August 25, 2021

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Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services Attention: CMS-1753-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals [CMS-1753-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 2022.

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 one request for information (RFI). With respect to these proposals and RFI, we urge CMS to take the following actions:

- **Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status**
  - Extend the rural SCH 340B payment policy exception, and signal an intent to continue this policy in the future
  - Extend the 340B payment policy exception to urban SCHs
  - Extend the 340B payment policy exception to 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 2022**
  - Signal an intent to continue the 7.1 percent payment adjustment in the future
  - Extend the payment adjustment to urban SCHs
  - Study the appropriateness of making a similar payment adjustment for MDHs

- **Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services**
  - Exempt MDHs, SCHs (urban and rural) and RRCs from all applications of the PFS relativity adjuster

- **Request for Information Rural Emergency Hospitals**
  - Ensure that any policies set forth by CMS in future rulemakings related to Rural Emergency Hospitals (REHs) are not detrimental to other rural hospitals, including MDHs, SCHs, and RRCs.

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 a 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. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

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. Specifically, CMS reduced payment from Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. For CY 2022, CMS is proposing to continue reimbursing certain separately payable drugs and biologics purchased under the 340B program at ASP minus 22.5 percent or Wholesale Acquisition Cost (WAC) minus 22.5 percent for WAC-priced drugs. While rural SCHs have been excepted from this payment adjustment—and are proposed to continue to be excepted in the current proposed rule—urban SCHs, along with MDHs and RRCs, are not. These hospitals continue to be subject to the 340B payment reductions.

The Alliance urges CMS to:

1. Make the rural SCH 340B payment policy exception permanent

CMS has recognized that SCHs play a vital role in the rural health care infrastructure. By definition, these hospitals are the sole source of hospital services for a large area (they are either many miles away, separated by geographic barriers, or a minimum driving distance). If an SCH fails, a community is left without access to inpatient hospital services, and residents must travel great distances to access this care. The uncertainty provided under the current policy—*i.e.,* not knowing if CMS will extend the policy from year-to-year—inhibits investment in services in rural communities, and further strains the rural health care safety net. While this protection helps rural SCHs, the uncertainty of not knowing if or when CMS may revoke the projection means many rural SCHs are not investing further in community outreach services that may be enabled by 340B program discounts. **ARHA urges CMS to remove the uncertainty around the durability of this policy, and telegraph an intent to consistently and continuously except rural SCHs from the ASP payment reduction, for as long as this payment reduction is in effect.**

2. Extend the 340B payment policy exception to urban SCHs

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 "urban" areas are as rural as the most isolated frontier area. In fact, to be an *urban* SCH, a hospital has to be even further (35 miles) from another hospital to qualify. Currently, there are 89 SCHs located in urban designated geographic Core Based Statistical Areas (CBSAs) in 37 states.[1] Some 60 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, but others have not sought or have not been able to avail themselves of this process, and so remain urban and without these protections. Of the 29 SCHs that remain urban, 15 currently participate in the 340B program.

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 Pima County in Arizona). There are instances where an SCH is designated urban by CMS, but is actually a considerable distance from the nearest urbanized area. For example, Verde Valley Medical Center (Provider Number 03-0007) 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.[2] 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.

Further, urban and rural SCHs serve very similar patient populations, face the same financial challenges, and both play an essential role as safety net providers in rural communities. By relying on MSA assignment, CMS perpetuates the shortcomings of using MSAs as the means to differentiate between rural and urban SCHs. Moreover, CMS is distorting its own policies by incentivizing hospitals to undergo urban-to-rural reclassification to take advantage of these protections. **ARHA recommends that CMS also exempt urban SCHs from current 340B payment policy.** Given the small number of hospitals affected – approximately 15 – the systemic impact would be nominal.

3. Extend the 340B payment policy exception to MDHs and RRCs

CMS has recognized that MDHs and RRCs play a vital role in the rural health care infrastructure. Many 340B participating hospitals—particularly rural safety net facilities, like MDHs and RRCs—are indispensable to their communities, and the discounts they receive through the 340B program play an essential role in allowing these facilities to provide care to otherwise underserved communities. Numerous studies, including a 2016 study by the U.S.

[1] Centers for Medicare & Medicaid Services. FY 2021 IPPS Impact File, September 17, 2020.
[2] 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

Department of Health and Services (HHS), confirm that rural hospitals tend to have much thinner Medicare and overall margins than their urban counterparts, as well as much higher Medicare and Medicaid exposure.[3] According to the North Carolina Rural Health Research Program, 138 rural hospitals have closed since 2010.[4]

The Medicare Payment Advisory Commission (MedPAC) highlighted the impact of these closures in its June 2016 Report to Congress: "…rural hospital closures have increased in the last three years. Some closures reflect excess capacity, but in other instances, the closed hospitals were the sole provider of emergency services in the area. From March 2013 through March 2016, 43 rural hospitals closed…While 27 of the closures were less than 20 miles from the nearest hospital, 13 were 20 to 30 miles from the nearest hospital and 3 were over 30 miles from the nearest hospital."

Moreover, according to the Chartis Center for Rural Health's February 2021 report titled "Crises Collide: The COVID-19 Pandemic and the Stability of the Rural Health Safety Net", another 453 hospitals are vulnerable to closure. According to Chartis' analyses, "the rapid spread of COVID-19 in rural communities has further destabilized the ability of rural hospitals to meet the needs of their communities." The report adds that rural communities are known to be older, less healthy, and less affluent than their urban counterparts, that they face declining access to services, and that rural hospitals face a range of financial and operational hurdles when combating the virus. For example, their analysis has shown that the average rural hospital has just 33 days cash on hand.

While CMS excepted rural SCHs from the 340B payment adjustments, MDHs and RRCs remain subject to these reduced payments. CMS has cited hospital operating margins, closure rates of rural hospitals, low-volume, and existing special payment designations among reasons for excepting rural SCHs, but not other rural safety net providers. MDHs and RRCs also play a vital role in the rural health care infrastructure, and exhibit some of the very same characteristics CMS used to justify excepting rural SCHs from the cuts. MDHs, SCHs and RRCs are **all** safety net providers that play an important role in maintaining access to hospital and other health care services in isolated rural communities. Policies that further reduce payments to these facilities jeopardize both their short- and long-term viability.

Congress has long appreciated the important role of MDHs and RRCs in the rural health care infrastructure and the need to afford them special protections to ensure their continued viability. **As such, ARHA urges CMS to extend the exception from current 340B payment policy to MDHs and RRCs.**

We recognize CMS' position that RRCs are neither as small as nor as isolated as rural SCHs, and in the final CY 2019 rule, CMS also noted that RRCs are not generally eligible for special payment status under the OPPS. Although RRCs are not eligible for add-on payments or

[3] Rural Hospital Participation and Performance in Value-based Purchasing and Other Delivery System Reform Initiatives, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Issue Brief, October 19, 2016.
[4] University of North Carolina. The Cecil G. Sheps Center for Health Services Research. North Carolina Rural Health Research Program. https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/

transitional outpatient payments, in 2010, Congress did seek to buttress RRC participation in the 340B program—the same as SCHs—by lowering the eligibility bar for both provider types. The current 340B payment policy erodes the benefit from this change, and CMS should extend the exception from current 340B payment policy to RRCs.

We also acknowledge CMS' concern that urban-to-rural reclassification under the process described at 42 C.F.R. § 412.103 allows certain truly urban hospitals to obtain rural status and to qualify for RRC status, and that the number of hospitals with RRC status has grown considerably in recent years. While we urge CMS to protect all RRCs, CMS could begin with an exception for only those RRCs that do not have urban-to-rural reclassification or that have other indications of rural character and serving rural populations.

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 2022

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,[5] 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 2022, CMS proposes to continue this payment adjustment for rural SCHs.

The Alliance urges CMS to:

1. **Make the 7.1 percent payment adjustment permanent, or signal an intent to continue this adjustment in the future.**

CMS has repeatedly and consistently extended the 7.1 percent payment adjustment since it was first finalized in CY 2006, but the agency has always kept open the possibility that it may discontinue the policy in the next year. Each year, CMS proposes to extend the adjustment, solicits comments, and determines whether to extend the adjustment into the following calendar year.

While this payment adjustment is helpful to the hospitals that receive it, many are unable to take full advantage of the additional revenues because they cannot count on the adjustment being there from year-to-year. When hospitals budget annual spending and investments, some will not build into their budgets revenues that are uncertain. In those instances, the additional revenues are a windfall at year-end. The additional revenues may help close negative margins, but the monies cannot be invested in new services or capacities for the communities these hospitals serve, because they cannot be counted on from year-to-year. CMS probably thinks that hospitals regard this policy as permanent, because it has been in place consistent for fifteen years. Regrettably, because CMS "proposes" it every year, many hospitals do not regard it as a given that it will be there in the next year.

[5] § 411(b), Pub. L. No. 108-173.

CMS could ensure that the recipients of these additional reimbursements are able to put those additional monies to maximum use and benefit by removing some of that uncertainty. **As such, ARHA urges CMS to make the 7.1 percent adjustment permanent for rural SCHs. Or, at the very least, make an affirmative statement about an intent to continue this policy until the agency proposes to reconduct the analysis; then cease to propose to continue the policy in each rulemaking notice.**

2. 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 urban and rural 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.[6] 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. Just as CMS has chosen to protect rural SCHs from ASP payment reductions for 340B drugs, CMS likewise could do the same with respect to urban SCHs with this policy in the interest of articulated policy objectives.

3. 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. The dependence of these hospitals on Medicare makes them financially vulnerable, and an analysis of FY 2018 Medicare Cost Report data demonstrates that the mean and median profit margins for MDHs are -1.45 and 0.64 percent, respectively. **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

[6] 2016 Rural Relevance: Vulnerability to Value Study. iVantage Analytics, February 2016.

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 $71.4 million to these facilities, and approximately $425,000 in additional Medicare revenue per hospital.

E. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2019, CMS finalized 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, but finalized the policy for all excepted off-campus provider-based outpatient departments.

In CY 2020, CMS implemented the second portion of the payment reduction, a change that reduced payments for these services to 40 percent of the OPPS rate. For CY 2022, 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. **ARHA urges CMS to reconsider its current policy and exempt MDHs, SCHs (both urban and rural) and RRCs from all applications of the PFS relativity adjuster.**

Rural hospitals are closing at alarming rates, and applying the PFS relativity adjuster to rural hospitals may be a contributing factor. As previously stated, a large majority of rural hospitals are already financially vulnerable due to a number of factors, including payment inadequacy and uncertainty. Data from the North Carolina Rural Health Research Program show that a total of 41 MDHs, RRCs and SCHs have closed since 2005.

The Alliance recognizes that this policy reflects CMS' concerns about hospitals purchasing additional physician practices to bill for physician services at OPPS payment rates. However, CMS should not have the same concerns with respect to MDHs, RRCs, and SCHs where expanding services to underserved rural areas is desirable, and perhaps trumps other concerns held by CMS. We estimate that this policy reduced payments to these providers by approximately $132 million in 2019. The payment impact probably would have doubled to $264 million in 2020 if the pandemic had not caused significant reduction of hospital outpatient visits. **CMS should carefully consider the impact of this policy on rural hospitals—and particularly MDHs, RRCs and SCHs, and the communities they serve—and exempt these providers.**

Provider Type	Total Number of Providers	Number of Providers w/ excepted off-campus PBDs	Separately Payable Units of G0463 (PO Modifier)	Estimated Impact
Rural SCHs	424	182	1,021,404	$(29,144,853)
Urban SCHs	29	12	57,787	$(1,611,456)
MDHs	170	46	124,397	$(4,361,613)
RRCs (non §401)	152	85	422,794	$(15,078,507)
RRCs (§401)	331	264	2,831,509	$(82,012,802)
Total	1,106	589	4,457,891	$(132,209,231)

F. Request for Information Rural Emergency Hospitals

The Consolidated Appropriations Act (CAA) of 2021 created a new type of Medicare hospital called the Rural Emergency Hospital (REH). This classification is designed to help meet the needs of rural communities that cannot adequately support a full-service hospital, but that otherwise would lack emergency services. While the statute is fairly prescriptive regarding what the definition of an REH is and what types of institutions can become an REH, the Alliance appreciates that CMS is seeking stakeholder input on a number of questions—ranging from scope of services offered, to quality measurement, to licensure and conditions of participation—in order to help inform future rulemaking on REHs.

As noted throughout this comment letter, ARHA member hospitals—which have MDH, RRC, or SCH status under the Medicare program—play a vital role in their local communities and in the larger rural health care safety net. Indeed, both Congress and CMS over the years have recognized the unique and important contributions that these hospitals bring to the Medicare program, and have provided and renewed various payment protections to protect their viability, therefore also protecting patient access to hospital services in rural communities.

In any future rulemaking on REHs, the Alliance urges CMS to keep in mind the important roles of MDHs, RRCs, and SCHs, and encourages CMS to set forth regulations for REHs that consider not just the opportunity to maintain access to emergency care in the community served by the applicant provider, but also the implications for access to emergency care throughout the rural areas served by that hospital and nearby hospitals, and to ensure that the transition from an IPPS hospital or Critical Access Hospital (CAH) to an REH is beneficial to the rural health care system of those communities as whole. CMS should first do no harm to other servants of the rural health safety net, and ensure that good intentions do not cause detrimental unintended consequences.

For example, hospitals qualify for SCH status by virtue of being a certain distance from a "like hospital." CAHs are not considered like hospitals. CMS must consider whether an REH will be

considered a “like hospital,” and if so, how the emergence of a “like hospital” might affect the nearby SCH’s eligibility.

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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