

Headquarters

4501 College Blvd. #225
Leewood, KS 66211-1921
816-756-3140
Fax: 816-756-3144

**Government Affairs Office**

1025 Vermont Ave. NW
Suite 1100
Washington, D.C. 20005
202-639-0550
Fax: 202-639-0559

September 27, 2019

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: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Dear Administrator Verma,

The National Rural Health Association (NRHA) appreciates the opportunity to offer our comments and concerns regarding proposed changes to the Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for calendar year 2020. NRHA appreciates your continued commitment to the needs of the 62 million Americans residing in rural and underserved areas and looks forward to collaborating with you to improve health care access and quality in rural America.

NRHA is a non-profit membership organization with more than 21,000 members nation-wide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care infrastructure, including rural community hospitals, critical access hospitals, doctors, nurses and patients. We work to address the healthcare needs of rural America through government advocacy, communications, education and research.

NRHA is pleased with the change of minimum required level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic services provided by all hospitals and critical access hospitals (CAHs). The Executive Summary to the rule indicates this change is for CY2020. However, the detailed discussion seems to indicate this is a permanent change. We request clarification that this is, in fact, a permanent change in

physician supervision requirements, and urge CMS to make this a permanent change if that was not the intent. 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 it is therefore within the regulatory authority of CMS to eliminate. 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 cause 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 applauds the continued exemption of Rural Sole Community Hospitals (SCHs) from the 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 PPS hospitals are financially vulnerable. Since 2010, 115 rural hospitals have closed, half of which were non-SCH rural hospitals paid under the PPS system. The percentage of rural hospitals operating at a loss has increased from 44 percent in 2018, to 46 percent in 2019, according to Chartis iVantage Health Analytics. Between 2011 and 2013, urban hospital profit margins increase by 7%, while rural margins decreased by 6%. Again, rural hospitals that were paid through the PPS system are the most financially vulnerable, especially the DSH hospitals impacted by this regulatory change. According to the Sheps Center at the University of North Carolina, all categories of rural PPS hospitals had profitability below the average PPS hospitals. The least profitable hospitals are the small rural PPS hospitals and the Medicare dependent hospitals. Furthermore, hospitals serving vulnerable patient populations, such as high poverty and minority populations, are more likely to have lower profit margins. These struggling 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, many hospitals are relying on this program to simply keep their doors open and to continue the provision of basic healthcare services.

The SCH exclusion from this policy has been an important tool for rural providers, essentially allowing them to continue to serve their patients and their communities. However, there are other struggling rural hospitals that have been hurt by lost revenues from the 340B program cuts. Rural health care delivery is challenging. Workforce shortages, older and poorer patient populations, geographic barriers, low patient volumes and high uninsured and under-insured populations are just a few of the uniquely rural complications. Rural Americans are more likely to be older, sicker and poorer than their urban counterparts. They 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. 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 health care is particularly essential for the 62 million 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 nine percent of rural counties have no practicing physicians at all. Although 20 percent of America consists of 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 20 percent of Americans live in rural areas, 60 percent of trauma deaths occur in rural America.

As a direct result of the 340B program, rural hospitals have been able to continue to serve their vulnerable communities despite harmful and continuous reimbursement cuts. Some facilities use 340B funds to staff their ED, to offset uncompensated care, or simply to keep their doors open to allow them to continue to serve their community. One hospital is only able to staff their labor and delivery unit because of the 340B program; loss of their service line would force women from their community to travel at least an additional 45 minutes to obtain obstetric care. The 340B program allows the Lake Regional Health System to set up primary care within their service area. They serve a predominately elderly population for whom transportation is a substantial challenge, this coupled with a service area that is made more difficult to traverse by a large and winding lake. These clinics are staffed by employed physicians at a loss to the hospital. It is difficult to attract primary care providers, and specialists into their remote service area without a payer mix and patient volume that would allow them to break even.

Multiple hospitals report the 340B program is the reason they can provide oncology infusions to those in their local community. These chemotherapy infusion centers are often small with variation in patients served based on the current need of their community. For one patient, the opening of the oncology infusion unit at Childress Hospital meant he no longer had to travel four hours – each way – to receive chemotherapy. Fort Madison Community Hospital in Fort Madison, Iowa is nearly two hours away from the next closest chemotherapy infusion center. Last year alone, this facility provided 1,035 chemotherapy infusions to 619 patients, the majority of which were Medicare beneficiaries. Sadly, the region served by Fort Madison Community Hospital is experiencing a rise in patients with cancer and is expecting greater demand for cancer infusions.

Other hospitals have reported dependence on the 340B program to simply maintain basic hospital services. For example, Neshoba County General Hospital utilizes the 340B program to offset losses from their high charity care, and to staff an infusion center. Without 340B, this facility would likely need to stop providing many of these outpatient infusions – forcing patients to either travel at least 35 miles to another facility, or to receive their care in an inpatient setting. While their infusion center does provide chemotherapy, this is a small portion of their patient population. Administration of intravenous antibiotics that would otherwise be provided in an inpatient setting represents a much larger portion of the patient population utilizing the infusion center. However, as doctors in the surrounding community have learned about the local availability of this valuable service, more patients are served by the infusion clinic. It is the very flexibility inherent in the 340B program that has allowed each of these rural communities to have the ability to identify the unique needs of their patient population and provides to ability to offer

access to those specific services. These programs are examples of the original intent of the 340B program: to allow safety net hospitals to stretch scarce federal resources to provide vulnerable patient populations with access to high quality healthcare services.

Rural Hospitals serve the precise vulnerable patient populations that the 340B program was designed for. 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, as 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 to rely on Medicaid; 21 percent versus 16 percent for urban populations. All of these factors impact the bottom line of rural hospitals. While there has been a 7 percent gain in median profit margins for urban providers, rural providers have experienced a median loss of 6 percent.

Compared to urban populations, rural residents tend to be poorer and are more likely to live below the federal poverty line. On the average, the rural per capita income is \$9,242 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 located 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 of 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.

This proposed rule and its continuation of cuts in payments for 340B drugs only exacerbates the strain already placed on hospitals serving vulnerable communities. We have seen numerous associations that have successfully challenged the previous cuts to the 340B program in court. Now that the court has ruled that those cuts are illegal and exceeded the Administration's authority, we urge CMS to refrain from doing more damage to impacted hospitals with another year of illegal cuts. Instead, as a remedy, CMS should be offering a plan to promptly restore funds to those facilities affected by the illegal cuts.

CMS requests feedback on implementing a remedy should CMS ultimately lose the current appeal of the district court decision regarding the 340B cuts implemented in 2018. We urge CMS not to retroactively recover funds from hospitals that received the redistribution of the 340B funds withheld from most 340B PPS hospitals. If, pursuant to a legal decision, CMS is required to reinstate funds to certain 340B hospitals, it should not be required to do so on a budget-neutral basis.

While NRHA supports transparency, we oppose mandating the disclosure of negotiated rates between insurers and hospitals. Mandating hospitals to make their negotiated rates publicly available will be unattainable for small rural providers. Proposing to require hospitals to post a list of all of their standard charges – both gross charges and all negotiated rates – for all items and services in a machine-readable format on their website is a grossly miscalculated effort. Rural providers do not have the same capacity as their urban counterparts to keep up with such a time-consuming effort. Requiring rural hospitals to post this file on their websites without any form of registration or “barrier” to access will put these already vulnerable institutions at a disadvantage in that they are publishing their contract details that were heretofore proprietary. Hospitals will now see the payments received by their competitors, essentially giving the answer to the test ahead of contract negotiation. These efforts at transparency are more likely to create antitrust issues for rural providers without the resources to deal with the fallout.

The enforcement of such mandated disclosures is inherently flawed. As previously stated, rural hospitals do not have the resources or staff to keep up with such an intrusive new system and should be exempt from any penalty. Rural providers should be carved out from the civil monetary penalties being proposed in this enforcement. The CMS estimate that it would take hospitals 12 hours, and a cost of \$1,017.24, to comply with these requirements is grossly underestimated. To simply generate the payment report and provide comparison to the same charges paid by insurance companies is an extreme burden on rural hospitals, which have limited ability to comply. These mandated disclosures can seriously limit the choices available to patients and fuel anticompetitive behavior among commercial health insurers in what is already a highly concentrated insurance industry. This proposal should be abandoned all together until stakeholders are brought into the conversation and transparency efforts can be met without burdening small rural hospitals.

NRHA opposes the full phase-in of Site-Neutral Payment Cut for Outpatient Clinic Visits in off Campus Provider Based Departments. These changes will reduce essential access to care in many rural communities. While we understand the desire to move care to a lower cost site of service where no alternative sites exist, as is the case in many rural communities, this policy change will not achieve that aim. This policy change will instead result in fewer available primary care services and result in greater use of Emergency Departments (ED). Ultimately, a full phase-in of site-neutral payment cuts will force patients to delay obtaining healthcare services until they are sicker, requiring more costly care.

Important rural access points are facing a closure crisis. There have been 113 rural hospitals that have closed since 2010. More than a third of all rural hospitals, 683, are currently vulnerable to closure. Continued cuts in hospital reimbursements have taken their toll on rural hospitals, especially considering the vulnerable populations served by these essential access points. In rural communities the hospital is essential for more than just inpatient medical care. Much of the health care work force in rural America is inextricably tied to the rural hospital. A closure results in more than just the loss of inpatient care; it results in the loss of emergency care and a variety of outpatient services including primary care. Additionally, the rural hospital is often one of the largest community employers. With a loss of local health care options, rural communities struggle to attract new businesses and struggle to retain existing companies. Rural hospitals are a key cog in the local economy in these communities.

While we appreciate this administration's focus on regulatory relief and reduction of unnecessary costs in health care, in a rural community myopically focusing on a single service line will result in a broad loss of access to care. Currently 46 percent of rural hospitals are operating at a loss, up from 44 percent last year. This level of operational loss is not sustainable, and each additional cut will result in more hospitals being unable to find the resources to make up for their losses. Furthermore, as the only point of access, rural hospitals often struggle to maintain the essential yet money-losing services, such as emergency care and obstetrics. We have seen a concerning increase in loss of these important service lines as hospitals must decide between a stopping a service or closing the hospital. In fact, nearly 200 rural counties lost obstetrics units between 2004 and 2014. Paying a higher rate for these services is the only way they can be provided in some rural areas.

Rural hospitals already lose money by providing care to Medicare patients in hospital outpatient departments. This is a particularly problematic situation since rural hospitals also serve a larger percentage of Medicare patients, compared to urban and suburban hospitals. For example, at Olympic Medical Center (OMC) in Oregon, the costs of providing physician clinic visits exceed the reimbursement that OMC currently receives from Medicare for hospital-based provider clinics. OMC receives approximately 85 percent of costs. OMC uses a local tax levy and interest income to help pay for these losses. The costs include physician salaries and benefits; for example, OMC employs primary care physicians at a cost of approximately \$250,000 annually including salary and benefits, while the salaries and benefits of cardiologists and oncologists are over \$400,000 annually. The costs of providing patient care also include the cost of staffing registered nurses, medical assistants, clinic receptionists, and includes the cost of supplies, electricity, buildings, equipment and infrastructure needs. Even without the threat of proposed cuts, it is a challenge to maintain services, due to the high percentage of Medicare-covered patients OMC serves. The proposed 60% cut in physician clinic expenses will result in a loss for OMC of approximately \$3.4 million in 2019. Over the next decade, the loss to OMC will be over \$47 million. If OMC closes down its provider clinics, the approximately 45,000 enrollees of Medicare, Medicaid and other government payors in their county would lose their primary care provider as there are no existing freestanding physician clinics accepting these patients.

Avera Queen of Peace Hospital in Mitchell, South Dakota's provider based OPD, created a necessary upgrade of the physical plant of previous clinics, many of which were difficult for their aging patient population to access. This facility provides necessary care to its community, including primary care, urology, internal medicine, dermatology and general surgery. The facility includes a pharmacy that allows patients local access to prescriptions that they did not previously have. After being open for regular primary care needs, this facility becomes an urgent care clinic, effectively diverting patients from the expensive emergency department. Mitchell's population, like much of rural America, is aging. Already the majority of patients are Medicare with an expected increase of 5-10 percent in the next 5 years. Without appropriate Medicare reimbursement, the viability of this clinic to serve the needs of the Medicare beneficiaries in the community is in jeopardy. While the dollar amounts are small in terms of the Medicare program, these small amounts are large and crucial to these facilities that are fighting to keep their doors open to continue to serve vulnerable rural patient populations. The geographic area which a

resident resides in should not stop them from having access to necessary and high quality healthcare.

Indeed, the rural hospitals impacted, according to CMS, are largely hospitals that have been identified by their overall quality of care and patient satisfaction, market share, cost and charges, as well as financial stability as the top 20 Rural Hospitals. Of the rural hospitals identified as losing money as result of this policy shift, 30 of these hospitals have been in the top twenty over the past three years with multiple hospitals being awarded all three years. These are the hospitals that provide high quality care to their rural communities and frontier areas, despite the many barriers, and to do so at a great value to the Medicare program. These cuts will impact their ability to continue to serve their communities.

NRHA urges caution in changes to off-campus EDs since these rural EDs are necessary access points with higher costs of capacity to provide care. In rural communities with a lower population base, emergency departments provide access to lifesaving, time sensitive, and in person care. The ability to sustain these essential local access points is necessary to allow rural patients with medical emergencies to receive the care they need. They are, however, very expensive to maintain, especially when patient loads are not full. Looking at the ED without looking at the overall financial viability of the facility will result in the total loss of this essential services in some of the most vulnerable communities with the most limited access to care.

NRHA encourages CMS to use the FY2020 hospital IPPS post-reclassification wage index for the OPPI. NRHA urges CMS to make the same changes to the lowest-quartile rural hospital wage indices as it made on the IPPS side. The focus and willingness of CMS to reexamine and adjust the wage index is long overdue and appreciated. NRHA has an extended history, dating back to the start of our organization, of fighting the wage index inequities harming rural providers seeking to care for rural Americans. This strong policy improvement will create greater equity among providers and will significantly help the many struggling rural hospitals who provide care for a disproportionately high number of seniors. Many rural hospitals in low wage index areas struggle on a daily basis to remain solvent following a plethora of payment cuts and policy changes that have led to the current astounding rate of rural hospital closures. As of last year, 46 percent of rural hospitals were operating at a loss, up from 40 percent just two years before with preliminary data showing the trend continues. Since 2010, 107 rural hospitals have closed with two occurring within a week of this writing.

Rural communities are greatly affected by the maldistribution of healthcare professionals. Indeed, the Robert Wood Johnson Foundation found that maldistribution was a much larger problem than an absolute shortage of primary care providers. One aspect of this maldistribution is the fact that urban facilities offer better salaries and benefits, plus the additional benefits of greater peer support from a larger workforce. Economic forces would indicate that paying higher, not the lower rates already provided for under the wage index, is the appropriate response to workforce maldistribution. Basic economic principles indicate the rural wage index should exceed that of the urban areas without shortages, instead of a low index based on the cost of living. Indeed the very existence of the wage index is self-perpetuating in that a rural community is provided fewer resources and is thus unable to afford higher wages resulting in either hiring only those that can and will accept lower wages, while also not filling other positions that if

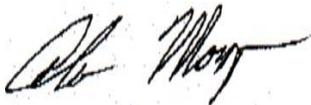
filled would potentially lift their wage index. In reality, professional markets do not drop abruptly at the county line, instead they change over areas with some professionals traveling from market to market for a variety of reasons including wages. It is expected that some rural areas would share professional marketplaces with neighboring communities that may be larger, while still retaining their rural nature. NRHA urges CMS to reconsider the wage index as a tool to reduce maldistribution of health care providers instead of just attempting to focus on the spending power of that money.

However, we need to ensure that in those rural places where the wage index is has already recognized the difficulty in recruiting and retaining a health care workforce are not penalized under this change. NRHA supports a hold harmless for rural providers that would be negatively impacted by this change to ensure access in these rural areas is not eroded by this policy.

NRHA supports the continued adjustment for rural sole community hospitals and essential access community hospitals. The existing 7.1 percent payment increase is an important lifeline to these rural hospitals that represent the primary source of hospital care to Medicare beneficiaries in their service areas, and we appreciate the CMS proposal to continue this payment increase for CY2020.

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 of and access to care in rural areas. If you would like additional information, please contact Max Isaacoff at misaacoff@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 the first name "Alan" and last name "Morgan" clearly distinguishable.

Alan Morgan
Chief Executive Officer
National Rural Health Association