PHYSICIAN-LED HEALTHCARE FOR AMERICA

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244–8013

Attention: **Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership (CMS-1785-P); Section X, Subsection B: Physician Self-Referral and Physician-Owned Hospitals**

Dear Administrator Brooks-LaSure:

Physician-Led Healthcare for America (PHA) appreciates the opportunity to comment on the above-referenced Hospital Inpatient Prospective Payment System (IPPS) Rule for Fiscal Year 2024 (the "Proposed Rule"), as published in the Federal Register on May 1, 2023 which would modify the regulatory requirements for expansion of "Applicable Hospitals" and "High Medicaid Facilities" as allowed under the Ethics in Patient Referrals Act, or "Stark Law" (the "Statute").[1] PHA promotes, educates and advocates for exceptional patient-centered care through physician leadership on behalf of our physician-owned hospital members across the United States. We represent physician-owned hospitals (POHs) and other physician-owned healthcare providers dedicated to a healthcare system that focuses on the most important partnership in healthcare: the patient-physician relationship. Since passage of the Patient Protection and Affordable Care Act of 2010 ("ACA"), POHs have consistently demonstrated that they reduce costs while delivering a high quality of care to patients. For example, a systematic review[2] published by the Mercatus Center found that POHs provide either higher quality care at lower cost with greater efficiency, or equivalent care, when compared to other community hospitals. The most recent Centers for Medicare & Medicaid Services Hospital Consumer Assessment of Healthcare Providers and Systems data shows that POHs have markedly higher patient experience ratings compared to all hospitals. Patient satisfaction and experience are critical components of improved health care delivery and important markers for healthcare access. In addition, specialty

[1] 42 U.S.C. § 1395nn(i)(3).

[2] Brian J. Miller et al., *Cost and Quality of Care in Physician-Owned Hospitals: A Systematic Review*, MERCATUS CENTER (Sept. 7, 2021), https://www.mercatus.org/research/research-papers/cost-and-quality-care-physician-owned-hospitals-systematic-review.

POHs (e.g., cardiology and orthopaedic) were found to deliver higher quality care than non-profit hospitals, with lower rates of hospital readmission or mortality for high-risk surgery.

PHA has grave concerns that the proposals advanced by CMS in the Proposed Rule exceed the agency's authority, contradict the Statute and are substantively flawed in addition to being procedurally flawed. CMS proposes sweeping changes to the process for applications for an exception to prohibitions on expansion of facility capacity, with no compelling justification demonstrating the need for changes. Moreover, the proposed process changes fail to consider important aspects of CMS's decision-making, potentially creating an arbitrary and capricious regulation. PHA strongly believes that multiple elements of the Proposed Rule, if finalized, would violate administrative due process.

Most importantly, even if CMS actually did have the statutory authority to make the sweeping changes laid out in the Proposed Rule, the changes have the very real potential to hinder access to high quality healthcare for U.S. citizens, with an especially dramatic impact on the Medicare and Medicaid populations that POHs seeking to expand valiantly serve. The proposed changes would serve to further entrench the anti-competitive impact of the Statute by allowing even fewer exceptions to the draconian POH expansion prohibitions in the Statute, which were adopted in 2010 as the result of an aggressive, systematic and illogical campaign by POH competitors.[3] In the 13 years since adoption of the ACA, PHA has been pleased to see CMS very rarely get entangled in the political battle between POHs and their aggressive competitors, but this Proposed Rule is a dramatic departure from CMS's historical more neutral stance. This departure from historic neutrality leaves the POH industry wondering if the low-brow tactics employed by those POH competitors—who cannot compete with POHs on quality and cost savings–are starting to impact even CMS.

## I. OVERVIEW OF PHA COMMENTS

Specifically, PHA opposes and urges CMS not to move forward with these elements of the Proposed Rule:

**A.** **New Factors for CMS Decisions** – The unlawful granting to CMS of additional authority not included in the Statute, including allowing CMS to base decisions on exception requests for an Applicable Hospital or High Medicaid Facility on additional new factors, including but not limited to: (1) the specialty of the hospital or services furnished by or to be furnished by the hospital, with a specific regulatory reference to maternity, psychiatric or substance use disorder care; and (2) program integrity or quality of care concerns related to the hospital.

**B.** **New Certificate of Need at Federal Level** – Establishment of a *de facto* federal "certificate of need" requirement, beyond the scope of CMS authority and not included in the Statute, by establishing that CMS will base decisions on exception requests for an Applicable Hospital or High Medicaid Facility on the need for additional operating rooms, procedure rooms, or beds: (1) for the hospital to serve Medicaid, uninsured and underserved populations; (2) in the county in which the main campus of the hospital is located; and (3)

[3] Patient Protection and Affordable Care Act of 2010.

in any county in which the hospital provides or plans to provide inpatient or outpatient services;

**C.** **Blanket CMS Authority** – The unprecedented and unlawful additional right CMS attempts to grant itself to consider any other data and information it deems relevant without notice, creating new criteria and factors on a case-by-case basis within an uncertain administrative process;

**D.** **New Application Requirements** – Requiring an Applicable Hospital or High Medicaid Facility requesting an expansion exception to provide additional information not required by the Statute or germane to whether the Statutory exception requirements are met, including: (1) whether the hospital plans to use expansion capacity to provide specialty services such as maternity or psychiatric services; and (2) information regarding the need for additional capacity: (i) for the hospital to serve Medicaid, uninsured and underserved populations, (ii) in the county in which the main campus of the hospital is located, and (iii) in any county in which the hospital provides or plans to provide inpatient or outpatient services;

**E.** **Community Input** – Expanding the community input provisions to essentially permit any input related to the expansion exception request beyond the application of the Statutory requirements for expansion into a potentially limitless litany of unhelpful and inappropriate comments that have nothing to do with Congressional intent for allowing High Medicaid Facilities and Applicable Hospitals to expand;

**F.** **New Notification Requirement** – Requiring an Applicable Hospital or High Medicaid Facility submitting an expansion exception request to identify and directly notify all hospitals within a specified community of the request, imposing a new reporting burden on the requesting hospital that is unnecessary and not supported by the Statute;

**G.** **High Medicaid Facility Restrictions** – Re-imposing on High Medicaid Facilities certain so-called "program integrity restrictions" (an intentionally confusing misnomer) that are unsupported by the Statute:

1. **High Medicaid Facility Main Campus Requirement** – Prohibiting a High Medicaid Facility from requesting an expansion exception unless the expansion location is in the county in which the main campus of the hospital is located – a requirement expressly not applied in the Statute to a High Medicaid Facility.

2. **High Medicaid Facility Request Time Limit** – Providing that CMS will only consider an expansion exception request from a High Medicaid Facility once every two years – yet another requirement expressly not applied in the Statute to a High Medicaid Facility.

3. **High Medicaid Facility 200 Percent Capacity Limit** – Providing that CMS will only consider an expansion exception request from a High Medicaid Facility if CMS has not previously approved a request that reaches 200 percent of the baseline number of operating rooms, procedure rooms and beds – yet another requirement expressly not applied in the Statute to a High Medicaid Facility.

The following material provides detailed comments in response to the proposed changes by CMS.

## II. ILLEGAL EXPANSION OF AUTHORITY AND VIOLATION OF ADMINISTRATIVE PROCESS

First, PHA is deeply disturbed by CMS's attempt to grab broad authority for the agency that both violates the Statute and Congressional intent. More specifically, we disagree with the following elements of the Proposed Rule:

### *A. General Discretion:*

CMS proposes to "further interpret this statutory language to mean that CMS has discretion to approve or deny a request for an expansion exception even if the requesting hospital meets the criteria for an applicable hospital or high Medicaid facility."[4] CMS states "for purposes of interpreting the statutory provisions, codification in our regulations, and discussion in our rulemakings, we use the term "request" in the same way as "apply" and "application," and use the term "approve" in the same way as statutory reference for "grant.'"[5]

This new and novel interpretation runs contrary to the statutory text and structure, constitutional doctrine, legislative history, and important administrative law principles, and CMS's long-standing interpretation of the statute.

The statute directs the Secretary to "establish and implement a process under which a hospital [meeting certain criteria] may apply for an exception . . . ."[6] The Statute does not provide CMS the authority to "approve" or "deny" applications from entities that meet the statutory definitions and descriptions – i.e., the criteria for expansion – nor does it give CMS authority to create new factors or criteria, beyond those listed in the Statute, for expansion exception applications.

Nothing in the plain meaning of the words Congress used suggests that CMS may deny a qualified application based on unenumerated criteria. A "process," which is what Congress directed the Secretary to establish, is simply "a series of actions or operations conducing to an end."[7] Nothing about establishing a "process" to grant exceptions connotes discretion to approve or deny them—and certainly does not suggest that CMS would have discretion to consider unenumerated criteria. The same goes for Congress's directive that qualified hospitals "may apply" for an exception. While the word "may" can connote discretion,[8] that discretion here would run to the qualified hospital deciding whether to "apply" for an exception, not to CMS in deciding whether to grant one.

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[4] 88 Fed. Reg. 27176.
[5] 88 Fed. Reg. 27177.
[6] 42 U.S.C. § 1395nn(i)(3)(A)(i).
[7] "Process." Merriam-Webster.com Dictionary, Merriam-Webster, https://www.merriam-webster.com/dictionary/process (last visited May 25, 2023).
[8] *See, e.g.*, *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016).

Statutory structure also proves that Congress knew how to give approval discretion when it wanted to.[9] Other statutory sections on self-referral explicitly include language allowing "other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse."[10] But this section deliberately excludes that language. And as discussed further below, similar language was specifically deleted from a prior draft of the bill. The structure of the statute thus further confirms that Congress did not give CMS discretion to deny otherwise qualified applications.

There is also nothing in the statute to provide an "intelligible principle" that would inform agency discretion if it did exist. CMS's proposed interpretation would thus render this provision an unconstitutional delegation of legislative authority, giving CMS unguided discretion to establish the rules for which eligible hospitals may expand and on what terms.[11] The mere presence of that serious constitutional question is enough to counsel against CMS's proposed interpretation.[12]

CMS's new and novel interpretation is also contrary to the legislative history of the Affordable Care Act. An earlier draft bill, Pub. L. 11-152, the Health Care and Education Reconciliation Act of 2010, included a substantially similar amendment of Section 1156. But unlike the enacted ACA text, that draft specifically included a subparagraph (E) (Conditions for Approval of an Increase in Facility Capacity) which would have established additional conditions an eligible hospital had to meet to receive an exemption, including "other conditions as determined by the Secretary."[13] Congress therefore specifically considered—but rejected—a proposal that would have given the Secretary discretion to impose additional conditions on receiving an exemption. CMS cannot end-run that legislative judgment by rule.[14]

Bedrock principles of administrative law also counsel against CMS's novel new interpretation. As the U.S. Supreme Court has admonished in numerous cases, Congress "does not 'hide elephants

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[9] *Cf. Univ. of Texas Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 357 (2013) (drawing negative inference from statutory language used elsewhere but not in the statute at issue); *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 298 (2006) (same).

[10] *See, e.g.,* 42 U.S.C. § 1395nn(b)(2) (setting forth the general premise of the in-office ancillary services exception to the Stark Law's prohibition on physician self-referral).

[11] *See Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality opinion) (explaining that a delegation is unconstitutional unless "Congress has set out an 'intelligible principle' to guide the delegee's exercise of authority") (citing *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)).

[12] *See Jones v. United States*, 529 U.S. 848, 857 (2000) ("'[W]here a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter.'") (quoting *United States ex rel. Attorney General v. Delaware & Hudson Co.*, 213 U.S. 366, 408 (1909)).

[13] HOUSE REPORT NO. 111–443(I), H.R. REP. 111-443, 707, 2010 U.S.C.C.A.N. 123, 474.

[14] If Congress had intended to grant CMS discretion to approve or deny exceptions on the "whole hospital exception," it also would have added the sentences found in the other sections on self-referral. Specifically, the other sections explicitly include language allowing "other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse"; but this section deliberately excludes that language. Further, before this proposed rule, the agency had no need to define "process" as "approval".

in mouseholes.'"[15] Congress's utter silence on CMS discretion to deny an otherwise qualifying application must therefore be understood to foreclose rather than permit the agency's assertion of such discretion. That is all the more true because "'[w]e expect Congress to speak clearly' if it wishes to assign to an executive agency decisions 'of vast economic and political significance.'"[16]

While some of these cases have involved sweeping assertions of authority over broad swaths of the economy, "[f]ar less consequential agency rules have run afoul of the major questions doctrine."[17] And as the Solicitor General recently argued in *Biden v. Nebraska*, No. 22-506 (U.S.), a pending case about the Department of Education's student loan forgiveness program, the concerns underlying the major questions doctrine are most acute when the agency is exercising regulatory authority over a private party. Here, CMS is asserting unfettered discretion to prohibit legally eligible hospitals from expanding—an assertion that undoubtedly has dramatic economic affects for the effected segment of the American hospital system.

Finally, CMS's new and novel interpretation runs contrary to the long-standing statutory reading it has employed ever since the enactment of the ACA over a decade ago. The agency's original and "contemporaneous construction carries persuasive weight," while its newly proposed "interpretation, being in conflict with its initial position, is entitled to considerably less deference."[18]

***B. Community Input:***

CMS also proposes to revise the statutory requirement that the "expansion exception process shall provide for community input with respect to an expansion exception request." CMS would interpret the law to "permit any input related to the expansion exception request— not just input related to whether the requesting hospital meets the criteria for an applicable hospital or high Medicaid facility."[19] CMS states that if the Congress did not intend for the Secretary to have "discretion to approve or deny an expansion exception request from a hospital that meets the criteria for an applicable hospital or high Medicaid facility, the statutorily-required community input would be limited to whether the hospital met such a requirement."[20] CMS states the plain language of the law is not limited in regards to the community assessment and "any" input is permitted.

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[15] *Turkiye Halk Bankasi A.S. v. United States*, 143 S. Ct. 940, 948 (2023) (quoting *Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001)).

[16] *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 142 S. Ct. 661, 667 (2022) (*per curiam*) (quoting Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs., 141 S. Ct. 2485, 2489 (2021) (*per curiam*)); *see also West Virginia v. EPA*, 142 S. Ct. 2587, 2608-2609 (2022) (explaining that this "major questions doctrine" applies where an agency claims an "[e]xtraordinary grant[] of regulatory authority" based on "'modest words,' 'vague terms,' or 'subtle devices,'" and the "'history and the breadth'" of the claimed power offer "'reason to hesitate before concluding that Congress'" conferred it).

[17] *Nat'l Fed'n of Indep. Bus.,* 142 S. Ct. at 668 (citing *MCI Telecommunications Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218 (1994)).

[18] *Watt v. Alaska*, 451 U.S. 259, 272–73 (1981).

[19] 88 Fed. Reg. 27177.

[20] *Id*.

This reading of the community input provision is ultimately derivative of CMS's proposed interpretation, addressed above, under which it has unfettered discretion to deny qualified applicants for any reason (or, apparently, no reason). CMS should abandon it for the same reasons. There is no reason for the community to provide input on factors that CMS lacks the statutory discretion to consider.

But this interpretation is also misguided because it invites extensive lobbying from incumbent providers against competition. Is the objective of the government or the President to lessen or bar hospital competition? If Congress had given CMS discretion and defined the parameters of relevant consideration, then CMS could likewise frame the scope of relevant community input to match. But Congress did not, and so the agency proposes instead to invite any and all community input without limitation. That will not improve agency decision making.

CMS has not proposed an information collection process for their newly revised community input even though they expect to get many more comments. Nor, has the agency provided any burden estimate in the rule or asked for the required separate public comment on the proposed collection of information or certified to the Office of Management and Budget (OMB) that efforts have been made to reduce the burden or asked for approval by OMB. The PRA applies whether the effort is voluntary or mandatory.

### *C. Publication:*

Because the Act requires the Secretary to publish a "final decision" with respect to a hospital's application, CMS interprets this statutory language to mean that after establishing it meets the criteria, CMS has discretion to approve or deny a request for an expansion exception even if the requesting hospital meets the criteria.[21] Further, the proposed rule states that "merely" meeting the criteria does not guarantee approval. CMS states that in decision-making it will consider community input and "*any* other data and information relevant to the basis for its decision", which may include data "provided by CMS' law enforcement partners and other government agencies (*whether publicly available or not*)" (emphasis added).[22] This proposed consideration of non-public (or effectively secret) information by CMS would create an environment wherein POHs are at the mercy of an agency with the power to justify its decisions by its reliance on information applicant POHs did not know it was considering (and to which such applicants may not have access).

As with the community input provision, this proposed interpretation is derivative of CMS's proposed interpretation, addressed above, under which it has unfettered discretion to deny qualified applicants and CMS should abandon it for the same reasons.

[21] 88 Fed. Reg. 27176.
[22] 88 Fed. Reg. 27178.

### *D. Administrative and Judicial Review:*

CMS stated, "we interpret the Statute to mean that neither the process itself nor CMS decision whether to approve or deny an expansion request are subject to administrative or judicial review."

CMS's reading of the judicial review provision is not entitled to any deference.[23] It is therefore unclear why CMS would even propose to address that issue in its final rule.

### *E. High Medicaid Facility Restrictions:*

CMS is proposing to add restrictions for Applicable Hospitals, including frequency restrictions, to High Medicaid Facilities. The statutory language establishes the frequency limit for Applicable Hospitals in (B) of the Section entitled Exception to Prohibition on Expansion of Facility Capacity. CMS states in the proposed rule, "…we are cognizant that the plain language of section 1877(i) of the Act does not expressly apply these program integrity restrictions to high Medicaid facilities in the same way that they are applied to applicable hospitals."[24]

CMS's candid recognition that these additional restrictions are unsupported by the plain language of the statute should be enough to justify removing them from the final rule.

### *F. New Criteria:*

CMS identifies a number of factors in the regulation that it will "consider in deciding whether to approve or deny" an expansion exception request. CMS states "These factors include: (1) the specialty (for example, maternity, psychiatric, or substance use disorder care) of the hospital or the services furnished by or to be furnished by the hospital if CMS approves the request; (2) program integrity or quality of care concerns related to the hospital; (3) whether the hospital has a need for additional operating rooms, procedure rooms, or beds; and (4) whether there is a need for additional operating rooms, procedure rooms, or beds in the county in which the main campus of the hospital is located, any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the expansion exception request."[25]

In addition to the four enumerated new factors, CMS reserves the right to consider any other factors it deems relevant, thereby proposing to provide the agency with the ability to create new criteria and factors on a case-by-case basis. (the proposed § 411.363(i)(2) does not limit CMS to the enumerated factors in making its decision.) For example, "CMS may also consider any other factors it deems relevant to its decision to approve or deny an expansion exception request, such as program integrity or quality concerns related to other hospitals in the requesting hospital's community or their ability to serve a growing patient population in the community."[26]

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[23] *See Smith v. Berryhill*, 139 S. Ct. 1765, 1778 (2019) ("The scope of judicial review … is hardly the kind of question that the Court presumes that Congress implicitly delegated to an agency.").
[24] 88 Fed. Reg. 27185.
[25] 88 Fed. Reg. 27179.
[26] *Id*.

As outlined above, CMS lacks discretion under the statute to deny an otherwise qualifying application based on these or any other considerations. There is thus no reason for CMS to be promulgating regulatory criteria that it cannot act on. This proposal also ignores the fact that Congress specifically considered but ultimately rejected a proposal that would have added specific additional criteria and authorized the Secretary to adopt more.

This proposal also appears to be a backdoor attempt to impose a new Federal Certificate of Need requirement in absence of any enacting legislation that gives CMS such authority. We have multiple concerns about this overreach that creates a new Federal requirement, including:

- **Congressional Intent**: Congress repealed the National Health Planning and Resources Development Act of 1974 and eliminated federal incentives for states to maintain their CON programs in 1986. The Department of Justice and the Federal Trade Commission said in the same year as the Federal repeal about CON:[27]

  > "The Agencies' experience and expertise has taught us that Certificate-of-Need laws impede the efficient performance of health care markets. By their very nature, CON laws create barriers to entry and expansion to the detriment of health care competition and consumers. They undercut consumer choice, stifle innovation, and weaken markets' ability to contain health care costs. Together, we support the repeal of such laws, as well as steps that reduce their scope."

- **Scope**: The creation of certificate of need at a Federal level is far beyond the scope of the law or the agencies' mandate from Congress.[28]

- **Difficulty**: Needs assessments are time-consuming processes, and difficult to analyze. A CON review requires epidemiologists, competition and health services experts and medical input.

- **Effectiveness**: CON is only effective if it offers concrete evidence to determine which solution is the best for achieving the desired results.

- **Lack of a Methodology**: CMS offers no information or method on how it would assess "need' for approval or denial of an application.

Not defining the decision making for incorporation and weighting of comments in determining "need" emphasizes the arbitrary and capricious nature of the rulemaking. For example: If hospital A is an investor-owned hospital expanding in an area as part of their national program and hospital B is a physician-owned hospital in the area that applies for an expansion, what is the public's interest? CMS specifically would direct hospitals to notify their competitors of an expansion request; how would that information be determinative for the agency?

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[27] Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission Before the Illinois Task Force on Health Planning Reform, September 15, 2008.

[28] CMS mentions that the word need was used for exceptions in a -similar but different process- in House Conference Report No. 443, 11th Cong., 2nd Session 357 (2010). Conference reports of passed bills are not binding on an agency; in this case the bill was not signed into law.

### *G. Evaluation Authority:*

CMS's proposal would allow the agency to consider the new criteria and factors differently for each expansion request. In the Proposed Rule, CMS would not create any type of objective criteria, but will subjectively review and judge each application differently. CMS writes: "Expansion exception requests are now and would continue to be assessed on a case-by-case basis, and CMS would base its decision to approve or deny an expansion exception request on the totality of the information available to the agency. Thus, decisions to approve or deny requests from hospitals that appear similar with respect to overall capacity to serve Medicaid and other underserved populations could differ based on factors such as planned expansion of needed psychiatric services instead of general acute care services or whether the requesting hospital seeks an expansion exception to replace operating rooms, procedure rooms, or beds that it has relocated (or intends to relocate) from its main campus to other areas in need of services."[29]

As described above, CMS lacks any discretion to deny otherwise qualifying applications. But this aspect of CMS's proposal injects additional problems including the risk of arbitrary and biased decision-making.

Even if CMS did have the discretion to deny qualifying applications, we would oppose any procedurally uncertain process for evaluation using differing factors on a case-by-case basis. Such a process:

- has the potential for material harm to applicants, their patients and their communities;
- may result in procedural errors due to a breach in the consistency of the administration of the process;
- is overly burdensome in amount of data that it orders the applicant to collect; and
- lacks administrative safeguards to ensure a lack of bias in the described "subjective" process.

Thus, even if CMS chooses to move forward with its proposed interpretation of its discretion (notwithstanding the legal deficiencies outlined above), it should adopt a framework that promotes transparency and predictability for regulated parties.

### *H. New Restrictions on High Medicaid Facilities:*

CMS proposes to apply certain restrictions to High Medicaid Facilities exception requests: a limit on expansion to 200% of the baseline; to limit requests to no more than once every two years; and to permit exceptions only for the main campus. These limitations were removed in the CY 2021 rule because these sections of the Statute do not expressly apply to High Medicaid Facilities. CMS states that "Although we are cognizant that the plain language of section 1877(i) of the Act does not expressly apply these program integrity restrictions to high Medicaid facilities in the same way that they are applied to applicable hospitals, we must balance the risk to patients and the Medicare program against any burden that the program integrity restrictions may impose on high Medicaid facilities. It is our position that protecting the Medicare program and its

[29] 88 Fed. Reg. 27179.

beneficiaries, as well as Medicaid beneficiaries, uninsured patients, and other underserved populations… outweighs any perceived burden on high Medicaid facilities."[30]

Once again, CMS's candid recognition that these additional restrictions are unsupported by the plain language of the statute should be enough to justify removing them from the final rule.

Moreover, CMS's reliance for this approach on community input submitted in connection with its most recently approved expansion request is misguided; as discussed in greater detail in this letter, community input CMS receives in opposition of expansion exception requests is often submitted by POH competitors, and not by the actual patient populations these hospitals serve. A review of the comments on which CMS relies to justify imposing these additional restrictions**,** which inaccurately cite patient care concerns and an interpretation of Congressional intent, is consistent with this trend. CMS received fourteen public comments in connection with the expansion exception request submitted by Doctors Hospital at Renaissance, Ltd. ("DHR") in 2021, twelve of which were submitted in support of DHR's request by stakeholders in DHR's community. Despite this unusually high amount of meaningful community participation, the two comments on which CMS relies to support re-imposing program integrity restrictions on High Medicaid Facilities were submitted by highly-biased representatives of DHR's competition and do not reflect the position of those populations CMS purports to protect with this change.

Clearly, the agency should address a report of patient care problems at one institution by forwarding that letter to the QIO or State survey agency for the appropriate processing.

Regarding Congressional intent, Congress does not legislate with a single-minded purpose in every case. It is clear in context that Congress intended both to limit the expansion of physician-owned hospitals in general and to provide a specific exemption for high Medicaid facilities. It flouts congressional intent, rather than respects it, to allow the first general purpose to swallow the second specific one. Indeed, "it is a commonplace of statutory construction that the specific governs the general."[31] Indeed, this instance provides a heartland example of that principle since it involves "a general . . . prohibition" (on expansion) "contradicted by a specific . . . permission" (for high Medicaid facilities).[32]

## III. LIKELY DETRIMENTAL IMPACT OF THE PROPOSED RULE'S SUBSTANTIVE ELEMENTS

In addition to our strong belief that the Proposed Rule is an inappropriate and unlawful expansion of CMS authority, many elements of the Proposed Rule would be harmful to the U.S. healthcare system if adopted. More specifically, we have significant substantive concerns with the following elements of the Proposed Rule:

### *A. The Proposed Rule Essentially Creates an Unfathomable Federal Certificate of Need Requirement Solely for POHs*

By requiring facilities requesting an expansion exception to demonstrate facility and community need, CMS is proposing to establish a *de facto* certificate of need ("CON") program at the federal

[30] 88 Fed. Reg. 27185.
[31] *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992).
[32] *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012).

level that will apply only to POHs. CON regimes currently exist in thirty-five states and Washington, D.C. While the federal government initially supported CON programs in the early 1970s, the repeal of the National Health Planning and Resources Development Act in 1986 signaled disfavor for these programs at the federal level and contributed to the abandonment of CON programs in many states and the substantial reduction in scope of such programs in many others. While originally conceived as a cost-control measure targeting unnecessary or duplicative expansion of healthcare services, CON programs may operate to limit competition in the healthcare marketplace and achieve the opposite of their intended result in many cases, contributing to market consolidation and increased costs. The Federal Trade Commission ("FTC") has repeatedly expressed concern with CON regimes, often in joint statements issued by the FTC and the Antitrust Division of the U.S. Department of Justice (together with the FTC, the "Agencies"). For example, in a joint statement issued by the Agencies in connection with the proposed repeal of Alaska's CON program, the Agencies note that "CON laws… limit consumer choice [and] stifle innovation," and that "incumbent firms seeking to thwart or delay entry or expansion by new or existing competitors may use CON laws to achieve that end."[33] The Agencies remind readers that they "historically have suggested that states consider repeal or retrenchment of their CON laws" because of the manner in which CON regimes negatively impact healthcare markets and undermine the goals of reducing cost and improving access.[34] In short, Congress has already encouraged CON programs in the past and, recognizing their shortcomings, withdrew that support and federal agencies now actively advocate for states to dismantle them. For CMS to implement a *de facto* CON program at the federal level and apply it narrowly to POHs ignores this prior experience with the impact of CON laws on the cost of, and access to, quality healthcare services.

If CMS were truly interested in the creation of a Federal CON law—which we do not actually believe is the case—then such a law would logically apply to any hospital type, not just those owned by physicians.

### *B. The Proposed Rule Would Hinder Access to Care for Medicare and Medicaid Beneficiaries*

The United States is—and has been—faced with a multi-generational shortfall of providers for Medicaid patients. The criteria to qualify as an Applicable Hospital or a High Medicaid Facility for purposes of an expansion exception request are tied to Medicaid inpatient admissions, meaning that POHs that satisfy these criteria have demonstrated a commitment to bridging the gap in access with which so many state Medicaid agencies constantly battle. These facilities should be rewarded for their efforts in this sphere, but the revised process for expansion exceptions CMS proposes is far more burdensome than the status quo, penalizing these facilities and disincentivizing future commitment to ensuring access. A more burdensome expansion exception process is also contradictory to the dual aims of improving access to and quality of care for

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[33] *Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission on Certificate-of-Need Laws and Alaska Senate Bill 62*, 1 (2017), https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-us-department-justice-regarding/v170006_ftc-doj_comment_on_alaska_senate_bill_re_state_con_law.pdf.

[34] *Id* at 2.

Medicaid beneficiaries underlying CMS's recently-announced proposed rulemaking titled "Ensuring Access to Medicaid Services" ("CMS 2442-P"). CMS acknowledges in the press release accompanying CMS 2442-P that timely access to services is fundamental to reducing disparities in healthcare[35], but the changes CMS is proposing with respect to the expansion exception request process for POHs will accomplish the opposite.

### *C. The Community Input Requirement Would Not Actually Give a Voice to Patients and Could Create an Administrative and Political Burden on CMS*

CMS's proposal to see community input would not actually result in getting input from the patient population served by the POH requesting expansion—and certainly not from the most vulnerable patient population with which CMS is most concerned, the Medicare and Medicaid populations. It seems unlikely that CMS intends to implement a costly and lengthy "on the ground" campaign to approach individual patients, physicians and patient advocate groups—an administrative burden that is not described in the Proposed Rule and seems highly unlikely given the tremendous strain on CMS resources that would entail. Therefore, it is not reasonable to think that soliciting community input in some remote, distant, publication fashion will result in individual patients, or even groups of patients, actually being aware of the opportunity to comment or having the time and resources to give input. What is instead more likely to occur with the Proposed Rule community input proposal is that competitors of the requesting POH—most of whom have deep pockets, scores of professional lobbyists at their disposal and existing platforms to air their anticompetitive aggression toward POHs—would have yet another platform, and one which CMS would now be forced to consider in its decision-making. Why would CMS want to implement a mechanism into which CMS would be dragged into the political debate between competitors?

This concern about community input and the lack of true feedback from the patient and provider populations that matter is borne out in a simple review of the eight prior expansion requests that have been submitted to CMS in the thirteen years since implementation of the ACA.[36] Of those eight expansion requests, CMS received no comments from the community on three requests, and received only one comment on another request that CMS ultimately disregarded because it addressed the expansion exception process generally and did not address the request in question. CMS received eighty-four comments on the request submitted by Lake Pointe Medical Center; of those, eighty-three advocated that a different hospital should be allowed to expand under the exception process, and the sole remaining comment was submitted by Rockwall Regional Hospital, LLC—a competitor hospital in the same county. Rockwall Regional Hospital, LLC later submitted an expansion exception request of its own, and of the forty-three comments CMS received, the only comment submitted opposing the request was submitted by Lake Pointe Medical Center. A review of the comments received by CMS in connection with these expansion exception requests demonstrates that community input on POH expansion exception requests is

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[35] *The Biden-Harris Administration Proposes New Standards to Help Ensure Access to Quality Health Care in Medicaid and CHIP*, CMS.GOV (April 27, 2023), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-proposes-new-standards-help-ensure-access-quality-health-care-medicaid.

[36] All expansion exception requests received by CMS, and the corresponding CMS decision on each, may be found at https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/physician_owned_hospitals.

infrequent and presents an opportunity to competitor facilities to oppose a request (rather than CMS receiving input from the patients a POH serves). Further, and as discussed previously in this letter, CMS's admitted reliance on two comments submitted in connection with DHR's 2021 expansion exception request by DHR's competitors—as opposed to and notwithstanding an unusual degree of meaningful (and positive) community comments that opposed those competitors' positions—suggests that CMS is already poised to give competitors' input greater weight.

### *D. CMS Should Be Proud of Its Prior Expansion Approvals*

What is perhaps the most confounding aspect of the Proposed Rule is one of the most foundational—which is that CMS's Proposed Rule implies that CMS somehow regrets granting the eight prior expansion requests that were lawfully submitted and lawfully granted during the past thirteen years. We are flabbergasted as to why CMS would regret such past actions when the POHs seeking expansion exceptions are doing so in order to better serve their communities. For example, DHR, the most recent facility to which CMS has granted an expansion exception, provided over $90 million in charity care in 2021, and 73% of the more than 110,000 children that have been delivered at DHR were covered by Medicaid. DHR has consistently demonstrated its dedication to ensuring equity and access for vulnerable populations, a mission facilitated by the opportunity to expand as the needs of DHR's community have dictated.

## IV. CONCLUSION

PHA appreciates the opportunity to comment on the Proposed Rule and strongly urges CMS to heed the comments above in order to avoid adoption of unnecessary, burdensome, and unlawful limitations on services to the nation's most vulnerable patients.

Sincerely,

Frederic Liss, M.D.
President and Chairman, Physician-Led Healthcare for America
Fred.liss@physicianled.us