September 1, 2022

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Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Attention: CMS-1772-P

Re: Medicare Program: 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 [CMS-1772-P]

Dear Administrator Brooks-LaSure:

On behalf of the Alliance for Rural Hospital Access (ARHA, or the Alliance), please accept these comments on the proposed Hospital Outpatient Prospective Payment System (OPPS) rule for CY 2023.

The Alliance is comprised of hospitals designated as Medicare-Dependent, Small Rural Hospitals (MDHs), Rural Referral Centers (RRCs) and Sole Community Hospitals (SCHs) under the Medicare program. MDHs, RRCs and SCHs provide rural populations with local access to a wide range of health care services. In doing so, MDHs, RRCs and SCHs localize care, minimize the need for further referrals and travel, and provide services at costs lower than their urban counterparts. These hospitals also commonly establish satellite sites and outreach clinics to provide primary and emergency care services to surrounding underserved communities, a function which is becoming increasingly important as economic factors force many small rural hospitals to close.

Congress and the Centers for Medicare and Medicaid Services (CMS) have reconfirmed their commitment to these hospitals repeatedly over the years by providing new protections to ensure their viability and to ensure patient access to hospital services in rural communities. ARHA and its members share this goal of ensuring that federal hospital payment policies recognize the unique role and important contributions these hospitals bring to the Medicare program and its

beneficiaries. Consistent with this mission, ARHA appreciates the opportunity to provide CMS with the comments set forth in this letter.

A. Executive Summary

The Alliance is submitting comments on three proposals, and we urge CMS to take the following actions:

- **Proposal To Exempt Rural Sole Community Hospitals From the Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)**
    - Finalize the proposal to exempt services furnished by excepted off-campus provider-based departments of rural SCHs.
    - Extend this exemption to *urban* SCHs, MDHs, and RRCs.

- **Proposed Adjustment for Rural SCHs and Essential Access Community Hospitals under Section 1833(t)(13)(B) of the Social Security Act (the Act) for CY 2023**
    - Extend the payment adjustment to *urban* SCHs.
    - Study the appropriateness of making a similar payment adjustment for MDHs.

- **Payment for 340B Drugs**
    - When determining new policy for CY 2023 in light of the recent Supreme Court ruling, consider potentially negative impacts on rural hospitals that continue to struggle financially.

B. Background on Rural Hospital Designations

Medicare Dependent Hospitals: The MDH program was established by Congress with the intent of supporting small rural hospitals for which Medicare patients make up a significant percentage of inpatient days and discharges. Because they primarily serve Medicare beneficiaries, MDHs rely heavily on Medicare reimbursement to sustain hospital operations. Consequently, these hospitals are more vulnerable to inadequate Medicare payments than other hospitals because they are less able to cross-subsidize inadequate Medicare payments with more generous payments from private payers. As such, Congress acknowledged the importance of Medicare reimbursement to MDHs and established special payment protections to buttress these hospitals. Congress recognized that if these hospitals were not financially viable and failed, Medicare beneficiaries would lose an important point of access to hospital services. To qualify as an MDH, a hospital must be (1) located in a rural area, (2) have no more than 100 beds, and (3) demonstrate that Medicare patients constitute at least 60 percent of its inpatient days or discharges.

Rural Referral Centers: Congress established the RRC program to support rural hospitals that treat a large number of complicated cases and function as regional referral centers. Generally, to be classified as an RRC, a hospital has to be physically located outside a Metropolitan Statistical

Area (indicating an urban area) and either have at least 275 beds or meet certain case-mix or discharge criteria.

Sole Community Hospitals: Congress created the SCH program to maintain access to needed health services for Medicare beneficiaries in isolated communities. The SCH program ensures the viability of hospitals that are geographically isolated and thus play a critical role in providing access to care. Hospitals qualify for SCH status by demonstrating that because of distance or geographic boundaries between hospitals they are the sole source of hospital services available in a wide geographic area. There are a variety of ways in which hospitals can qualify for SCH status, but the majority qualify by being more than 35 miles from another provider.

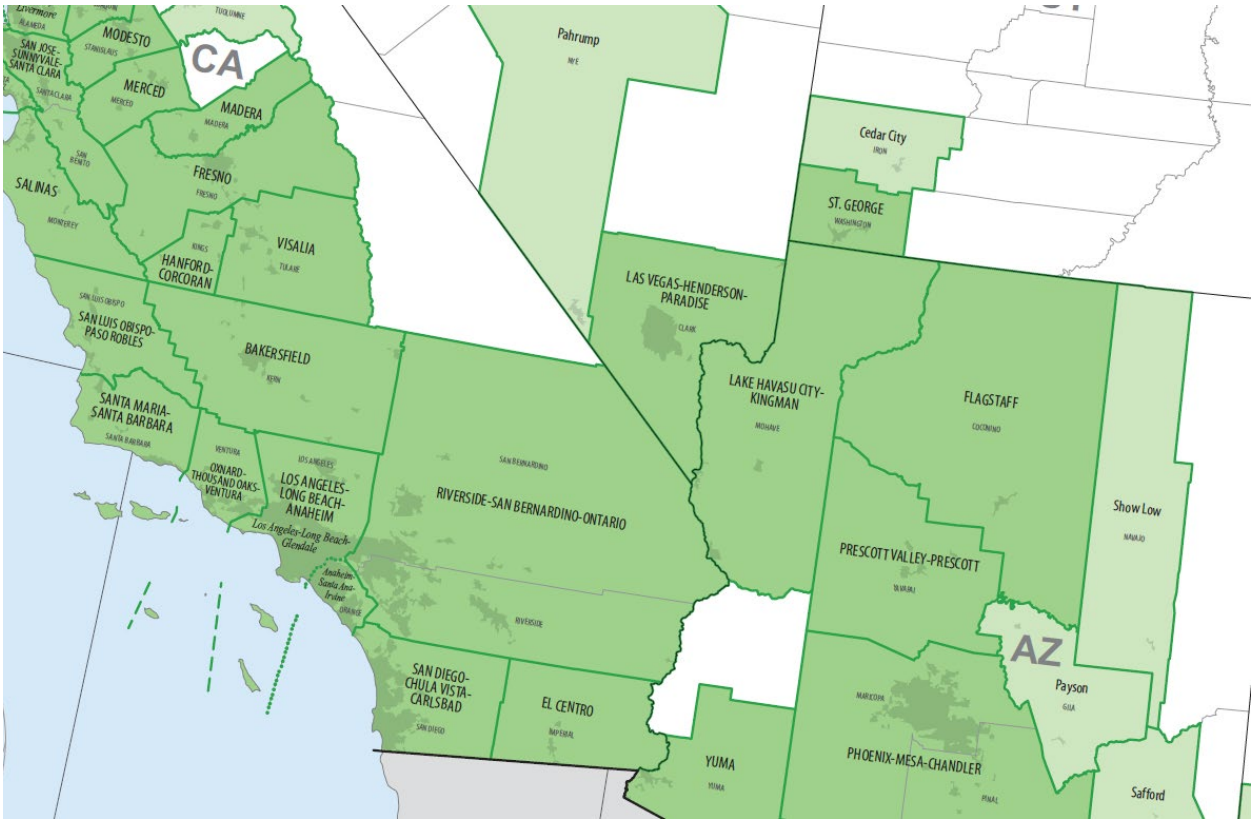
C. Proposal To Exempt Rural Sole Community Hospitals From the Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

In CY 2019, CMS began implementing a policy to pay for clinic visit services described by HCPCS code G0463 furnished by excepted (grandfathered) off-campus provider-based outpatient departments at the Physician Fee Schedule (PFS) relativity adjuster rate, *i.e.,* the same payment amount used to pay for services furnished by non-excepted (non-grandfathered) off-campus provider-based outpatient departments. As part of that rulemaking, CMS echoed ARHA's concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. The Alliance repeatedly urged CMS to exempt SCHs, MDHs and RRCs from this policy, but CMS finalized the policy for all excepted off-campus provider-based outpatient departments.

For CY 2023, CMS proposes to continue the policy of paying the PFS-equivalent rate of 40 percent of the OPPS payment rate for hospital outpatient clinic visits coded under HCPCS G0463 when delivered by a previously excepted off-campus provider-based department, but CMS is now proposing to exempt services furnished by excepted off-campus provider-based departments of rural SCHs. CMS also seeks input on other types of rural hospitals that it should consider exempting. **ARHA welcomes the proposed rural SCH exemption, and urges CMS to finalize the proposal. In addition, ARHA urges CMS to extend the same relief to urban SCHs and MDHs.**

CMS uses Metropolitan Statistical Areas (MSAs) to delineate between urban and rural areas. While we appreciate the need to distinguish urban and rural for a number of payment and policy mechanisms, MSAs are not the most precise tool for characterizing urban and rural areas. Given that MSAs use counties as building blocks, many areas are designated as "urban" because they have a single urbanized area. But if the county is unusually large, significant portions of that county may be as rural as the most isolated frontier area.

Using MSAs to identify urban and rural areas is particularly problematic in the western United States where there are many very large counties that comprise MSAs (see, for example, San Bernardino County in California and Flagstaff and Pima Counties in Arizona).



There are instances where an SCH is designated urban by CMS, but the hospital is actually a considerable distance from the nearest urbanized area. Verde Valley Medical Center (Provider Number 03-0007), for example, is located in Prescott, AZ and is considered an urban SCH. However, the closest urbanized area with more than 40,000 people is Flagstaff, AZ, which is nearly 100 miles away.[1] Verde Valley has undergone an urban-to-rural reclassification, so it is eligible for these protections. Hospitals like Methodist Hospital South (45-0165) in Jourdanton, Texas have not undergone urban-to-rural reclassification, and so are not eligible for these protections. These are not urban areas by most reasonable standards, except the MSA standard.

Currently, there are 92 SCHs located in urban designated geographic Core Based Statistical Areas.[2] Some 77 of these have undergone urban-to-rural reclassification under the process described at 42 C.F.R. § 412.103 to retain rural status and access to these protections. Others have not sought or have not been able to avail themselves of this process, and so remain urban and without these protections.

CMS should extend this exemption to urban SCHs because using MSAs to determine urban and rural areas is imprecise, and distinguishing between urban and rural SCHs when applying payment policy unfairly disadvantages urban SCHs that are the sole source of hospital services in their communities, like their rural counterparts. Urban SCHs are serving communities that are

[1] Metropolitan and Micropolitan Statistical Areas of the United States and Puerto Rico, US Census Bureau. July 2015. https://www2.census.gov/geo/maps/metroarea/us_wall/Jul2015/cbsa_us_0715.pdf
[2] Centers for Medicare & Medicaid Services. FY 2023 IPPS Proposed Rule Impact File, April 18, 2022.

truly rural in character. In fact, as CMS knows, to be an *urban* SCH, a hospital has to be even further (35 miles) from another hospital to qualify than if it were a *rural* hospital. CMS also can reduce incentives to undergo urban-to-rural reclassification to take advantage of these protections.

CMS also should do this to protect access to hospital care in these communities by protecting the hospitals that serve these communities. Rural hospitals are closing at alarming rates, and applying the PFS relativity adjuster to rural hospitals may be a contributing factor. A large majority of rural hospitals are already financially vulnerable due to a number of factors, including payment inadequacy and uncertainty. The COVID-19 pandemic has compounded these vulnerabilities. When looking at the types of hospitals that comprise the ARHA, data from the North Carolina Rural Health Research Program show that a total of 42 MDHs, RRCs and SCHs have closed since 2005.

As set forth in the May 2022 Bipartisan Policy Center (BPC) report titled "The Impact of COVID-19 on the Rural Health Care Landscape," rural hospitals continue to face challenges that threaten their financial well-being. The report notes that, although federal support during the pandemic has temporarily helped many vulnerable hospitals, once the federal public health emergency ends and this financial relief is no longer available, many of the rural hospitals that were struggling before the pandemic will again be at risk of closure—unless additional actions are taken to shore up these facilities.

Rural SCHs, urban SCHs and MDHs have below average patient care margins. On average, patient care margins[3] are negative for rural SCHs, urban SCHs and MDHs.

	Patient Care Margin
Hospital Type	Mean
Rural Sole Community Hospital	-2.4%
Urban Sole Community Hospital	-1.7%
Medicare Dependent Hospital	-3.0%
All other OPPS Hospitals	0.5%

Note: McDermottPlus' analysis of Medicare Hospital Cost Reports with cost report ending date before the pandemic started in April 2020. Patient care margins are defined as net income from service to patients divided by patient care revenues. We excluded hospitals with missing Cost Reports data and removed highest and lowest 5% of data as outliers.

GAO likewise found that Medicare profit margins and total hospital profit margins declined for MDHs from fiscal year 2011 through 2017, from -6.9 percent to -12.9 percent and 1.6 percent to -0.2 percent, respectively. [4] The degree to which Medicare margins declined for MDHs during

[3] McDermottPlus' analysis of Medicare Hospital Cost Reports with cost report ending date before the pandemic started in April 2020. Patient care margin is calculated by dividing net income from services to patients by total patient care revenues. We excluded hospitals with missing Cost Reports data and removed highest and lowest 5% of data as outliers.

[4] GAO, Information on Medicare-Dependent Hospitals, GAO-20-300 (Washington, D.C.: February, 2020). https://www.gao.gov/assets/gao-20-300.pdf

this time period (6 percentage points) was greater than the degree to which they declined for rural hospitals (3.8 percentage points) and all hospitals (2.5 percentage points). The number of Medicare-Dependent Hospitals declined 28 percent from 193 hospitals in fiscal year 2011 to 128 hospitals in 2017 as hospitals became ineligible for MDH status, and 16 closed between 2013 and 2017, or experienced other changes.[5]

Supporting SCHs and MDHs in this way would help secure access for Medicare beneficiaries and Medicaid enrollees in underserved communities. Rural SCHs, urban SCHs and MDHs are often the sole health care providers in isolated areas where health care access is lacking. Our analysis shows that 56 percent of rural SCHs, 73 percent of urban SCHs, and 60 percent of MDHs are located in at least one type of medically underserved area as defined by Health Resources and Services Administration Medically Underserved Area designations.

Hospital Type	Hospital Count	Hospitals in MUA	Percent
Rural Sole Community Hospital	448	251	56%
Urban Sole Community Hospitals redesignated as rural under § 412.103	77	33	43%
Urban Sole Community Hospitals *(not redesignated as rural)*	15	11	73%
Medicare Dependent Hospital	169	102	60%

M+ Analysis of Medically Underserved Area (MUA)[6] designations from the Health Resources and Services Administration.

Moreover, rural SCHs, urban SCHs and MDHs serve a higher proportion of Medicare and Medicaid beneficiaries. More than half of their inpatient days come from Medicare, Medicaid or Children's Health Insurance Program (CHIP) beneficiaries. The median share of Medicare, Medicaid and CHIP inpatient days for rural SCHs, urban SCHs and MDHs, is 52 percent, 58 percent and 54 percent respectively, compared to 42 percent for all other outpatient providers.[7]

	Share of Medicare, Medicaid and CHIP from Total Inpatient Days
Hospital Type	Median
Rural Sole Community Hospital	52%
Urban Sole Community Hospital	58%
Medicare Dependent Hospital	54%
All other OPPS Hospitals	42%

M+ Analysis of Medicare Cost Reports ending before the pandemic started in April 2020. Excludes hospitals with missing Cost Reports data.

[5] GAO, Rural Hospital Closures: Number and Characteristics of Affected Hospitals and Contributing Factors, GAO-18-634 (Washington, D.C.: Aug. 29, 2018). https://www.gao.gov/products/gao-18-634

[6] A hospital is determined to be in a Medically Underserved Area (MUA) if the hospital's main address meets the requirement of at least one MUA designation type based on either geographic area, specific population characteristics of that geographic area (i.e., homeless population), or a governor's designation. For detail, please refer to the Health Resources and Services Administration website: https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation

[7] McDermottPlus' analysis of Medicare Hospital Cost Reports with cost report ending date before the pandemic started in April 2020. We excluded hospitals with missing Cost Reports data.

Extending this exemption to MDHs and urban SCHs would add nominally to the cost. CMS estimates that the proposed exemption for rural SCHs "would increase OPPS spending by approximately $75 million in CY 2023 compared to spending if [CMS] did not implement this exemption…." 87 *Fed Reg.* at 44698 (July 26, 2022). Medicare's CY 2023 Outpatient PPS Impact File shows 463 hospitals with SCH status and 169 with MDH status. Of the 463 hospitals with SCH status, 371 are geographically located in a rural area; 92 are geographically located in an urban area, but 77 of those hospitals undergo urban-to-rural reclassification pursuant to 42 C.F.R. § 412.103 to be eligible for benefits CMS has chosen to confer only on rural SCHs; 15 of those hospitals have not undergone urban-to-rural redesignation either because they are ineligible or it is impractical to do so. Also exempting from the PFS-equivalent rate services furnished by MDHs and urban SCHs would benefit 184 (169 MDHs and 15 urban SCHs) mostly rural hospitals, all of which have earned special Medicare safety net designation because of the role they play in providing access to hospital care for Medicare beneficiaries. Our analysis estimates that exempting urban SCHs and MDHs as suggested will increase Medicare spending by $0.9 million and $7.8 million, respectively, on top of the $75 million that CMS predicts to be the amount by which exempting rural SCHs from the site neutral policy would increase spending in CY 2023.[8] In other words, CMS could buttress a small number of additional vulnerable Medicare safety net hospitals for a nominal additional cost, approximately $8.7 million, or $84 million in the aggregate.

For these reasons, we urge CMS to finalize the proposed change to exempt rural SCHs from the site neutral policy. In addition, ARHA urges CMS to extend the same relief to urban SCHs and MDHs.

D. Proposed Adjustment for Rural SCHs and Essential Access Community Hospitals under Section 1833(t)(13)(B) of the Social Security Act (the Act) for CY 2023

Under current CMS policy, Medicare payments to rural SCHs for outpatient services are increased by 7.1 percent. CMS makes this adjustment because it found, pursuant to a study required by Congress,[9] that compared to urban hospitals, rural SCHs have substantially higher costs, and need a payment adjustment to be comparably treated under the OPPS. For CY 2023, CMS proposes to continue this payment adjustment for rural SCHs, and the Alliance supports CMS in this proposal and urges the agency to finalize it as proposed.

The Alliance also urges CMS to take the following additional actions with respect to this policy.

1. Extend the adjustment to urban SCHs

CMS consistently makes this adjustment available only to rural SCHs because Congress directed CMS to study only rural hospitals. CMS should extend this adjustment to *urban* SCHs as well. As previously mentioned, there is no policy basis for distinguishing between urban and rural

[8] McDermottPlus' analysis of CY 2023 OPPS proposed rule data (2021 claims) ratesetting file.
[9] § 411(b), Pub. L. No. 108-173.

SCHs. CMS has historically used MSAs to differentiate urban and rural, which becomes problematic when applied to SCHs.

Both urban and rural SCHs serve challenging patient populations with higher rates of health disparities and poorer health outcomes. Both urban and rural SCHs face similar financial challenges leading to increasing rates of closures. Further, both urban and rural SCHs play an essential role as safety net providers in rural communities, with many residents relying on the hospital for a variety of health services from routine care to treatment for complex medical cases. **For these reasons, ARHA urges CMS to extend this adjustment to urban SCHs.**

CMS has the authority to extend this same protection to urban SCHs. The statutory command that was the basis for this adjustment directed CMS to study the costs incurred by hospitals located in rural areas as compared to those in urban areas, and to make an appropriate adjustment for rural hospitals based on those findings. CMS conducted that study and made the adjustment. CMS is not precluded by this language from conducting a follow-up broader study not prompted by this section that examines urban SCHs as a cohort, and from making a similar adjustment to urban SCHs.

We estimate that extending the 7.1 percent payment increase to urban SCHs would result in an additional $16.8 million for these hospitals.[10]

2. Study the appropriateness of making a similar payment adjustment for MDHs

MDHs—like rural SCHs—serve challenging rural patient populations, face financial uncertainty, and play an essential role as safety net providers in rural communities and for the Medicare program in particular. As noted above, our analysis of Medicare Cost Report data demonstrates that mean patient care margins for MDHs are among the worst of all hospital cohorts. **For these reasons, the Alliance urges CMS to study whether it would be appropriate to extend a similar adjustment to MDHs.**

CMS has the authority to extend this same protection to MDHs. The statutory command that was the basis for this adjustment directed CMS to study the costs incurred by hospitals located in rural areas as compared to those in urban areas, and to make an appropriate adjustment for rural hospitals based on those findings. CMS conducted that study and made the adjustment. CMS is not precluded by this language from conducting a follow-up study that examines MDHs as a cohort, and from making a similar adjustment to MDHs, especially since MDHs also are by definition located in rural areas. We estimate that extending this adjustment to MDHs would provide an additional $72.7 million to these facilities.[11]

E. Payment for 340B Drugs

In 2018, CMS instituted a policy change reducing the amount Medicare pays hospitals for drugs covered under Part B of the program when those drugs are purchased through the 340B program.

[10] McDermottPlus' analysis of 2019 Medicare FFS outpatient claims data. Impacts estimated in 2019 dollars.
[11] McDermottPlus' analysis of 2019 Medicare FFS outpatient claims data. Impacts estimated in 2019 dollars.

Specifically, CMS reduced payment from Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. This policy continued through CY 2022.

Hospitals brought suit to invalidate this change and, on June 15, 2022, the U.S. Supreme Court ruled unanimously that the Department of Health and Human Services may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. As such, CMS must revise the payment policy in light of the Supreme Court's decision, but given that the decision came just one month before the proposed rule was released, the Alliance understands that CMS is not yet ready to articulate a new policy for CY 2023.

For CY 2023, CMS—for now—proposes a payment rate of ASP minus 22.5% for drugs and biologicals acquired through the 340B program, but notes its intention to apply a payment rate of ASP plus 6% to such drugs and biologicals beginning in 2023, and that it hopes to articulate a new policy in the final rule for CY 2023.

Given that CMS implemented the current policy in a budget neutral fashion, when undoing the current policy it likely will choose to make a corresponding adjustment to the conversion factor to preserve budget neutrality in the other direction. That adjustment also is not reflected in this proposed rule, and it is expected to meaningfully impact the proposed update to the conversion factor for CY 2023. Per the Supreme Court decision, CMS also must compensate hospitals that unlawfully had payments reduced for the past year, and CMS is also evaluating how to apply the decision to prior calendar years, including CYs 2020–2022, which were not subject to the Supreme Court decision.

As CMS works to finalize and articulate its new policy for CY 2023 in light of the recent Supreme Court ruling, **the Alliance respectfully requests that the agency consider potentially negative impacts on rural hospitals that continue to struggle financially, particularly as it relates to budget neutrality challenges, as CMS decides whether and how to recoup money from hospitals that experienced payment increases in previous years.**

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Thank you for your consideration of these comments. Please contact me at 202.204.1457 or ezimmerman@mcdermottplus.com if you have any questions.

Sincerely,

Eric Zimmerman