September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1772-P; 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.

Submitted electronically via regulations.gov

Dear Administrator Brooks-LaSure,

The National Rural Health Association (NRHA) is pleased to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the Medicare Hospital Outpatient Prospective Payment System for calendar year (CY) 2023. We appreciate CMS’ continued commitment to the needs of the more than 60 million Americans that reside in rural areas, and we look forward to our continued collaboration to improve health care access throughout rural America.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America’s health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America’s health needs through government advocacy, communications, education, and research.

II. Proposed Update Affecting OPPS Payments

B. Proposed Conversion Factor Update

NRHA has significant concerns about the low payment update (2.7%), particularly given the inflationary environment and continued labor and supply cost pressures that rural hospitals and health systems face. The most recent Consumer Price Index released by the Bureau of Labor Statistics shows an 8.3% increase over the past twelve months ending in August 2022.\(^1\) Even if inflation subsides prices are not decreasing to pre-2022 levels. Inflation rates may be lower in 2023, yet that rate is built upon the excessive growth in inflation during 2022. In light of this, CMS’ proposed OPPS payment update is inadequate.

https://www.bls.gov/news.release/cpi.nr0.htm
CMS uses the same market basket percentage update for the OPPS rate as in the Inpatient Prospective Payment System (IPPS), which CMS projected to be 3.1% in the FY 2023 IPPS proposed rule.\(^2\) The final IPPS rule was published on August 10, 2022, and included an increase to the proposed market basket update using second quarter 2022 forecast data.\(^3\) CMS finalized a market basket update of 4.1%, the largest update in 25 years. NRHA asks that CMS adopt a market basket update of no less than 4.1% in the final OPPS rule to increase payments to better reflect the current economic reality that hospitals are facing. Further, because rural hospitals provide a more significant portion of outpatient services compared to inpatient and are more reliant on Medicare payments, receiving the higher market basket update will be especially important to long-term rural hospital viability.

In addition, NRHA asks that CMS work within its statutory authority to do more to improve the CY 2023 payment update. A market basket percentage change in the final rule would be significant, but more must be done to ensure rural hospitals’ financial viability. Since 2010, 139 rural hospitals have ceased operation\(^4\) and 453 more are vulnerable to closure.\(^5\) While government intervention in the form of pandemic relief funds temporarily stabilized rural hospitals, the end of those funds coupled with 8.3% inflation,\(^6\) increased labor costs, and the statutorily required Medicare sequestration and Pay-As-You-Go (PAYGO) policies could be disastrous. To mitigate this, CMS must explore pathways to increase the FY 2023 payment update. Low OPPS payments and the aforementioned challenges mean that many rural hospitals will struggle to stay financially viable and keep their doors open as an access point for rural beneficiaries.

CMS may investigate its authority under Section 1833(t)(2)(E) of the Social Security Act (SSA), which states that the Secretary shall, in a budget neutral manner, establish outlier adjustments necessary to ensure equitable payments to hospitals.\(^7\) CMS is using such authority to authorize lump-sum payments for hospitals purchasing domestic made N95 respirators, see infra at X.H., and NRHA urges CMS to expand OPPS payments in the same manner.

C. Proposed Wage Index Changes

\(^2\) Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates. 87 Fed. Reg. 28403 (May 10, 2022) (to be codified at 42 C.F.R. pts. 412, 413, 482, 485, and 495).

\(^3\) Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates. 87 Fed. Reg. 49029 (Aug. 10, 2022) (to be codified at 42 C.F.R. pts. 412, 413, 482, 485, and 495).


\(^5\) The Chartis Group, Pandemic Increases Pressure on Rural Hospitals & Communities (2022), 1 https://www.chartis.com/sites/default/files/documents/Pandemic%20Increases%20Pressure%20on%20Rural%20Hospitals-Chartis.pdf.


NRHA is pleased to see that CMS has proposed a 5% cap on any decrease to a hospital’s wage index. External factors outside of a hospital’s control, such as COVID-19 labor demands, can contribute to significant fluctuations in the wage index, and a cap on any decrease will help to mitigate those factors.

However, NRHA urges CMS to apply this cap in a non-budget neutral manner for rural hospitals. There is substantial variation in the hospital wage index adjustment of rural and urban hospitals, which CMS recognized in its FY 2020 IPPS Final Rule stating “the growing disparities between low and high wage index hospitals, including rural hospitals that may be in financial distress and facing potential closure.” Given that all hospitals are affected by the budget neutrality to offset changes in wage index, hospitals receiving a cap will receive a benefit, but non-protected hospitals may receive a detriment if not implemented in an appropriate manner.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

6. OPPS Payment Methodology for 340B Purchased Drugs
NRHA thanks CMS for proposing to reinstate the average sales price (ASP) plus 6% payment rate for 340B drugs in the final rule in light of the Supreme Court decision in American Hospital Association v. Becerra, 596 U.S. ___ (2022).

In order to make hospitals whole, NRHA encourages CMS to remedy the payment cuts by repaying hospitals the full amounts that were lost to the ASP – 22.5% policy from 2018 to 2022. Further, when CMS complies with the AHA decision to make hospitals whole, we urge CMS not to take funds from rural hospitals exempted from the payment cuts in order to achieve a budget neutral implementation. As discussed, rural hospitals face unique challenges and operate under financial strains such that any lost payments threaten viability and thus access to care for rural residents.

X. Nonrecurring Policy Changes

A. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

5. CY 2023 OPPS Proposal To Pay for Mental Health Services Furnished Remotely by Hospital Staff
The COVID-19 pandemic worsened the overall mental health of Americans and rural communities were no exception. Compounding the effects of the pandemic, rural areas face a severe lack of access and availability of the full range of mental health care services. To illustrate, over 96% of residents in Wyoming live in a mental Health Professional Shortage Area (HPSA), while only 0.4% of New 

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Jerseyans live in a mental health HPSA. Over two-thirds of mental health HPSAs are in rural or partially rural counties. While other factors like acceptability among rural communities may impact some rural residents’ willingness to seek out mental health care, availability and access are substantial barriers as well.

NRHA thanks CMS for taking steps to help overcome the challenges that rural Americans face in obtaining mental health services. Covering mental health services furnished remotely by hospital staff to at-home patients increases access and availability of options for Medicare beneficiaries requiring mental health care. It is critical that patients’ continuation of care is not disrupted at the end of the COVID-19 Public Health Emergency (PHE) because remote options end. Over the course of the PHE, patients have built relationships and rapport with mental health practitioners via virtual care and returning to regular travel to receive in-person mental health care would be a burden for many rural patients. Retaining remote mental health services will encourage rural beneficiaries to continue care with their trusted practitioner. NRHA also commends CMS for permitting Critical Access Hospitals to bill for these services even though they are not paid under OPPS.

NRHA recommends that the clinical staff do not need to be “in” a hospital outpatient department to furnish mental health services to a remote beneficiary. We hold that 42 C.F.R. § 410.27(a) should be amended to include an exception for outpatient mental health services furnished to remote patients, particularly if reimbursement for these services will be under the lesser Physician Fee Schedule and not the OPPS rate because of the lesser hospital costs associated with remote care.

Moreover, NRHA is troubled by the lesser reimbursement for outpatient remote mental health services. Hospitals may not accrue the same costs associated with an in-person service when providing remote care, but rural hospitals are not in a place financially to receive less reimbursement. We reiterate our comments above highlighting the importance of telehealth options for rural beneficiaries, especially because of the access challenges that they face. Considering the immense benefit of remote care for rural beneficiaries, a lower reimbursement rate may disproportionately disadvantage rural hospitals when providing remote mental health services.

The in-person requirements for continuation of remote mental health services provide adequate flexibility for rural beneficiaries. NRHA appreciates that beneficiaries need only make an annual in-person visit, after an initial in-person visit, to continue to receive remote care. However, NRHA requests clarification on the exceptions to the annual in-person visit proposed rule. CMS states that the 12-month visit may be excused if “the risks and burdens of an in-person service outweigh the

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11 Mack, et al., supra note 8, at 1 (“Barriers to mental health care in rural areas can be grouped into availability, access, and acceptability”).
NRHA believes that in rural areas the travel time and distance are burdens and could create undue hardship on some rural beneficiaries, and thus may outweigh the benefits of in-person service.

NRHA supports CMS’ proposal to continue the use of audio-only technology for mental health services post-PHE for beneficiaries that cannot use audio/video technology due to broadband limitations. Rural areas are more likely to have limited access to broadband and have benefitted greatly from audio-only telehealth.

E. Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients

NRHA supports the ability of nonphysician practitioners (NPPs) to practice at the top of their license and clinical training. We thank CMS for proposing that NPPs may provide general, direct, and personal supervision of outpatient diagnostic services, per state scope of practice laws. Staffing flexibilities are crucial for rural providers that face enduring challenges in recruiting and retaining an adequate workforce. NPPs are critical to maintaining and increasing access to health care in rural areas and will continue to be with broader supervision privileges.

H. Proposed Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators

NRHA supports CMS’ proposal to adjust payments to hospitals that purchased domestic made, NIOSH-approved surgical N95 respirators. We appreciate the proposal for biweekly lump-sum payments to hospitals that purchased N95 respirators. Payment adjustments will protect rural hospitals against potential future demand crises and allow health care personnel to use the most effective PPE available.

I. 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)

NRHA applauds CMS for exempting rural Sole Community Hospitals (SCHs) from paying the site-specific Medicare Physician Fee Schedule equivalent payments. By paying SCHs the full OPPS rate when a clinic visit is furnished in an off-campus provider-based department, CMS ensures that rural communities retain access to care and that providers are appropriately compensated.

Accordingly, NRHA believes that other rural hospitals, such as those with less than 100 beds including Medicare Dependent Hospitals, Low-Volume Hospitals, and Rural Referral Centers, should similarly be exempted from the site-specific payment cuts. The same reasoning that led CMS to propose to exempt SCHs also applies to small rural hospitals. Factors other than the payment differential can be attributed to the volume of services in provider-based clinics at rural hospitals.
off-campus provider-based departments are often the only point of access to care in rural communities.

Likewise, if rural hospitals with less than 100 beds are exempted from the site-specific policy, these hospitals should receive the rural SCH 7.1% payment increase. 42 C.F.R. § 419.43(g)(1) should be amended to add these hospitals as eligible for receiving additional payment for covered outpatient services.

**XVI. Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program**

**B. REHQR Program Quality Measures**

2. Request for Comment on Potential Measures for an REHQR Program

d. Request for Comment on Additional Measurement Topics and for Suggested Measures for REH Quality Reporting

NRHA supports the recommendations made by in the National Quality Forum’s (NQF) Rural Health Advisory Group 2022 Key Rural Measures report. These measures are the best available to address needs of rural populations and, importantly, are resistant to low-volume challenges. We champion these measures for their use in Rural Emergency Hospitals (REHs) as they are scientifically valid, tailored for rural populations, and are less likely to face low-volume challenges.

(1) **Telehealth.** NRHA supports measures recommended in NQF’s Rural Telehealth and Healthcare System Readiness Measurement Framework for quality reporting on telehealth.

(3) **Mental health.** For behavioral and mental health measures, NRHA recommends that REHs adopt several quality measures.

- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment. (NQF ID 0004)
- Follow-Up After Hospitalization for Mental Illness. (NQF ID 0576)
- Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling. (NQF ID 2152)
- Safe Use of Opioids – Concurrent Prescribing (NQF ID 3316e).

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13 Id. at 3.

Additionally, NRHA recommends that CMS allow REHs to use telemedicine for mental and behavioral health services to the fullest extent possible. The proposal to allow mental health services furnished remotely to beneficiaries in their homes, supra X.A., should be available to REHs. This is an outpatient service and therefore REHs face no statutory or regulatory obstacles to providing this service. REHs should also be able to provide audio-only telemedicine for mental health services as their patients may face technological barriers to using audio/video telemedicine. Similar to CMS’ proposal in the CY 2023 Physician Fee Schedule proposed rule, REHs should further be authorized to initiate buprenorphine treatment via telehealth in order to help increase access to substance use and opioid treatment for rural beneficiaries.\textsuperscript{15}

(4) \textit{ED services}. NRHA recommends that CMS adopt the following measure pertaining to emergency care.

- Emergency Transfer Communication Measure. (NQF ID 0291)
- Follow-Up After Emergency Department Visit for Mental Illness or Alcohol and Other Drug Abuse or Dependence. (NQF ID 2605)

(5) \textit{Equity}. NRHA recommends that CMS adopt several quality measures related to health equity and social drivers of health. NRHA supports using measures finalized in the FY 2023 IPPS final rule regarding health equity in REH quality reporting.\textsuperscript{16} NRHA further recommends that REH reporting on these measures be optional to avoid increased reporting burdens.

- Hospital Commitment to Health Equity.
- Screen Positive Rate for Social Drivers of Health.
- Screening for Social Drivers of Health.

XVIII. Rural Emergency Hospitals (REH): Payment Policies, Conditions of Participation, Provider Enrollment, Use of the Medicare Outpatient Observation Notice, and Physician Self-Referral Updates

A. Rural Emergency Hospital Payment Policies

4. Payment for Services Performed by REHs
NRHA is pleased with CMS’ proposal to include all outpatient department services otherwise paid under OPPS as REH services payable under the REH payment policy. NRHA also applauds CMS for the monthly payments proposed for CY 2023. Robust payments for REHs will ensure that facilities are financially feasible and can best serve the surrounding rural communities.

Yet NRHA is concerned with the potential impacts of the market basket and inflation upon REHs. CAHs have generally been protected from inflation because they are not paid under a PPS, but instead receive 101\% of reasonable costs. Now CAHs that convert to an REH will be subject to the same

\textsuperscript{16} 87 Fed. Reg. 48785.
market basket as PPS hospitals because REHs are reimbursed under the OPPS rate, albeit increased by 5%. Like hospitals are seeing now, inflation will likely continue to outpace the market basket updates, thus REHs could become unprofitable and close, meaning that rural beneficiaries lose a point of access to care that the REH model was meant to sustain. To illustrate, in 2023 a hypothetical REH will receive its $3.2 million in total monthly payments, plus a hypothetical $1.8 million for REH services. The REH’s costs may be $4.9 million, so it would have a $100,000 surplus for 2023. However, in 2024, if costs rise by 8% and the market basket increase by 3%, the previous year’s $100,000 surplus would become a loss. If this trend continues for several years, the REH would close.

NRHA also urges CMS to add the additional 5% to certain services that do not fall under covered outpatient department services. For example, CMS should apply the 5% add-on to the respective fee schedules for laboratory and outpatient therapy services, including those listed at 42 C.F.R. § 419.22(h). Likewise, substance use and opioid use are perennial issues facing rural populations. CMS acknowledges in the preamble of the proposed Conditions of Participation for REHs that some REHs may be interested in becoming opioid treatment providers (OTP). However, to encourage REHs to do so, CMS must also consider applying the additional 5% to OTP services paid under the Physician Fee Schedule.

More robust payment policies will not only encourage more CAHs and small rural hospitals to convert rather than close but to offer more necessary services after conversion. REHs should receive the extra 5% payment when they determine that their communities need additional services that do not fall under OPPS services, like outpatient therapy and opioid use treatment.

NRHA also asks that CMS allow REHs to elect to be paid under the Optional Payment Method, or Method II. Method II allows CAHs to be paid 101% of reasonable costs for outpatient facility services, plus 115% of the Physician Fee Schedule amount for outpatient physician services and 115% of the Physician Fee Schedule amount normally paid for outpatient NPP services. For REHs, physicians and NPPs should be eligible to be paid 115% of their respective Physician Fee Schedule rates while the REH receives the OPPS rate plus 5% for the facility payment. CAHs that convert to an REH should maintain the option to bill under Method II and PPS hospitals that convert should be allowed to elect to participate in Method II.

5. Monthly REH Facility Payment
Again, NRHA appreciates CMS’ calculation of the monthly facility payments. Additionally, NRHA requests confirmation on whether the monthly facility payments begin with payments for REH services on January 1, 2023.

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17 Physical therapy, speech-language pathology, and occupational therapy.
18 Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates. 87 Fed. Reg. 40360 (July 6, 2022) (to be codified at pts. 42 C.F.R. 485 and 489).
In the proposed monthly REH facility payment methodology, CMS assumes that all CAHs meet the standard for the low volume payment adjustment. Generally this is true because most CAHs must either be 35 miles or 15 miles from the next nearest hospital. However, some CAH designations were grandfathered in 2006 under “necessary provider” status and thus these CAHs do not necessarily meet the 15-mile low volume adjustment criteria. By making this assumption, CMS may be artificially inflating the estimated prospective payment system (PPS) reimbursement which in turn decreases the monthly add-on. CMS should account for the CAHs that have necessary provider status to improve the monthly add-on.

NRHA is also concerned about the absence of Medicare Advantage (MA) days in calculating the monthly facility payments. CMS does not explicitly mention that MA is part of the calculation. MA plans are approaching the 50% mark versus traditional Medicare enrollment, with MA projected to surpass traditional enrollment next year. CMS is only considering a portion of the Medicare-entitled beneficiaries that CAHs serve when calculating the payments. MA is paid through the Medicare Trust Fund, like traditional Medicare, and accordingly, should be considered in the calculation. NRHA suggests that CMS include MA data in the monthly facility payment calculation.

Relatedly, it is unclear how MA plans will pay REHs. MA plans pay cost-based rates to CAHs. CAHs serve a high proportion of MA beneficiaries and when a CAH converts to an REH, CMS has not stated how MA plans will pay the REH. If the plans pay REHs under OPPS or at a negotiated rate that is less than cost, the conversion will cause revenue loss, which may impact long term viability of the model. CMS must require MA plans to pay REHs with the same payment methodology as under traditional Medicare.

NRHA is further concerned about Medicare sequestration and the impending Pay-As-You-Go (PAYGO) sequester. Medicare sequestration is currently in effect and reduces Medicare payments by 2%. PAYGO is set to go into effect on January 1, 2023, absent congressional action to further delay the implementation and this would reduce Medicare payments by another 4%. NRHA believes that because REHs are a new provider type and did not exist when Medicare sequestration began that they should be exempt from these payment cuts. Sequestration should not apply to either the OPPS rate plus 5% or the additional facility payments. However, if Medicare sequestration must apply to REHs, NRHA urges CMS to exempt the additional facility payments and only reduce the

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20 42 C.F.R. § 485.610(c) (2021).
21 Id. (“A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.”).
24 Id.
reimbursement for REH services. A total reduction of 6% in payments would be detrimental to REHs and undermine their purpose as a point of access for rural beneficiaries amidst staggering rural hospital closures.

Miscellaneous REH Payment-Related Provisions
NRHA requests that the Medicare Geographic Classification Review Board (MGCRB) reclassification be allowed for the REH wage index and for the rural floor. REHs should be allowed to apply for reclassification by the MGCRB in order to reclassify to a higher wage area and receive a higher payment rate.

NRHA would like to see REHs become eligible to participate in the 340B program. Participation in 340B would likely increase the number of rural hospitals considering converting to an REH. NRHA members have voiced significant concerns over whether to convert without 340B eligibility. NRHA recognizes that CMS does not have the regulatory authority to allow REHs to participate in 340B. But we ask that the Administration work alongside Congress to ensure that a statutory change is made in the 340B statute to include REHs as eligible participants. NRHA would also appreciate any clarification from CMS on anticipated action related to REHs and 340B.

NRHA also requests clarification from CMS on payment for provider-based rural health clinics (RHCs). Consistent with legislative intent, CMS must provide guidelines for payment to REH provider-based RHCs. CMS must allow REHs to maintain operation of existing provider-based RHCs at grandfathered by April 1, 2021, that meet the qualifications in section 1833(f)(3)(B) of the SSA for the special payment rules that establish non-capped rates instead of the national statutory payment limit. This must be explicitly stated in the REH payment regulations.

CMS is also silent on REHs and how the Medicare bad debt policy will apply. NRHA calls on CMS to apply the current bad debt policy of a 35% reduction to REHs, especially because hospitals that convert to REHs should be allowed to maintain consistency in anticipated payments. CMS should also make bad debt payments to REHs on a biweekly basis, as they are for PPS hospitals.

B. Conditions of Participation

Section 1861(kkk)(4)(a)(i) of the SSA requires that a hospital applying to convert to an REH must submit, at a time and in a form as the Secretary may require, an action plan for initiating REH services including a detailed transition plan that lists the services the REH will retain, modify, add, and discontinue, as well as a list of intended outpatient services. The proposed CoPs do not elaborate on the time and form required for these submissions. NRHA requests clarification on how converting

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25 42 U.S.C. § 1395x(kkk)(6)(B) (2018) (“A rural emergency hospital may be considered a hospital with less than 50 beds for purposes of the exception to the payment limit for rural health clinics under section 1833(f)(9).”)

26 CENTER FOR MEDICARE AND MEDICAID SERVICES, Update to Rural Health Clinic (RHC) All Inclusive Rate (AIR) Payment Limit for Calendar Year (CY) 2022, (Nov. 19, 2021)

hospitals may submit this information, and whether it would be part of filing the Form 855A for conversion.

Thank you for the chance to offer comments on this proposed rule and for your consideration of our comments. We very much look forward to continuing our work together to ensure our mutual goal of improving quality and access to care for rural residents. If you would like additional information, please contact Alexa McKinley at amckinley@ruralhealth.us or 202-639-0550.

Sincerely,

Alan Morgan
Chief Executive Officer
National Rural Health Association