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September 27, 2020

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals

Dear Administrator Verma,

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 and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for calendar year (CY) 2021. We appreciate your continued commitment to the needs of the more than 57 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, doctors, nurses and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

NRHA applauds the continued exemption of Rural Sole Community Hospitals (SCHs) and Critical Access Hospitals (CAHs) from Part B drug payment reductions proposed for hospitals eligible to purchase 340B discounted drugs and strongly encourages CMS to expand this carve out to other struggling rural hospitals who rely upon the 340B program. Rural hospitals, particularly rural PPS hospitals, are financially vulnerable. Since 2010, more than 130 rural hospitals have closed, half of which were non-SCH rural hospitals paid under the PPS system. Unfortunately, the rural hospital closure crisis has continued at an alarming rate in 2020. So far this year, 15 rural hospitals have shuttered their doors, and many of these have come since the beginning of the public health emergency (PHE). The percentage of rural hospitals operating at a loss increased to 47 percent by the beginning of this year, according to Chartis iVantage Health Analytics. Unfortunately, this data does not factor in the impact of the PHE. We anticipate the number of rural hospitals operating at a loss to currently be near 70 percent. However, the number of rural hospitals operating at a loss has been on a rise long before the PHE. In 2017, 41 percent of hospitals were operating at a loss. Further, between 2011 and 2013, urban hospital operating margins increased by seven percent, while rural margins decreased by six percent.

Rural hospitals paid through the PPS system are the most financially vulnerable, especially the DSH hospitals impacted by this regulatory change. According to Cecil G. Sheps Center for Health Services Research at the University of North Carolina, all categories of rural PPS hospitals had profitability below the average PPS hospitals. Small rural PPS hospitals and Medicare Dependent Hospitals (MDH) are the least profitable hospitals. Furthermore, hospitals that serve vulnerable patient populations, such as high poverty and minority populations, are more likely to have lower profit margins. These vulnerable hospitals rely heavily on the 340B program to provide access to expensive and necessary healthcare services, such as labor and delivery and oncology infusions. Even more fundamentally, three-quarters of rural hospitals said they used 340B savings to simply keep their doors open and continue providing basic healthcare services.

NHRA supports the exclusion of SCH from proposed cuts to the 340B program, which is essential to these hospitals and their patients. However, other rural PPS hospitals continue to struggle and are hurt by lost revenues from cuts to the 340B program. Health care delivery is challenging in rural areas; rural hospitals are disproportionately impacted by workforce shortages and geographic barriers, and they care for patient populations that are on average older, sicker, poorer, and more likely to be uninsured or underinsured than those of their urban counterparts. Notably, rural Americans are more likely to have chronic diseases, such as diabetes and heart disease, making access to medications and regular medical care essential for avoiding debilitating, costly, and painful complications. Unfortunately, the PHE has exacerbated this issue. Dedicated rural physicians and hospitals work around these obstacles to successfully provide high quality and personalized care to their communities. Still, the very characteristics of the rural patient population means that access to quality, affordable care is particularly essential for the 60 million-plus Americans living in rural and increasingly remote communities.

Despite the high demand for healthcare services, many rural Americans live in areas with limited health care resources, restricting their available options for primary and specialty care. Seventy-seven percent of rural counties in the U.S. are designated Primary Care Health Professional Shortage Areas, and nearly one in ten of rural counties have no practicing physicians at all. Although 20 percent of Americans are rural citizens, only 10 percent of the nation's physicians practice in rural areas. A lack of care options forces vulnerable populations to travel to obtain services, especially specialty services. In an emergency, for example, rural Americans must travel twice as far as their urban counterparts to receive care. As a result, while one out of five Americans live in rural areas, three out of five trauma deaths occur in rural America.

As a direct result of the 340B program, rural hospitals have been able to continue to serve vulnerable communities despite harmful and continuous reimbursement cuts. Keeping 340B reimbursement rates steady for rural providers allows them to keep important services in their communities. While we are happy that no additional reductions came to SCHs and CAHs, NRHA believes it is important for CMS to understand the benefit 340B brings to rural America. Future cuts to these providers would greatly diminish the ability for rural providers to provide the care needed. NRHA continues to advocate that rural providers as a whole should be exempt from 340B Drug Pricing Program payment reductions.

The 340B Drug Pricing Program has been invaluable to the Outer Cape Health Services (OCHS), a Federally Qualified Health Center (FQHC) serving the ten outermost communities of Cape Cod, Massachusetts. The outer three towns of OCHS's service area are nationally designated as rural, and most of the rest of the communities in our service area are designated as rural by the Massachusetts Office of Rural Health. While many view Cape Cod as a vacation paradise, it is also a geographically and socially isolated place that is deserted for nine months of the year. Because of the tourism nature of Cape Cod, many residents lack affordable housing and permanent work with benefits. Unfortunately, given the nature of Cape Cod's tourism industry, there is virtually no available land for the creation of affordable housing. Because of this, most tourism employees live in outdated cottages and motels that served the

vacation rental market 50 years ago but have become de facto affordable housing. Most of these structures were not built for four seasons and have inadequate insulation and electric heat or space heaters that are expensive and inefficient. The reality is depression, anxiety, social isolation, and addiction during a long, grey winter. OCHS provides primary care, behavioral health, addiction treatment, and social services to the permanent and part-time residents of this area.

For instance, the LGBTQ population on Cape Cod, which is at risk for infectious disease such as HIV and Hepatitis C, depend on the 340B program for affordable drugs that would be otherwise unaffordable. For years, OCHS's pharmacy revenue has offset losses from unreimbursed services, and have been responsible for the ability for them to grow to meet increasing demand for services. Now, in an era of COVID-19 when patient revenues from primary care have plummeted, their pharmacy revenues have been more important in ever in enabling them to keep their doors open. The loss of even a few percent of our 340B pharmacy income, which is a sizeable fraction of their overall patient revenues, would be devastating. Not only would 340B patients be denied access to medications, but the survival of OCHS could be in jeopardy. If OCHS were to close or reduce services, patients would have to travel over one hour by way of private vehicle to reach the next closest community health center. Access to care would be jeopardized and almost 200 permanent, benefitted jobs could be at risk. The outer Cape Cod communities depend on OCHS for jobs and to support the workforce and families. The 340B Drug Pricing Program allows OCHS to remain a stable source of affordable medications for a vulnerable patient population and a reliable source of funding for their health center. The alternative is the creation of yet another healthcare service desert and increased health inequity for the most vulnerable, low-income patients.

Another community in Bishop, California, benefits immensely from the savings generated by the 340B Drug Pricing Program. The Northern Inyo Health Care District, a CAH in Bishop, serves a community of about 4,000 people. Because of the 340B Drug Pricing Program, Northern Inyo Healthcare District can fund their obstetric services, which is vital to the safety and health of mothers and babies in rural communities. Allowing mothers and babies to receive this important care in their local community is critical. Maintaining obstetric care in rural America is vital to helping prevent the maternal morbidity and mortality that disproportionately affects black and American Indian/Alaska Native women in the United States. Further, there is a large disparity in access to obstetric care between rural and urban populations. It is imperative to the care in rural America that obstetric departments, like that of Northern Inyo Healthcare District, remain a viable option for these communities. The alternative risks the health and lives of rural mothers and their children.

Rural hospitals serve the precise vulnerable patient populations that the 340B program was designed to serve. Rural PPS hospitals have a 16 percent higher level of uncompensated care compared to their urban counterparts. Overall, rural hospitals face 24 percent higher levels of uncompensated care, twice the levels of bad debt, and substantially lower profit margins than urban hospitals. Specifically, SCHs face 47.5 percent higher levels of bad debt and 55 percent lower profit margins. Rural hospitals are substantially more likely to serve Medicare beneficiaries; 18 percent of rural populations are over the age of 65, compared to 12 percent in urban populations. Even with substantially smaller eligible populations due to a lack of Medicaid expansion in rural states, rural Americans are more likely on Medicaid: 21 percent versus 16 percent for urban populations. All these factors impact the bottom line of rural hospitals. As forementioned, while there has been a seven percent gain in median profit margins for urban providers, rural providers have experienced a median loss of six percent.

Compared to urban populations, rural residents tend to be poorer and more likely to live below the federal poverty line. On average, the rural per capita income is nearly \$10,000 lower than the average per capita income in the United States. About 25 percent of rural children live in poverty. As a result, Medicaid is disproportionately important to rural patients. As reimbursements are often below the cost of the provision of care, there is a disproportionately high burden placed on rural hospitals to avoid operating at

a loss. Particularly concerning is the fact that 86 percent of persistent poverty counties – those with a poverty rate of 20 percent or higher in 1990 through 2010 – are in rural America. The rural hospitals serving these counties face a persistent challenge to their bottom line that cannot be achieved by the same types of efficiencies that a hospital with a more favorable payor mix could employ. All these statistics together indicate rural hospitals are exactly the types of providers, and thus patients, that the 340B program was designed for. Rural hospitals rely upon the 340B program for their unique population, and the continued cuts harm access to care.

We strongly urge CMS to uphold the integrity of the 340B Drug Pricing Program. These proposed cuts, coupled with recent attacks to the program from large pharmaceutical manufacturers such as Eli Lilly & Co. and Merck, have rural providers worried. This program serves as a valuable lifeline for rural providers, and it allows them to provide better care for their uniquely challenging patient population and to expand their scope of services. CMS should be upholding and expanding this program, not weakening it with another round of proposed cuts.

NRHA supports CMS’s decision to change the minimum required level of supervision from direct supervision to general supervision for nonsurgical extended duration therapeutic services. As with last year’s change to general supervision for all hospital outpatient therapeutic services provided by all hospitals and CAHs, this change ensures a standard minimum level of supervision for each hospital outpatient service furnished incident to a physician’s service, which is a critical component for rural hospitals. The original 2009 change introducing the requirement for “direct supervision” by physicians as a “restatement or clarification” was produced by CMS, and therefore it is within the regulatory authority of CMS to take these actions. The requirement that physicians must be physically present in the outpatient therapy department did not include clinical rationale, allegations, or evidence that quality of care or patient safety had been compromised in hospital outpatient departments. The enforcement of this rule would have caused rural facilities to reduce therapy services, further threatening access to needed procedures for rural Americans – a concern already exacerbated by the shortage of healthcare professionals in many rural areas. NRHA is optimistic about the direction CMS is going in relation to supervision and believes setting minimum standards throughout outpatient services will greatly benefit rural facilities.

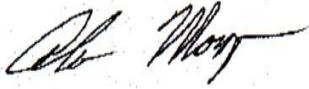
NRHA continues to advocate that CMS should abandon the Hospital Quality Star Ratings methodology. We appreciate the proposals to improve the Overall Hospital Quality Star Ratings in CY 2021, but we firmly believe the utilization of this methodology does not reflect the true quality of care provided. Reducing all the measures of judging efficiency and quality of care in hospitals into a single score (stars) between one and five is wrong. Unfortunately, CMS has continued down a path of rating hospitals, which are extremely complex, on the same scale utilized by hotel booking sites. NRHA believes that reducing the complexity of hospital efficiency and quality into a star rating is not advantageous to the public or hospitals, especially in rural areas. Thus, while NRHA is supportive of CMS’s effort to simplify and modernize the hospital ratings methodology, we strongly urge CMS to work with providers, rural and urban alike, to devise a better system. CMS must adapt a system that provides information that is meaningful to patients making purchasing decisions and fair to hospitals providing high-quality, low-cost care to their patients.

NRHA is concerned about proposals to undo current restrictions on physician-owned hospitals. Countless studies have shown that physicians tend to self-refer patients to facilities in which they have ownership, commonly referred to as ‘cherry-picking’ patients. This practice can jeopardize a community’s ability to provide full-service care and ultimately cost the Medicare program more money. By loosening restrictions on physician-owned hospitals, CMS may accelerate a trend that allows certain providers to benefit from influxes and wealthier, more-affluent patients and forces sicker, less-affluent patients to seek care from community hospitals, which will threaten the financial viability of the health

care safety net. NRHA believes that restrictions on physician-owned hospitals need to remain in place to ensure that rural and community hospitals have equal opportunity to patients.

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. If you would like additional information, please comment Josh Jorgensen at jjorgensen@nrharural.org, or 202-639-0550.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Morgan". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Alan Morgan
Chief Executive Officer
National Rural Health Association