September 18, 2020

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Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1716-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Addition of New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy; Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years; and Physician-owned Hospitals

Dear Administrator Verma:

On behalf of the Rural Hospital Coalition, please accept these comments on the Hospital Outpatient Prospective Payment System ("OPPS") proposed rule.

The Rural Hospital Coalition ("Coalition") 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 access to hospital services in rural communities. The Coalition shares the common goal of ensuring that federal hospital payment policies recognize the unique and important role and contributions of these hospitals to the Medicare program and its beneficiaries. Consistent with this mission, the Coalition is pleased to provide CMS with these comments.

A. Executive Summary

The Coalition is submitting comments on six proposals. With respect to these proposals, the Coalition urges CMS to take the following actions:

1. Adjustment for Rural SCHs and Essential Access Community Hospitals under Section 1833(t)(13)(B) of the Act
    - Make the 7.1 percent payment adjustment permanent
    - Extend the payment adjustment to urban SCHs
    - Study the appropriateness of making a similar payment adjustment for MDHs

2. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment
    - Make the rural SCH 340B payment policy exception permanent
    - Extend the 340B payment policy exception to urban SCHs
    - Extend the 340B payment policy exception to MDHs and RRCs

3. Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)
    - Exempt MDHs, SCHs (urban and rural) and RRCs from all applications of the PFS relativity adjuster

4. Waivers Under the Public Health Emergency (PHE) that Protect MDHs and SCHs
    - Ensure an adequate transition for MDHs and SCHs (urban and rural) after expiration of the PHE

B. Background: Rural Hospital Designations

Medicare Dependent Hospitals: The MDH program was established by Congress in 1990 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. Many of these hospitals also have substantial Medicaid patient populations.

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 nearly 40 years ago to maintain access to needed health care services for Medicare beneficiaries in isolated communities. Congress was concerned that as it moved Medicare to fixed, per-service payments under the IPPS, hospitals whose costs exceeded IPPS payments could be financially threatened, and that the Medicare program and its beneficiaries would suffer if hospitals serving isolated, rural populations failed because of this financial shortfall. The SCH program is intended to maintain the viability of hospitals providing critical health care services to their communities.

C. Proposed Adjustment for Rural SCHs and Essential Access Community Hospitals under Section 1833(t)(13)(B) of the Act

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,[1] that compared to urban hospitals, rural SCHs have substantially higher costs, and need a payment adjustment to be comparably treated under the outpatient PPS. For CY 2021, CMS proposes to continue this payment adjustment for rural SCHs.

The Coalition urges CMS to:

1. Make the 7.1 percent payment adjustment permanent

While CMS indicated in the CY 2020 final rule that it will maintain the 7.1 percent payment adjustment until data support a change to this payment adjustment, it did not make the payment adjustment permanent. This payment adjustment is helpful to the hospitals that receive it, however, 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 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. *For this reason, the Coalition urges CMS to make the 7.1 percent adjustment permanent for SCHs.*

[1] § 411(b), Pub. L. No. 108-173.

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.[2] Both urban and rural SCHs face similar financial challenges leading to increasing rates of closures. And, *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, the Coalition 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, 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 Coalition 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 $71.4 million to these facilities, and approximately $425,000 in additional Medicare revenue per hospital.

[2] 2016 Rural Relevance: Vulnerability to Value Study. iVantage Analytics, February 2016.

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

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 2021, CMS is proposing to reduce payment from ASP minus 22.5 percent to ASP minus 28.7 percent. *Rural* SCHs are excepted from this payment adjustment, however, *urban* SCHs, MDHs and RRCs are not. These hospitals continue to be subject to the adjustments and will be further impacted if CMS finalizes it proposal to reduce payment to ASP minus 28.7 percent.

The Coalition 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 – inhibits investment in services in rural communities, and further strains the rural health care safety net. While this protection helps rural SCHs, the uncertainty surrounding it – *i.e.,* 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. *In the CY 2019 final rule, CMS indicated that the agency will continue to analyze the data to determine whether a permanent exemption for rural SCHs is warranted. However, the agency failed to discuss a permanent exemption in the CY 2020 rulemaking and in the CY 2021 proposed rule. Moreover, in the CY 2021 proposed rule CMS creates uncertainty regarding the current exemption for rural SCHs by indicating that the agency may revisit in future rulemaking its policy to exempt rural SCHs from the 340B drug payment reduction. The Coalition urges CMS to make permanent the SCH exception to the ASP payment reduction.*

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

CMS uses MSAs to delineate between urban and rural areas. While the Coalition appreciates 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 CBSAs in 37 states.[3] Some 60 of these have undergone urban-to-rural reclassification under the process described at 42

[3] Centers for Medicare & Medicaid Services. FY 2021 IPPS Impact File, September 17, 2020. There is one urban SCH in Maryland, but it is not included in the total count or in the state count provided herein, since Maryland hospitals are under the all-payer model and are exempt from the IPPS and OPPS.

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. We estimate that, if finalized, CMS' proposal to set payment for 340B drugs at ASP minus 28.7 percent will reduce payments to these hospitals by nearly $35 million. This estimate reflects the difference between payments at ASP plus 6 percent and ASP minus 28.7 percent.

Provider Type	Count of Provider Type	Count of 340B Providers	Estimated Impact of ASP minus 28.7 percent
Urban SCH	29	15	$(34,600,745)

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.[4] 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. *The Coalition recommends that CMS also exempt urban SCHs from current 340B payment policy. The Coalition is not recommending an exemption of off-campus departments of urban SCHs, like was suggested in the CY 2019 final rule, but rather an exemption from current 340B payment policy for hospital departments paid under the OPPS, including, but not limited to off-campus departments.*

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 recent government study by the US Department of Health and Services, confirm that rural hospitals tend to have much thinner Medicare and overall margins than their urban counterparts, as well as much higher

[4] 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

Medicare and Medicaid exposure.[5] According to the North Carolina Rural Health Research Program, more than 132 rural hospitals have closed since 2010.[6] Moreover, the National Rural Health Association (NRHA) suggests that many more—673—are vulnerable to closure. These vulnerabilities represent more than one-third of the rural hospitals in the U.S., and up to 11.7 million rural patients could lose direct access to care should this trend continue.

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." *While CMS excepted rural Sole Community Hospitals (SCHs) from ASP payment adjustments, MDHs and RRCs remain subject to these adjustments.*

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 maintaining access to hospital and other health care services in isolated rural communities. Policies that further reduce payments to these facilities jeopardize their short and long-term viability. We estimate that, if finalized, CMS' proposal to set payment for 340B drugs at ASP minus 28.7 percent will reduce payments to MDHs by nearly $27 million and to RRCs by over $1.2 billion. This estimate reflects the difference between payments at ASP plus 6 percent and ASP minus 28.7 percent.

Provider Type	Count of Provider Type	Count of 340B Providers	Estimated 340B Impact
MDH	170	40	$(26,796,172)
RRCs (non §401)	152	83	$(232,523,665)
RRCs (§401)	331	199	$(996,802,112)
Total	**1072**	**609**	**$(1,256,121,949)**

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, the Coalition urges CMS to extend the exception from current 340B payment policy to*

[5] 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.

[6] 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/

MDH and RRC hospital departments paid under the OPPS, including, but not-limited to off-campus departments.

We recognize CMS's position that RRCs are neither as small nor as isolated as rural SCHs. In the CY 2019 final rule, CMS also notes that RRCs are not generally eligible for special payment status under the OPPS. Although, RRCs are not eligible for add-on payments or transitional outpatient payments, in 2010, Congress sought 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. *CMS should extend the exception from current 340B payment policy to RRCs.* We also acknowledge CMS's 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 indicia of rural character and serving rural populations.

E. Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

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 Coalition 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. *The Coalition urges CMS to reconsider its current policy and exempt MDHs, SCHs (urban and rural) and RRCs from all applications of the PFS relativity adjuster.*

Rural hospitals are closing at alarming rates. 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 and data from the North Carolina Rural Health Research Program show that 37 MDHs, RRCs and SCHs have closed since 2010 with 6 MDHs and RRCs closing in 2019 and 4 MDHs closing so far in 2020.

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Grand Total
MDH			1	3	6	1	2	1	4	4	4	26
RRC						1						1
SCH	1	1			1	1	2		2	2		10
Grand Total	**1**	**1**	**1**	**3**	**7**	**3**	**4**	**1**	**6**	**6**	**4**	**37**

The Coalition 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. In 2019, we estimate that this policy reduced payments to these providers by approximately $132 million. *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. Waivers Under the Public Health Emergency (PHE) that Protect MDHs and SCHs

Under the current PHE, CMS has waived certain eligibility requirements for MDHs and SCHs classified as such prior to the PHE. For SCHs CMS waived the distance requirements at paragraphs (a), (a)(1), (a)(2), and (a)(3) of 42 CFR § 412.92 and the "market share" and bed requirements (as applicable) at 42 CFR § 412.92(a)(1)(i) and (ii). For MDHs, CMS waived requirements at 42 CFR § 412.108(a)(1)(ii) that the hospital has 100 or fewer beds during the cost reporting period, and the eligibility requirement at 42 CFR § 412.108(a)(1)(iv)(C) that at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the specified hospital cost reporting periods. CMS waived these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID-19 patients. These waivers are intended to expire at the conclusion of the PHE. While it is reasonable for these requirements to expire after the PHE, the Coalition is concerned that an immediate return to current requirements after the PHE might jeopardize the ability of MDHs and SCHs to meet market and/or patient share requirements as service delivery and care patterns normalize. *The Coalition urges CMS to consider extending these waivers through the end of the cost reporting year in which the PHE ends.*

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We likewise urge CMS to explore and pursue other ways to buttress healthcare in rural areas.

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