percent-the effect of price discounts, rebates, utilization controls, and other tools that a PDP might use to control spending. By relying on the bargaining power of drug plans, this bill will drive down the costs of prescription drugs."

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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.

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

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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.

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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

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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
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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

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.

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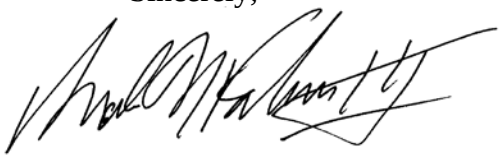
The FAH appreciates the opportunity to submit these comments on these important issues. If you have any questions, please contact me or any member of my staff at (202) 624-1534.

Sincerely,



Surprise Billing/Independent Dispute Resolution (IDR) Process

September 2022

- In July 2021, CMS issued an interim final rule (IFR) to implement sections of the *No Surprises Act* relating to the calculation of the qualifying payment amount (QPA), patient notice and consent for post-stabilization services, and a surprise billing complaint process.

- A second IFR to implement the IDR process to resolve payment disputes between providers and payers was issued on September 30, 2021.

- FAH had success with improving the *No Surprises Act* from earlier versions moving through Congress, and we were able to level the field between providers and insurers while protecting patients. The September 2021 IDR rule largely reversed that success by establishing a clear presumption that the initial QPA (which is the median contracted rate) is the correct amount, inconsistent with the law which contemplates that the IDR entity would consider on an equal footing with the QPA several other key factors to ensure adequate payment.
    - This approach aligned with the position of insurers, employers, unions, and consumer/patient groups.

- FAH worked closely with Hill allies and provider partners to counter this IDR provision.
    - The AHA and AMA jointly filed a legal challenge in December 2021 asking the federal DC District Court to declare that the Administration acted unlawfully in promulgating the IDR presumption and to stop enforcement of the rule.
    - The FAH coordinated with the AHA and AMA and led a group of hospital associations in filing an amicus brief in December 2021 support of the lawsuit.
    - After hearing oral arguments in March 2021, DC District Court Judge Leon said it would not be efficient for the Court to issue a decision before the Administration issues its IDR final rule in summer 2022. The case is still pending before the Court.

- The Texas Medical Association also challenged the IDR rule, and in February 2022, a federal District Court in Texas issued a favorable decision. It applies nationwide and concludes that the IDR regulation's heavy-handed presumptive standard, favorable to insurers, is inconsistent with the surprise billing law and does not comply with procedural notice and comment rulemaking requirements.

- Following these efforts, the Administration issued an IDR final rule in August 2022 that eliminates the presumption that the QPA is the correct payment amount, which is a more balanced approach to the IDR process.

- The next key battleground in the IDR process will be whether the QPA transparently captures all relevant information as well as explaining how the QPA may fail in this regard. As the IDR process moves forward, FAH staff is working with members to engage CMS in pushing back on plans' strategies to propose QPAs that are non-transparent and clearly invalid and avoid good faith negotiations with providers through the IDR process.

Hospital Price Transparency

September 2022

- The Patients Right Advocate group conducts the Semi-Annual Hospital Price Transparency Compliance Report. It's third and most recent report issued in August 2022, reviewed 2,000 hospitals and claims that 16 percent of hospitals are in compliance with the hospital price transparency final rule and that 5.1 percent did not post any standard charges at all.
- Two previous reports released by the group allege a 14.6 hospital compliance rate one year after the rule became effective and 5.6 percent six months after the rule became effective.
- The group is advocating for stronger enforcement penalties for hospitals.
- The group's report is highly questionable given that the consulting firm, Milliman, found a 68 percent compliance rate and both organizations' findings varied significantly from CMS – in June 2022, CMS had sent a total of 352 warning letters to noncompliant hospitals requesting corrective action plans and of those citations, CMS said only 157 non-compliant remained noncompliant.
- These types of reports typically generate one-day stories, with CMS enforcement efforts targeted toward outliers that show complete disregard of rule. However, the environment could become more hostile with a possible House Republican majority next year.

<u>CMS Hospital Price Transparency Enforcement</u>

- In June 2022, CMS fined two hospitals for noncompliance the hospital price transparency rules that took effect January 2021 – both were Georgia hospitals within the same system and the fines totaled nearly $1.1 million.
- Before issuing the fines, CMS provided warning notices to both hospitals and requested a corrective action plan, but neither provided a plan.
- Beginning in 2022, the maximum annual penalty for noncompliance for larger facilities increased from $109,500 to over $2 million per hospital.

<u>HHS OIG Hospital Audits</u>

- To evaluate CMS's monitoring and enforcement of the hospital price transparency rule, which took effect January 1, 2021, the HHS OIG announced this month that beginning in 2023 it will review the controls in place at CMS and statistically sample hospitals to determine whether CMS's controls are sufficient to ensure that hospital pricing information is readily available.
    - If hospitals are not in compliance with the transparency rule, the OIG will contact the hospitals to determine the reason for noncompliance and determine whether CMS identified the noncompliance and imposed consequences on the hospitals.

<u>Hospital Price Transparency Legislation</u>

- In June 2022, Senator Braun (R-IN) introduced S. 4414, the *Expose Hospitals Violating Price Transparency* Act, which would require HHS to publish a list of hospitals found not to be in compliance with the hospital price transparency rule.

Requirements Related to Surprise Billing (CMS-9909-F and CMS-9908-F); Summary of Final Rules

On August 26, 2022, the Departments of Treasury, Labor, and Health and Human Services (HHS) published in the Federal Register (FR) final rules entitled Requirements Related to Surprise Billing (87 FR 52618). The rules finalize two significant policy matters. The first relates to certain disclosure requirements for information that group health plans and health insurance issuers must share about the qualifying payment amount (QPA) under the interim final rules issued in July 2021 (the "July 2021 IFC"[1]). The second addresses requirements under the interim final rules issued in October 2021 (the "October 2021 IFC"[2]) for the consideration of information when a certified independent dispute resolution (IDR) entity makes a payment determination under the Federal IDR process. The remaining provisions of the July 2021 IFC and October 2021 IFC will be finalized in future rulemaking after further consideration of comments.

The rules are effective October 25, 2022, and apply to items and services furnished on or after that date for plan or policy years beginning on or after January 1, 2022.

I. Background

A. Overview

The No Surprises Act was enacted as part of the Consolidated Appropriations Act, 2021 (CAA).[3] It established protections for enrollees of health plans from surprise medical bills when they receive emergency services (including certain post-stabilization services), certain non-emergency services from nonparticipating providers at participating facilities, and air ambulance services from nonparticipating providers of air ambulance services under certain circumstances. Under certain conditions and with the enrollee's notice and consent, the limitations on balance billing and cost sharing may be waived with respect to post-stabilization and non-emergency services.

It established an IDR process to resolve disputes regarding certain out-of-network payment rates as well as a patient-provider dispute resolution process to resolve disputes about rates between providers and uninsured or self-pay patients.

[1] Requirements Related to Surprise Billing; Part I (86 FR 36872, July 13, 2021).
[2] Requirements Related to Surprise Billing; Part II (86 FR 55980, October 7, 2021).
[3] Public Law 116-260; December 27, 2020; https://www.govinfo.gov/link/plaw/116/public/260?link-type=pdf.

B. July 2021 IFC

The July 2021 IFC implemented limits on cost sharing for certain protected out-of-network services, prohibited balance billing, and required cost sharing to count towards in-network deductibles and out-of-pocket maximums. The rules specify that cost-sharing amounts for emergency services furnished by nonparticipating providers or facilities, and for nonemergency services furnished by nonparticipating providers at certain participating facilities, must be calculated based on one of the following: (1) an amount determined by an applicable All-Payer Model Agreement; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed charge or the plan's or issuer's median contracted rate, the latter referred to as the qualifying payment amount (QPA).

The July 2021 IFC established the methodology for calculating the QPA, which in most cases will be the median contracted rate of the plan or issuer in effect for the particular item or service on January 31, 2019, increased for inflation. Plans and issuers must make certain disclosures about the QPA with each initial payment or notice of denial of payment as well as certain additional information upon request of the provider, facility, or air ambulance provider (hereinafter in this summary generally referred to as a provider). If a provider seeks to initiate a 30-day open negotiation period to determine the total payment amount, the IFC required a plan or issuer to furnish to the provider contact information (i.e., the telephone number and email address) of the appropriate personnel for the provider to contact to initiate open negotiation using a standard notice developed by the Departments. The Departments report that some providers are being required to use web systems owned by the plan or issuer to initiate an open negotiation period. While use of a plan or issuer online portal may be a permissible practice for plans or issuers, they may not refuse to accept the standard notice of initiation of open negotiation from a provider who complies with the requirements under both IFCs (e.g., emailing the standard notice to the email address provided by the plan or issuer) in lieu of using the online portal.

Under the IFC, plans and issues must also furnish to providers upon request additional information, including whether the QPA includes contracted rates that were not set on a fee-for-service basis, whether the QPA was determined using underlying fee schedule rates or a derived amount, which database was used to determine the QPA, the related service code that was used to determine the QPA for an item or service billed under a new service code, and, if applicable, whether contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments that were excluded when calculating the QPA.

C. October 2021 IFC

The October 2021 IFC codified other requirements of the No Surprises Act. This IFC established the Federal IDR process to determine the out-of-network rate for certain protected emergency, non-emergency, and air ambulance services, including setting the timeframes for open negotiation over payment rates and other timelines, choosing the certified IDR entity, specifying the selection criteria for the IDR to use in making a determination of the appropriate payment rate, certifying IDR entities, and establishing reporting requirements. For external

review requirements, the IFC required health insurance issuers and group health plans to make external review available for adverse benefit determinations related to claims protected by the No Surprises Act, and it expanded the scope of these external review rules to apply to grandfathered health plans.

Another provision of the IFC required providers and facilities to furnish good faith estimates of expected charges to uninsured or self-pay individuals upon request or upon scheduling an item or service. HHS also established a patient-provider dispute resolution process for an uninsured or self-pay patient who receives a bill for an amount substantially in excess of expected charges as described in the good faith estimate to seek a determination of the amount to be paid to the provider or facility.

The October 2021 IFC also established a presumption under the Federal IDR process that the QPA is the appropriate payment amount unless other considerations suggest it is materially different from the appropriate payment. Thus, in selecting between the offers from the parties involved, the certified IDR entity must assume that the QPA is the appropriate payment amount and, unless other credible information suggests that the QPA is materially different from the appropriate payment, select the offer closest to the QPA. The term "materially different" was defined to mean a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out-of-network rate and view the information as showing that the QPA is not the appropriate out-of-network rate.

D. Comments to the IFCs

The Departments report having received thousands of comments on the two IFCs. The areas of comment addressed in these final rules are as follows:

- A clarification in the October 2021 IFC stating that a plan or issuer is not required to calculate the participant's, beneficiary's, or enrollee's cost sharing using the QPA for the service code submitted by the provider or facility; instead, the plan or issuer could calculate that cost sharing using the QPA for a downcoded service code that the plan or issuer determined was more appropriate.
- The information required by the July 2021 IFC that must be shared about the QPA.
- Payment determination standards under the Federal IDR process, including provisions governing the certified IDR entity's consideration of the enumerated factors.

1. <u>QPA Disclosure Requirements</u>

Many comments supported the disclosure requirement and emphasized the importance of providing that information at the time of the initial payment of notice of denial. Stressing the importance of transparency in calculating the QPA, the Departments were encouraged to expand the range of information shared with providers. Some commenters posited that the degree of disclosure was insufficient thereby granting more power and discretion to plans and issuers. Some observed that plans may not have access to all the relevant information, which may be in

the control of other providers or vendors. Providers were concerned that plans and issuers would calculate the QPA for a lower level service code or modifier instead of using the particular service code or modifier specified in the claim submitted for reimbursement. Providers asked for access to information on downcoding to prepare for the open negotiation process and the federal IDR process; some requested that plans or issuers be required to disclose whether the claim was downcoded when computing the QPA and the rationale for that downcoding.

2. Payment Determination Standards Under the Federal IDR Process

The Departments indicate that many comments supported their interpretation of the requirement for IDR entities to consider the factors listed in statute, stating that using the QPA as a baseline would lead to lower health care costs for consumers. They argued this interpretation would facilitate achieving Congressional Budget Office savings estimates and shield consumers from surprise bills and higher insurance premiums. These commenters also noted that the October 2021 IFC provided a process for rates in excess of the QPA where they could be justified. Other comments raised concerns with giving the same weight to all the different statutory factors arguing that some of those factors could already be built into the QPA. However, notwithstanding these arguments, the Department's statutory interpretation did not withstand judicial scrutiny.

Commenters opposed to the Department's statutory interpretation that established a rebuttable presumption in favor of the QPA noted it was inconsistent with congressional intent and tips the scales in favor of plans and issuers. This policy was seen as ignoring the complexity of billing factors and creating an incentive for the plan or issuer to downcode claims in bad faith. They worried that the prominence of the QPA may drive down reimbursement rates for those currently reimbursed above the median contracted rate; this in turn may jeopardize network adequacy and viability of physician practices. Some commenters believe the policy provided incentives for plans and issuers to prefer out-of-network care, which may result in reduced networks, because plans and issuers would pay the QPA rather than a market rate under certain circumstances. Many of these commenters asked the Departments to remove these provisions and to direct certified IDR entities to consider all permissible and relevant information submitted by the parties.

3. Payment Determinations for Air Ambulance Services

Similar support of and concerns with the QPA, and transparency of the calculation of the QPA, were raised in the context of air ambulance services. Commenters argued that using the QPA as a baseline for air ambulance services ignores concerns unique to the provision of these services. Some argued that the prevalent use of single-case agreements for these services means a QPA would not adequately reflect market rates. Others noted that hospital-based air ambulance providers are subsidized by their hospitals, and they believe including rates of these providers in the QPA calculation with the rates of other air ambulance providers would improperly lower the QPA.

4. Certified IDR Entity's Written Decision

There was support for the requirement that the certified IDR entity provide a written decision that includes the underlying rationale for its determination. Some commenters were very concerned that only requiring an explanation of the rationale if the certified IDR entity determined that the QPA was materially different from the appropriate out-of-network rate may discourage those entities from considering additional factors. They believe requiring an explanation in all cases would ensure that certified IDR entities consider all information submitted by the parties and allow the parties to fully understand the rationale behind the determination. It could also improve the IDR process over time because parties will have a better understanding of the types of information these entities find credible and when the parties should pursue the IDR process.

E. Litigation

Certain parts of the IFCs were vacated due to court orders in *Texas Medical Association* and *LifeNet.*[4] The plaintiffs were successful in arguing that the IFCs ignored congressional intent that certified IDR entities must consider the QPA and other factors without favoring any factor. In the *Texas Medical Association* case, the District Court issued an order vacating portions of the October 2021 IFC governing aspects of the Federal IDR process for non-air ambulance qualified IDR items or services. Provisions vacated include the following:

- The definition of material difference;
- The requirement that a certified IDR entity must select the offer closest to the QPA unless it determines credible information submitted by either party clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for qualified IDR items or services, or if the offers are equally distant from the QPA but in opposing directions;
- The requirement that the certified IDR entity may only consider the additional information submitted by either party if the credible information clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for qualified IDR items or services;
- The examples of dispute resolution; and
- The requirement that, if the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on the factors those entities may consider for the qualified IDR item or service.

Similarly, LifeNet, an air ambulance provider, prevailed in its challenge to the provisions of the IFCs applicable to air ambulance services and the determination of the QPA. Specifically, the District Court vacated the rule that certified IDR entities may only consider information

[4] Texas Medical Association, et al. v. United States Department of Health and Human Services, et al., Case No. 6:21–cv–425 (E.D. Tex.) (Texas Medical Association) (February 23, 2022) and LifeNet, Inc. v. United States Department of Health and Human Services, et al., Case No. 6:22–cv–162 (E.D. Tex.) (LifeNet) (July 26, 2022).

submitted by a party if the information clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate.

F. Scope and Purpose of These Final Rules

These final rules are narrow in scope; they only address issues raised by the decisions of the District Court to vacate portions other the IFCs noted above, and discrete issues raised in comments to the IFCs. These include information that must be disclosed about the QPA related to downcoding,[5] the certified IDR entity's consideration of the statutory factors when making a payment determination,[6] and the entity's written decision.[7] The regulations are also amended to remove language vacated by the District Court's orders.

The remaining provisions of the July 2021 IFC and October 2021 IFC will be finalized in future rulemaking after further consideration of comments.

II. Overview of Final Rules

A. Information To Be Shared About the Qualifying Payment Amount

Disclosures of certain information are required from plans and issuers with each initial payment or notice of denial of payment. Under the IFCs, where the QPA serves as the recognized amount (or as the amount that cost sharing is based on for air ambulance services), the QPA and certain information related to the QPA for the item or service involved must be disclosed by the plan or issuer with each initial payment or notice of denial of payment. Certain additional information must be provided upon request of the provider, facility, or air ambulance provider (collectively referred to as providers) for each item or service involved.

The Departments agree with comments that additional information would be helpful to providers where the plan or issuer has downcoded the billed claim. If the plan or issuer downcodes the billed claim and asserts that the QPA that corresponds with the downcoded claim is the correct total payment amount, providers must (1) know that the item or service has been downcoded and (2) have information on the QPA for the downcoded claim and the amount that would have been the QPA without downcoding. The Departments believe this is critical information in developing an informed offer or submitting information to the certified IDR entity, which the entity will use in selecting the best offer.

The term "downcode" is defined to mean the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower QPA than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

[5] See 26 CFR 54.9816–6T(d), 29 CFR 2590.716–6(d), and 45 CFR 149.140(d).
[6] See 26 CFR 54.9816–8T(c)(4)(iii)–(iv) and 54.9817T–2(b), 29 CFR 2590.716–8(c)(4)(iii)–(iv) and 2590.717–2(b), and 45 CFR 149.510(c)(4)(iii)–(iv) and 149.520(b).
[7] See 26 CFR 54.9816–8T(c)(4)(vi)(B), 29 CFR 2590.716–8(c)(4)(vi)(B), and 45 CFR 149.510(c)(4)(vi)(B).

Under these final rules, if the QPA is based on a downcoded service code or modifier, the plan or issuer must provide the following information with the initial payment or notice of denial of payment for the item(s) or service(s) involved:

- A statement that the service code or modifier billed by the provider was downcoded;
- An explanation of why the claim was downcoded, including a description of which service codes were altered and which modifiers were altered, added, or removed; and
- The amount that would have been the QPA had the service code or modifier not been downcoded.

The Departments are still considering comments on the July 2021 IFC on whether additional disclosures related to the QPA calculation methodology should be provided with an initial payment or notice of denial of payment, or upon request. They stress that payment determinations in the Federal IDR process should focus on the determination of a total payment amount for a particular item or service based on the facts and circumstances of the dispute—not scrutinizing the methodology a plan or issuer uses for the QPA.

B. Payment Determinations Under the Federal IDR Process

1. Background

Under the October 2021 IFC, no later than 10 business days after the selection of the certified IDR entity, each party to a determination must submit to the certified IDR entity:

- An offer for a payment amount expressed as both a dollar amount and as a percentage of the QPA;
- Information requested by the certified IDR entity related to the offer;
- For providers and facilities, information about the size of their practices and facilities, and practice specialty or types;
- For plans and issuers, information about the coverage area and geographic region and whether the coverage is insured, partially insured or self-insured; and
- For carriers in the Federal Employees Health Benefits (FEHB) Program, if the item or service relates to FEHB.

Parties may submit other information so long as the information does not include information that is prohibited from being considered in the Federal IDR process, as described more fully below.

No later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the two offers submitted. Under the October 2021 IFC, in selecting the offer, the certified IDR entity must assume that the QPA is the appropriate payment amount and, unless other credible information suggests that the QPA is materially different from the appropriate payment, select the offer closest to the QPA. If both offers are equidistant from the QPA, the IDR must choose the amount that best reflects the value of the item or service.

In addition to the QPA and other requested information, the certified IDR entity must consider information submitted by the parties relating to the following circumstances insofar that the information is credible and that it is not already taken into account in the QPA:

- The level of training, experience, quality and outcomes of the provider or facility.
- The market share held by the provider, facility, or plan within the geographic region in which the item or service was provided.
- The acuity of the individual, or the complexity of furnishing the item or service to the individual.
- The teaching status, case mix, and scope of services of the facility furnishing the item or service.
- Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan to enter into network agreements with each other during the previous 4 plan years.

The presumption that the QPA is the appropriate payment amount unless other considerations suggest it is materially different from the appropriate payment was based on the belief that typically the QPA will be the reasonable out-of-network rate. In addition, the Departments described policy considerations that supported the reliance on the QPA as reflecting standard market rates as well as the oversight and enforcement applicable to the calculation of the QPA to ensure that it reflects its intended rate. They believed that reliance on the QPA as the likely payment amount is appropriate and promotes efficiency and predictability as long as the parties have the ability to rebut the presumption with credible information.

Under the October 2021 IFC, the process for a certified IDR entity to select an offer for air ambulance services is essentially the same as for all other services but includes the following additional considerations:

- The quality and outcomes measurements of the provider that furnished the services.
- The acuity of the condition of the participant or beneficiary receiving the service, or the complexity of furnishing the service to the participant or beneficiary.
- The training, experience, and quality of the medical personnel that furnished the air ambulance services.
- Ambulance vehicle type, including the clinical capability level of the vehicle.
- Population density of the point of pick-up for the air ambulance (such as urban, suburban, rural, or frontier).
- Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan to enter into network agreements with each other during the previous 4 plan years.

Certain factors may not be considered by the certified IDR entity:

- Usual and customary charges nor rates expressed as a proportion of usual and customary charges.
- The amount that would have been billed if not for the prohibition on balance billing. The Departments interpret this prohibition to also prohibit consideration of the billed charges to the plan or issuer for the qualified IDR item or service.

- Payment or reimbursement rates for the items or services under a public program including Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and TRICARE.

2. Court Orders

As noted above, the District Court in *Texas Medical Association* and *LifeNet* issued opinions and orders that vacated certain provisions of the October 2021 interim final rules that govern aspects of the Federal IDR process, including provisions that the District Court construed as creating a rebuttable presumption in favor of the QPA. These final rules do not create a rebuttable presumption in favor of any factor considered by the certified IDR entity.

The Departments believe the QPA will always be relevant to the payment determination. They note that if the QPA is determined consistent with the July 2021 IFC detailed rules and communicated per the applicable disclosure requirements, the QPA will meet the credibility requirement that applies to the additional information and circumstances under these final rules. They also state that it is reasonable to ensure that certified IDR entities consider the QPA, a quantitative figure, and then consider the additional factors which they describe as qualitative, when determining the out-of-network rate—another quantitative figure.

3. Revisions in the Final Rules

In these final rules, the Departments revise a number of policies adopted in the October 2021 IFC.

a. Requirement To Consider the QPA and Additional Information Submitted

The No Surprises Act requires the certified IDR entity to always consider the QPA; the parties do not have to specifically bring it to the certified IDR entity's attention. The Departments repeatedly state that their implementation of the Federal IDR process is designed to ensure all certified IDR entities approach payment determinations in the same manner, which promotes consistency and predictability. They believe the QPA, a quantitative figure, will help entities in considering each of the other statutory factors because they can evaluate whether those other factors present information that has not already been captured in the calculation of the QPA. While noting that these final rules do not require certified IDR entities to default to the offer closest to the QPA, they nonetheless believe that the QPA will most often represent an appropriate out-of-network rate. However, the final rules specify that certified IDR entities should select the offer that best represents the value of the item or service under dispute after considering the QPA for the applicable year for the item or service and all permissible information submitted by the parties to determine which offer best reflects the appropriate out-of-network rate.

Under these final rules, the certified IDR entity must evaluate whether the information relates to the offer submitted by either party for the payment amount for the qualified IDR item or service in dispute; this includes information requested by the entity. The certified IDR entity should

evaluate the credibility of the information and should not give weight to information that is not credible.

b. Avoidance of Double-Counting Information

Some commenters argued that some information submitted by the parties, such as patient acuity or the complexity of furnishing the qualified IDR item or service, is already accounted for in the QPA calculation and should not receive additional weight. Others noted that in some circumstances, such as outlier cases, the QPA would not adequately account for those factors. The Departments believe that in many cases the additional factors will already be accounted for in the QPA. The final rules require certified IDR entities to consider the QPA and then all additional information submitted by the parties relating to the offer for the payment amount. However, each factor should be weighted only once. To the extent a factor is not already reflected in the QPA, the certified IDR entity should give that factor appropriate weight based on information related to it provided by the parties.

c. Examples

The final rules strike the examples added to the regulations by the October 2021 IFC and substitute five new examples that illustrate the consideration of factors when making a payment determination, including whether and how to give weight to additional information submitted by a party. The examples are reproduced in the Appendix to this summary.

Stakeholders are reminded that a certified IDR entity must not consider information on the prohibited factors (noted above) when making a payment determination. The Departments will monitor the effects of the requirements for payment determination and may make what they refer to as appropriate adjustments to the process to ensuring a fair, cost-effective, and reasonable IDR payment determination process that does not have an inflationary impact on health care costs.

C. Payment Determinations Under the Federal IDR Process for Air Ambulance Services

The process for a certified IDR entity to select an offer in a dispute involving air ambulance services is much the same as the process that applies to other qualified IDR items and services. The difference in the case of air ambulance services is that there are different additional factors that the entity must consider, which are listed above.

Consistent with the revisions to the October 2021 IFC for making payment determinations for non-air ambulance services described above, any presumption that the QPA is the appropriate payment amount is eliminated. The certified IDR entity must consider additional information submitted by a party (including information requested by the entity) in determining which offer to select in a dispute related to air ambulance services as well as the QPA for the applicable year for the same or similar service to determine the appropriate out-of-network rate. The entity must evaluate whether each piece of submitted information is credible, relates to the offer for the payment amount for the qualified IDR service, and does not include information on prohibited factors.

The certified IDR entity must not give weight to the information if it is not credible, does not relate to either party's offer, or is included in the QPA calculation or other credible information.

D. The Certified IDR Entity's Written Decision

The October 2021 IFC required the certified IDR entity to submit its decision and rationale for the decision through the Federal IDR portal. If the decision is for an amount that is not closest to the QPA, the rationale must include a detailed explanation of the additional considerations taken into account which demonstrated that the QPA is materially different from the appropriate out-of-network rate.

The District Court in *Texas Medical Association* issued an order that invalidated the requirement for the certified IDR entities to provide an explanation of the credible information that demonstrated that the QPA was materially different from the appropriate out-of-network rate. The Departments note that the order did not invalidate the general requirement that a certified IDR entity issue a written decision. They believe that each written decision should include a comprehensive discussion of the rationale for the decision to ensure that the parties understand the outcome of a payment determination under the Federal IDR process.

Under these final rules, a certified IDR entity must explain in all cases its determination in a written decision provided to the parties and to the Departments, in a form and manner specified by the Departments in separate guidance. To provide greater transparency, each written decision must include an explanation of the determination, including what information the entity determined showed that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the QPA and any additional credible information submitted by the parties. Additionally, when the certified IDR entity relies on additional information or additional circumstances in selecting an offer, the written decision must explain why the entity concluded that the information was not already reflected in the QPA. This latter requirement is designed in part for monitoring and future policymaking by the Departments.

III. Applicability

These rules finalize certain provisions of the IFCs and make changes in light of the two decisions in *Texas Medical Association* and *LifeNet*. The July 2021 and October 2021 IFCs apply for plan or policy years beginning on or after January 1, 2022, except as modified in these rules.

The following requirements apply with respect to items or services furnished on or after October 25, 2022, for plan or policy years beginning on or after January 1, 2022:

- Requirements for additional information that must be provided with each initial payment or notice of denial of payment if the QPA is based on a downcoded service code or modifier.
- Requirements for certified IDR entities payment determination standards, written decisions, and reporting.

For the additional information that must be included in each initial payment or notice of denial of payment if a QPA is based on a downcoded service code or modifier, the final rules permit plans and issuers to use reasonable methods to provide this additional disclosure with the initial payment or notice of denial of payment while their systems and procedures are updated to provide the additional notice in a more streamlined and automated manner. The flexibility does not obviate the requirement to provide that information with respect to items or services furnished on or after October 25, 2022.

IV. Regulatory Impact Analysis

The Departments have examined the effects of the final rules pursuant to Executive Order 13563, Executive Order 12866, the Paperwork Reduction Act, and other authorities. They have determined that the final rules are "economically significant" within the meaning of Executive Order 12866 because they are expected have economic impacts of $100 million or more in any one year. Accordingly, the Departments provide an analysis of the potential costs, benefits, and transfers associated with these rules. They note that they are unable to quantify some of the benefits, costs, and transfers.

The Departments review the need for the regulatory action, citing the decisions in *Texas Medical Association* and *LifeNet* as well as comments received from the July 2021 and October 2021 IFCs. Table 1 (Accounting Statement) summarizes the benefits, costs, and transfers associated with the regulations and is reproduced below.

Table 1—Accounting Statement

Benefits:

- These final rules will increase transparency in the Federal IDR process.
- These final rules will help a provider, facility, or provider of air ambulance services ascertain what information will demonstrate that the provider's, facility's, or provider of air ambulance services' offer best represents the value of the item or service and aid the certified IDR entity in selecting an offer that best represents the value of the item or service.
- These final rules will promote more consistent payment determinations in the Federal IDR process for providers, facilities, providers of air ambulance services, plans, and issuers.
- These final rules will promote transparency with respect to the certified IDR entity's payment determination and will help to ensure that the determination of a total payment amount for a particular item or service is based on the facts and circumstances of the dispute at issue in each case.

Costs:

Costs (in millions)	Estimate	Year dollar	Discount Rate (%)	Period Covered
Annualized Monetized ($/Year)	$5.9	2021	7	2022-2031
	$5.9	2021	3	2022-2031

Quantified Costs: The Departments estimate the total annual cost associated with these final rules to be $5.9 million, with $4.3 million annually attributable to the additional information plans and issuers will be required to provide related to the QPAs, $1.2 million annually attributable to the preparation of IDR payment determination notices by certified IDR entities for nonparticipating providers or emergency facility claims, and $0.3 million annually attributable to the preparation of IDR payment determination notices by certified IDR entities for nonparticipating air ambulance providers' claims.
Transfers: These final rules make no changes that impact the transfers as described in the July 2021 and October 2021 interim final rules.

The Departments estimate that the total annual cost burden associated with the final rules is $5.9 million. Of that aggregate annual amount, $4.3 million is attributable to the additional information related to the QPAs, $1.2 million is attributable to the certified IDR entity's payment determination for nonparticipating provider and emergency facility claims, and $0.3 million is attributable to the certified IDR entity's payment determination notification for nonparticipating provider of air ambulance service claims.

Estimates of the number of health care providers, health care facilities, providers of air ambulance services, group health plans, issuers, third-party administrators (TPAs), FEHB carriers, and certified IDR entities are provided. The Departments note that there are 11 certified IDR entities that will be impacted by the final rules. They also expect that the final rules will only indirectly affect individuals with private health coverage who visit an emergency room, visit a health care facility, or are
transported by an air ambulance; the outcomes of payment disputes may impact premiums.

The benefits of the final rules include requirements for plans and issuers to provide additional information about the QPA with an initial payment or notice of denial of payment in cases involving downcoding, without the need for the provider to request this information. This in turn will provide better information for providers in submitting offers and greater transparency in the Federal IDR process. Certified IDR entities must consider the QPA as well as all additional permissible information submitted by a party to determine which offer best reflects the appropriate out-of-network rate; it must also consider whether additional credible information has already been accounted for in the QPA. Finally, the certified IDR entity's written decision must explain what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the QPA and any additional credible information. These policies will ensure that certified IDR entities carefully evaluate all credible non-duplicative information and will promote transparency for payment determinations by certified IDR entities.

V. Paperwork Reduction Act

The changes made by the final rules affect the existing OMB control number, 1210–0169; a copy of the information collection requirement (ICR) for this control number may be obtained at https://www.RegInfo.gov. OMB will consider all written comments regarding the ICR received on or before September 26, 2022. The final rules result in additional burdens to the ICR presented in the October 2021 IFC.

In addition, the Departments provide annual burden estimates for a number of components of the ICR including the following more significant items:

A. ICRs Regarding Additional Information To Be Shared With the Initial Payment or Notice of Denial of Payment

With respect to the requirement for plans and issuers to include additional information in an initial payment or notice of denial of payment where the QPA is calculated based on a downcoded service, the Departments assume TPAs will provide this information for self-insured plans and that issuers and TPAs will automate the process for providing this information. It is estimated that 1,477 issuers and 205 TPAs will incur a burden to comply with this provision. The Departments assume that approximately 10 percent of claims from nonparticipating providers, facilities, and nonparticipating providers of air ambulance services will involve downcoding. The annual burden will be approximately 84,475 hours (at an hourly rate of $50.76), with an associated equivalent cost of $4.3 million. For air ambulance services, it is estimated that the additional QPA information will be provided for approximately 4,968 claims, resulting in additional burden of 828 hours annually with an equivalent cost of $42,029.

It is estimated that 50 percent of the burden will be accounted for by HHS ($2,164,990), and 25 percent ($1,082,495) each by the DOL and the Department of the Treasury.

B. ICRs Regarding the Certified IDR Entity's Payment Determination Written Decision in the Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities

The requirements for information included in a written decision of a certified IDR entity are expanded under the final rules. The Departments estimate that 17,435 claims will be submitted as part of the Federal IDR process each year, and that the total cost burden for all certified IDR entities to prepare this notice for Federal IDR claims will be approximately $1.2 million ($69.24 x 17,435). The total annual cost burden for certified IDR entities to provide the payment determination notices regarding Federal IDR claims will be $1,192,641.

It is estimated that 45 percent of the burden ($536,689) will be accounted for by HHS, 25 percent ($298,160) each by the DOL and the Department of the Treasury, and 5 percent ($59,632) by OPM.

C. ICRs Regarding the Certified IDR Entity's Payment Determination Written Decision in the Federal IDR Process for Nonparticipating Providers of Air Ambulance Services

The Departments estimate there will be 4,968 claims for air ambulance services submitted to the Federal IDR process each year, and that the total cost burden for all certified IDR entities to prepare the notice of the entity's determination for Federal IDR claims will be approximately $0.3 million ($69.24 x 4,968). The total annual cost burden for certified IDR entities to provide the payment determination notices regarding air ambulance claims will be $339,836.

It is estimated that 45 percent of the burden ($152,926) will be accounted for by HHS, 25 percent ($84,959) each by the DOL and the Department of the Treasury, and 5 percent ($16,992) by OPM.

VI. Appendix; Examples of Consideration of Factors in Making Payment Determinations

The final rules substitute the following examples of how factors are to be considered by certified IDR entities making a payment determination. The new examples are required because portions of the October 2021 IFC that instructed certified IDR entities to apply a rebuttable presumption in favor of the QPA in making those determinations were vacated. The following examples are reproduced from section 149.510(c)(4)(iv) of title 45, Code of Federal Regulations, as added by the final rule.

(iv) *Examples*. The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does not include information on factors described in paragraph (c)(4)(v) of this section:

(A) *Example 1—(1) Facts*. A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(2) *Conclusion*. In this paragraph (c)(4)(iv)(A) (Example 1), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section [i.e., the enumerated additional factors besides the QPA] and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) *Example 2—(1) Facts*. A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that

the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(2) *Conclusion*. In this paragraph (c)(4)(iv)(B) (Example 2), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) *Example 3—(1) Facts*. A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(2) *Conclusion*. In this paragraph (c)(4)(iv)(C) (Example 3), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) *Example 4—(1) Facts*. A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan

years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written information, with the intent to show that the case mix and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(2) *Conclusion*. In this paragraph (c)(4)(iv)(D) (Example 4), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) *Example 5—(1) Facts*. A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 149.140(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 149.140(d)(1)(ii) at the time of the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(2) *Conclusion*. In this paragraph (c)(4)(iv)(E) (Example 5), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then

must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

Litigation Update

September 2022

Medicare DSH

Allina Health Services

- In early June 2019, the US Supreme Court ruled in favor of hospitals in *Azar v. Allina Health Services* regarding Medicare DSH payments. The Court ordered CMS to vacate its 2012 policy regarding the formula for calculating a hospital's Medicare DSH percentage, and in particular how to deal with Medicare Advantage beneficiaries entitled to Supplemental Security Income benefits.

- In August 2020, in response to the Supreme Court's decision, CMS issued a proposed rule that would retroactively apply to the prior years at issue in the litigation, the same DSH payment that was adopted beginning with fiscal year 2014 and that is not being legally challenged, which the FAH opposed on comments to the agency. If CMS finalizes the rule, as proposed, it likely would lead to more litigation by hospitals.

- In July 2021, a DC district court struck down a challenge (in *Florida Health Sciences Center, Inc.*) to the 2014 Part C policy that was promulgated through notice and comment in FY 2014 (after the Allina I court concluded that the 2004 rule was not the logical outgrowth of the proposed rule). The hospital plaintiffs' appeal has been docketed at the DC Circuit under the name *Allina Health System v. Becerra*.

- At the request of the parties in *Allina Health System*, the DC Circuit ordered that the *Allina Health System* case be held in abeyance pending the Supreme Court's decision in Empire Health Foundation (Medicare DSH Part A exhausted days).

- On September 12, after considering motions filed by the parties regarding future proceedings, the DC Circuit ordered that (1) the *Allina Health System* case remain in abeyance pending further order of the court and (2) appellants (the hospitals) file a motion to govern future proceedings in this case by October 24, 2022.

Empire Health Foundation

- In June 2022, the Supreme Court issued a decision in *Empire Health Foundation*. The Court overruled the Ninth Circuit in upholding HHS's interpretation of the Medicare statute establishing payments for DSH hospitals that treat a statistically significant share of low-income patients. HHS can therefore continue to calculate the DSH adjustment in a manner that generally reduces DSH payments to hospitals.

Dobbs v. Jackson Women's Health Organization

- In late June, in the case of *Dobbs v. Jackson Women's Health Oranization*, the Supreme Court overturned *Roe v. Wade* which had legalized abortion nationwide.

- Through extensive outreach with FAH members, and responding to White House inquiries, FAH staff developed a list of federal policy issues that could be implicated by the Dobbs decision, including for example, patient privacy protections, conflicts between state laws and federal EMTALA law, federal financial impact on the Medicaid program, impact on health care workforce, including mental health provider shortages, and ERISA pre-emption.

- HHS released guidance clarifying that termination of pregnancy would in some emergency cases be appropriate under EMTALA, and any state law that conflicts with this requirement would be preempted. The FAH also released a "Hospitals In Focus" podcast regarding EMTALA pre-emption in these emergency circumstances.

- In response to a Texas challenge of HHS' statutory authority to issue the guidance, a Texas federal judge has blocked enforcement of the HHS EMTALA guidance, holding that it does not preempt state law, exceeds the authority of EMTALA, and was improperly issued without notice and comment. The court blocked the guidance in Texas only and also with respect to the plaintiffs in the case. It is unclear at this point whether the Administration will file an appeal.

- In response to a Biden Administration legal challenge of Idaho's abortion 'trigger law' that does not provide an exception for the health of the pregnant patient, a federal judge preliminarily blocked the Idaho law in circumstances where it would conflict with EMTALA. Idaho, acting through its legislature and not its AG, has appealed the decision.

CMS/OSHA Vaccine Mandates

- In January 2022, the Supreme Court issued opinions regarding whether the CMS COVID-19 vaccine mandate for health care workers and OSHA mandate for employers with 100 or more employees could remain in place while challenges to their legality continue in lower courts. The Court allowed the CMS mandate to go forward and blocked the OSHA mandate.

- In May 2022, a group of states, led by Missouri, filed a petition with the US Supreme Court asking the Court to review whether the CMS vaccine mandate: (i) violates the Administrative Procedure Act (APA); (ii) is unconstitutional; and/or (iii) exceeds CMS's statutory authority.

- The Supreme Court is currently considering this request and it is not clear whether it will be granted. But, if so, it could be argued during the 2022 and 2023 term of the Court, with a decision likely in Spring 2023.

Charles N. Kahn III
President and CEO

September 6, 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-1770-P, Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts; Proposed Rule (Vol. 87, No. 145), July 29, 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.

II. D. Telehealth Services

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

Throughout the duration of the COVID-19 public health emergency (PHE), the use of telehealth modernized the provision of essential health services. We commend CMS for recognizing the value of telehealth beyond the PHE in the proposed provisions for the payment of Medicare telehealth services and appreciate CMS' proposals to continue to advance the use of telehealth in Medicare.

d. Services Proposed for Removal From the Medicare Telehealth Services List After 151 Days Following the End of the PHE; and
e. Implementation of Telehealth Provisions of the CAA 2021 and CAA 2022

In the physician fee schedule final rule for calendar year (CY) 2022, CMS discussed that when the PHE ends, the associated waivers and interim policies will expire and payment for Medicare telehealth services will be limited by the requirements of section 1834(m) of the Social Security Act. Services that had been added to the Medicare Telehealth Services List on a Category 3 basis will remain on the list through the end of 2023.

Further, under current policy, all services that CMS temporarily added to the Telehealth Services List on an interim basis but have not been added on a Category 1, 2, or 3 basis would not remain on the list after the end of the PHE. CMS proposes that these services would remain on the Telehealth Services List for a period of 151 days following the end of the PHE consistent with provisions in the *Consolidated Appropriations Act, 2022* (CAA, 2022). **The FAH supports this proposal, including CMS implementation of the telehealth provisions in CAA, 2022, and in particular we support the proposal to delay the in-person visit requirement for mental health services furnished via telehealth for 151 days after the end of the PHE (although we note our support for Congressional action to repeal this in-person requirement prior to its implementation).** This extension will provide the flexibility needed to offer many types of non-Category 3 services through telehealth, which is essential to ensure that patients have access to care in a reasonable timeframe. It will also ensure that providers have adequate time to phase out these telehealth services in a careful and deliberate manner that does not undermine patient care, while also allowing providers the time needed to collect data supporting a clinical benefit for purposes of adding them to the Telehealth List.

Moreover, exclusion of mental health audio-only services from the in-person visit requirement during the 151-day extension will increase access to care, particularly in geographic areas and populations without widespread access to broadband and will help alleviate the persistent shortage of mental health care professionals.

2. Other Non-Face-to-Face Services Involving Communications Technology under the Physician Fee Schedule

a. Expiration of PHE Flexibilities for Direct Supervision Requirements

Current Medicare regulations permit supervising professionals to satisfy direct supervision requirements using real-time audio-visual technology through at least the end of the

CY in which the COVID-19 PHE ends.[1] **The FAH continues to support making this method of providing direct supervision permanent.** In the experience of our member hospitals, physicians and other professionals have been able to provide clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth. Further, requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits. The reality is that a physician office, clinic, or hospital outpatient department typically has many other practitioners on site who can assist if a physical presence is required. Moreover, in an emergency, the most appropriate course of action is to admit the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. A virtually available supervisor may even facilitate a faster transfer of the patient to the emergency department when necessary.

When the current policy is made permanent, there should not be a requirement for a service-level modifier to identify when direct supervision is provided via appropriate telehealth technology. Physicians and other supervising practitioners benefit from the flexibility to supervise in person, via telehealth, or through a combination of modalities depending on clinical need and circumstances. In some cases, services may even be supervised in part through an in-person presence and in part through a telehealth modality. Requiring practitioners to track whether and to what extent they supervised through telehealth would significantly increase administrative burdens associated with these flexibilities, undermining their ability to improve physician care delivery. Because there is no obvious benefit to collecting data on how supervision is facilitated, the burdens associated with a modifier requirement cannot be justified. **Thus, the FAH requests that the definition of direct supervision be permanently amended to allow for telehealth supervision, without the requirement for a new modifier.**

XXXX

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The FAH appreciates the opportunity to submit these comments on these important issues to providers and patients. If you have any questions, please contact me or any member of my staff at (202) 624-1534.

Sincerely,

[1] See 42 C.F.R. § 410.32(b)(3)(ii).

HHS Questions
Medical Debt Collection

Characteristics of consumers and their debt

- What types of consumers are most affected by debt?
- What types of conditions, services, and provider types account for the most debt?
- How is medical debt distributed? Do a small proportion of patients account for a large proportion of medical debt?
- What percentage of charges to consumers are never collected?

Practices around collecting and reporting debt

- What if patient does not pay bill
- How do providers go about collecting debt – after a specified period of time; at a dollar amount
- At what point is medical debt sent to collections?
- Where is the debt sent for collection and when -- 30 days, 90 days, or 6 months
- Where are collection practices posted – websites, in hospital, financial counselor
- How is medical debt currently being handled by credit bureaus

Financial assistance policies and practices

- Policy around financial assistance for people with unpaid bills
- Once it is determined that there is a need for financial assistance, what are the methods for determining financial need
- Once the financial need assessment is completed, how is the financial aid handled
- Do these policies work – is there data collection on how successful the programs work; any impact analysis; outcomes
- Are there facilities with no policies on website

Practices around helping consumers manage debt

- Best practices

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.

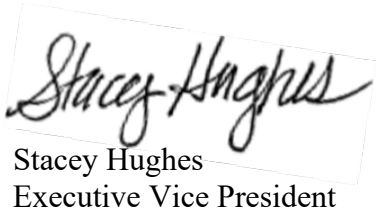
In short, the extraordinary facts presented by DHR make clear that it is inappropriate for CMS to approve a physician-owned hospital expansion simply because the three high Medicaid facility criteria are met. The creation of a new physician-owned hospital in Brownsville risks distorting the hospital 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.

Labor and Workforce Issues

September 2022

National Labor Relations Board (NLRB)

- The NLRB currently has five members:
    - Three Democrats:
        - Lauren McFerran (Chair; term ends December 2024)
        - Gwynne Wilcox (term ends August 2023)
        - David Prouty (terms ends August 2026)
    - Two Republicans
        - John F. Ring (term ends December 2022)
        - Marvin Kaplan (term ends August 2025).

- NLRB General Counsel: Jennifer Abruzzo (term ends July 2025).

- In July 2022, the NLRB entered into a formal Memorandum of Understanding with the FTC and Department of Justice to closely collaborate by sharing information, conducting cross-training for staff at each agency, and partnering on investigative and enforcement efforts within each agency's authority.
    - Among the areas of focus: "one-sided and restrictive contract provisions, such as noncompete and nondisclosure provisions; the extent and impact of labor market concentration; and the ability of workers to act collectively."

- In September 2022, the NLRB issued a proposed rule to rescind the current, narrower joint employer rule that took effect under the Trump Administration in April 2020 and replace it with the broader Obama-era standard of joint employment set forth in *Browning-Ferris Industries.*
    - Currently, joint employer status may be established only where a company exercises "substantial direct and immediate control" over the essential terms and conditions of another company's employees.
    - Under the proposed rule two or more employers would be considered joint employers if they "share or codetermine those matters governing employees' essential terms and conditions of employment."
    - FAH staff is working with the LOP Committee, as well as the US Chamber, to provide comments by the November 21 comment deadline.

Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS) for Healthcare Workers

- In March 2022, OSHA issued a *Notice of Limited Reopening of Comment Period* (Notice) for its interim final rule establishing an ETS on *Occupational Exposure to COVID–19* (issued in June 2021 and withdrawn by OSHA in December 2021.).

- In April, FAH submitted comments to OSHA, which: (i) urged OSHA to align its requirements with guidance and recommendations issued by the CDC and CMS; and (ii) raised procedural concerns with OSHA's request for public comment.

- OSHA has not yet issued a final rule.

- In August 2022, the DC Circuit Court of Appeals dismissed a lawsuit brought by a coalition of nurse unions asking the Court to order OSHA to issue the June 2021 ETS as a permanent rule with 30 days, maintain the temporary ETS until it promulgates the permanent standard, and enforce the ETS.

Workforce Issues

- In 2022, FAH partnered with the Bipartisan Policy Center (BPC) to produce a series of events with leaders and stakeholders across health care to identify key challenges in staffing shortages with leaders from FAH membership participating.

- BPC, in conjunctions with FAH, produced a Workforce resource website with recordings of the virtual events and infographics targeting Beltway audiences as well as the media.

- BPC is currently partnering with FAH on a Workforce Task Force with key stakeholders to develop policy solutions to the health care staffing crisis.

- FAH established a Workforce Workgroup to address staffing issues impacting health systems. The Workgroup has identified a wide array of challenges facing hospitals and is working to develop policy solutions to address the issue.

- Working on policy solutions for the hospital staffing challenge continues to be a priority for FAH. FAH staff will continue to convene and work with leaders in the industry, Capitol Hill, and regulatory agencies throughout the year.