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July 16, 2018

Alex Azar

Secretary

Department of Health and Human Services

Hubert H. Humphrey Building

200 Independence Avenue, SW, Room 445‐G

Washington, DC 20201

**RE: RIN 0991-ZA49 – Comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs**

Dear Secretary Azar,

The National Rural Health Association (NRHA) is pleased to offer comments on the Request for Information on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. We appreciate your continued commitment to the needs of the 62 million Americans residing in rural areas, and look forward to our continued collaboration to improve health care access and quality 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.

**At a time when rural hospitals are closing at an alarming rate, NRHA is concerned that a move towards site neutral payments for Part B drug administration facility fees would reduce access for rural Americans to these important medications.** Rural hospitals have long struggled to do more with less, however, the plethora of reimbursement cuts that have occurred in recent years have resulted in 44 percent of rural hospitals operating at a loss, up from 40 percent just a year ago. The continuous stream of payment cuts have resulted in average Medicare margins being negative since 2016 according to MedPAC. Yet rural hospitals have also been hit by losses to their bottom line caused by policies that are not expressed as explicit cuts, for example DRG recalibrations have resulted in a de facto cut to rural hospitals based on their case mix. All of this mixes together with additional challenges in rural health care delivery including workforce shortages, older and poorer patient populations, geographic barriers, low patient volumes and high uninsured and under-insured populations. Rural physicians and hospitals have historically worked around many of these barriers to provide high quality personalized care to their communities, however, each of these policy changes reduce the ability of these providers to care for their patients.

While we recognize the purpose of a site neutral policy would be to encourage administration at the lowest cost setting, when the rural hospital is the only local site for administration, such a policy would not function to channel patients to lower cost sites but simply add to a legacy of cuts to rural hospitals. NRHA believes the examination of these potential consequences through the rural lens, outlined in the recently released CMS Rural Health Strategy, highlights how these unintended consequences would negatively impact vulnerable patients and communities and hope to continue to work with HHS to identify and avoid any unintended consequences of such policy changes.

**NRHA urges cautious examination of unintended consequences and access in site neutrality between inpatient and outpatient setting for prescription drugs.** NRHAbelievesthe examination of this policy through the rural lens outlined in the CMS Rural Health Strategy, coupled with continued engagement with rural health stakeholders will allow for a policy that recognizes the unique access challenges of rural America. There is a trend in medical care towards more outpatient care and less inpatient care as medical technology allows for more patients to be safely cared for outside the hospital walls. Generally, this trend is a great for patients and health care providers alike, however, the payment models have not kept pace with these changes. Rural hospitals, based on the type of care they provide, are on the leading edge of this trend. Resulting in lower daily censes at many rural hospitals. The result is many communities are losing their hospital. For example, the Stamford Health Care System in Stamford, Texas recently shut down their hospital resulting in a loss of the local emergency department because the inpatient census fell below the required two inpatient average required for the “primarily engaged in inpatient care” standard to remain designated a hospital. The result of this closure is not just the loss of inpatient care, but of essential outpatient services such as the emergency department. While this single change from inpatient to outpatient administration of specific drugs is unlikely by itself close hospitals, it must be considered as part of the larger move away from inpatient care. Such changes highlight the need for a new provider type, an outpatient hospital with a 24/7 emergency department.

Rural hospitals do their best to stretch resources to provide maximum patient care and choice. However, where proposals look only at the immediate cost of a single service in a vacuum without regard to the overall financial viability of the entity providing that care we risk losing necessary access to essential treatments. NRHA supports patient care in outpatient settings where payments are sufficient to allow the hospital to continue to remain open to provide these, and other, services. Moving certain medications from inpatient to outpatient settings may require changes within the infrastructure of the facility, such as setting up costly outpatient infusion centers. Some rural hospitals have such infusion centers, for example Neshoba County General Hospital utilizes its 340B program savings to build and staff an infusion center. Without 340B they would likely stop providing outpatient infusion services, 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, other uses such as IV antibiotics that would otherwise be provided in an inpatient setting are a much larger portion of the patient utilizing the infusion center. This outpatient center is popular among patients and as doctors in the surrounding community have learned about the local availability of this valuable service, more patients are served by the infusion clinic. Yet, this facility is only able to provide that care because of the funding offered through the 340B program. Without sufficient funds, this service line could not be offered.

**The 340B Program is an essential part ensuring the continued existence of the rural safety net and is not a driver of high drug costs.** 340B discounts account for less than two percent of overall manufacturer revenues[[1]](#footnote-1) and 3.6 percent of all discounts and rebates offered by manufacturers[[2]](#footnote-2). And nearly one third of the total 340B discount is the result of penalties enforced against drug manufacturers for raising the price of drugs higher than the rate of inflation or voluntarily providing a discount lower than the 340B price.[[3]](#footnote-3) Comparatively, the 340B discounts are 78 percent less than what the manufactures spend on advertising their medications. At the same time, Medicare Part D brand-name drugs’ unit costs increased nearly six times more quickly than the inflation rate from 2011 to 2015.[[4]](#footnote-4)

**While the cost of the 340B program is small for the manufacturers, it is immensely important to the rural hospitals that rely on it to keep their doors open to serve their community.** Since 2010, eighty five rural hospital have closed. At the same time, a third of all remaining rural hospitals are vulnerable to closure according to Chartis iVantage Health Analytics, with 44 percent of rural hospitals operating at a financial loss, up from 41 percent just a year ago. Indeed, between 2011 and 2013 we saw urban hospital profit margins increase by 7% while rural margins decreased by 6%. Rural hospitals 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, which showed that all rural PPS hospital categories profitability was below average PPS hospitals with the least profitable being small rural PPS hospitals and Medicare dependent hospitals. Furthermore, hospitals serving more vulnerable patient populations, such as high poverty and minority populations, were more likely to have lower profit margins. These are the very hospitals relying on the 340B program to provide access to expensive necessary care such as labor and delivery or oncology infusions, or even more fundamentally to simply keep their doors open providing any services.

Even without the continuous stream of payment cuts that have resulted in average Medicare margins being negative for the past two years according to MedPAC. 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 barriers. Rural physicians and hospitals work around many of these barriers to provide high quality personalized care to their communities.

Yet 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 remote communities. Rural Americans are more likely to be older, sicker and poorer then their urban counterparts. Specifically, they are more likely to have chronic diseases, such as diabetes, that make access to regular medical care and medications essential to avoiding debilitating, costly, and painful complications. Yet, many rural Americans live in areas with limited health care resources, restricting their available options for care, including primary care. Seventy-seven percent of rural counties in the U.S. are Primary Care Health Professional Shortage Areas while nine percent have no physicians at all. Rural seniors are forced to travel significant distances for care, especially specialty services. In an emergency, rural American 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 communities despite continuous reimbursement cuts. One hospital is only able to staff their labor and delivery unit because of the 340B program, preventing women from needing to travel at least an additional 45 minutes to deliver a baby. Other 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. For Lake Regional Health System the 340B program allows them to set up primary care within their service area. They serve a large population of the elderly 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 since it is difficult to get primary care providers, and specialists as the local patient needs dictate, 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 the hospital 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. While Childress Hospital is about 100 miles from another hospital that provides oncology care, for one patient the opening of the oncology infusion unit meant he did not have to travel four hours each way to receive his chemotherapy, as he had done with this first round of treatment. This sort of travel is particularly difficult in light of common chemotherapy side effects such as fatigue, nausea and vomiting, and diarrhea. Fort Madison Community Hospital in Fort Madison Iowa is a 1 hour and 45 minutes drive from the next hospital providing chemotherapy infusions. Last year alone they provided 1,035 chemotherapy infusions to 619 patients, 466 of these patients 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 report the 340B program simply allows them to provide the fundamental needs of keeping the hospital open, such as staffing the emergency department. Neshoba County General Hospital utilizes the 340B program to offset losses from their high charity care and to staff an infusion center. Without 340B they 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, other uses such as IV antibiotics that would otherwise be provided in an inpatient setting are a much larger portion of the patient 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 identify what specifically their patients needs and provide access to those specific services.

Rural Hospitals serve the precise vulnerable patient population that the 340B program was designed for. Rural PPS Hospitals have a 16 percent higher level of uncompensated vs. 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, Sole Community Hospitals 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 with 18 percent of rural populations being over 65, verses only 12 percent for 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 vs 16 percent for urban populations. All of these factors impact a hospitals bottom line and thus we have seen 7% gains in median profit margins for urban providers while rural providers have experienced a median loss of 6%.

Rural residents tend to be poorer and are more likely to live below the poverty level. On the average, the rural per capita income is $9,242 lower than the average per capita income in the United States. About 25% of rural children live in poverty. As a result, Medicaid is disproportionately important to rural patients and with reimbursements often below the cost of providing care, a disproportionately high burden on rural hospitals ability to avoid operating at a loss. Particularly concerning is the fact that 86 percent of persistent poverty counties, having a poverty rate of 20 percent or higher in 1990 through 2010, are located in rural America. The rural hospitals serving these patients 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.

**NRHA applauds CMS’s efforts to reduce regulatory burden and urges CMS to apply this same rigor to keeping regulatory burdens low for rural hospitals within the 340B program.** For a small rural hospital, the administrative burden of the program is already high. Not only is the burden the result of statutorily required elements of the program but also in preparing for the random audits and ensuring that they never run afoul of the program guidelines. One hospital has two consulting companies they work with regularly for these mock audits to make sure no mistakes are made. These hospitals are complying with the letter and intent of the law and are afraid that if they lose the 340B benefits they cannot keep their doors open or their cancer infusion center running. While NRHA thoroughly supports safeguards to ensure program integrity, we urge CMS to ensure that small providers are protected from unnecessary burdens that threaten their participation in this program. Unfortunately, when regulatory burdens are increased the small rural providers are disproportionately impacted as the fixed costs of regulatory adherence are diverted from a much smaller program. NRHA has consistently applauded CMS’s efforts to reduce regulatory burden for hospitals and encourage CMS to utilize that same effort within the 340B program. Particularly within this program designed to stretch scarce federal resources it is essential that those resources are not further diverted from patient benefit to regulatory compliance.

**NRHA is pleased with exclusion of Sole Community Hospitals from the OPPS rule Part B drug payment reductions proposed for hospitals eligible to purchase 340B discounted drugs. NRHA appreciates the continued efforts on the part of CMS to work with rural providers to protect rural patient access to care and urges an extension of the exclusion as well as an expansion to other rural PPS facilities.** Unfortunately, rural hospitals paid under the PPS system represent 65% of these closed hospitals. Overall, rural hospitals paid through the PPS system are the most financially vulnerable especially the DSH hospitals impacted by the Part B regulatory change, according to the Sheps Center at the University of North Carolina which showed that all rural PPS hospital categories profitability was below average PPS hospitals with the least profitable being small rural PPS hospitals and Medicare dependent hospitals. Furthermore, hospitals serving more vulnerable patient populations, such as high poverty and minority populations, were more likely to have lower profit margins. These are the very hospitals relying on the 340B program to provide access to expensive necessary care such as labor and delivery or oncology infusions, or even more fundamentally to simply keep their doors open providing any services.

**NRHA is concerned about the administrative complexity that would be introduced into the 340B program if a value based purchasing filer is coupled with the 340B program.** While it may be possible to administer this change, NRHA urges caution in examining a change to 340B based on a value based purchasing scheme that is likely complex and has not been tested. While it may be appropriate in the future until value based purchasing for drugs is well tested it should not be further complicated by entanglement with the 340B program.

**Any changes to the patient definition must be consistent with how health care services are provided and recognize the interconnected, team based concept of health care to avoid unnecessarily eliminating the benefit of 340B for vulnerable patients and facilities reliant on the program.**

The health care system is moving toward a “patient centered medical home” concept, a system of collaborative care and greater responsibility for the whole patient instead of the traditional fee for service (FFS) payment methodology. This is an effort to provide better care at lower cost while improving the health of populations. This shift is broadly evident through a variety of programs including Accountable Care Organizations (ACOs), demonstration programs through the Center for Medicare and Medicaid (CMS) Innovation Center (CMMI), and other programs with the goal of increasing payment connected to quality and value-based care through alternative payment models (APMs). In fact, rural communities have been using Patient Centered Medical Home concepts for decades now. While our metropolitan areas are trying to implement PCMH, rural communities have been coordinating care across the continuum consistently and for a long time.

This move towards collaborate care promises increased value for the patient and better overall outcomes. The definition of patient must avoid a narrow concept of “responsibility” for patient care so as to not entrench the 340B program in the FFS system with a single provider responsible for a single discrete portion of the patient’s healthcare. Multiple providers can be responsible for an individual patient and a particular patient encounter. Considering patient status on “a prescription-by-prescription or order-by-order basis” will make the program progressively more obsolete and inconsistent with healthcare and other government healthcare programs. When a rural provider refers a patient to another provider for more specialized care, the patient does not stop being their patient and their responsibility. New models of care are designed to ensure the provider remains invested in the patient’s entire continuum of care. Thus, the patient remains the patient- and the responsibility- of the provider until that relationship is severed by the patient or provider.

To arbitrarily limit the definition of a patient, which provides access to a 340B discount, to only prescriptions written during an encounter with a practitioner, is inappropriate and NRHA urges a broad the definition of patient to include all prescriptions written for a patient, regardless of the location, as long as the primary medical home or equivalent is in a covered 340B clinic or ambulatory care center.

The plethora of available pharmaceuticals help patients live longer and healthier lives. There is no doubt that without the innovations in medications, many patients’ quality and quantity of life would be diminished. However, for an individual patient to achieve these results patients must adhere to the treatment protocol. There is clear evidence that patient’s adherence to a medication protocol is essential to experiencing the benefits of that medication, either maintaining or regaining health or slowing decline. However, it is also well documented that patients often modify medication regimens or forego medications due to financial considerations. A practitioner’s ability to connect their patient with appropriate medications that are affordable to the patient is an important part of ensuring patient’s adherence to the medication regiment prescribed. A provider’s need to ensure patient’s have access to affordable medications does not end when the provider must refer a patient to a specialist, often this is when medication adherence is the most important since the patient is experiencing a complex or acute medication condition.

In addition to the provider maintaining responsibility for the overall health of the patient, the patient continues to view themselves as a patient of each of these providers. This view of themselves of a patient of their local or primary care provider persists between visits to that provider. This is particularly true in rural America where patients are older, sicker, and poorer than their urban counterparts and are more likely to have multiple chronic conditions that require continual care. These vulnerable patients are more likely to be concerned about the cost of health care as a whole and their medications specifically. As an integral part of the community, rural providers tend to be keenly aware of the needs of their patients and community and to participate in programs like 340B in order to help their vulnerable patient population. A limited definition of patient to exclude both the perception of the patient and the continued responsibility of the provider is inconsistent with how health care is provided and is counter to the purpose of the 340B program of assisting patients and providers with providing the most good with limited federal resources.

Not all care of patients happens on site at a facility. In rural America facilities often work to provide care to their patients, even when the patient is homebound and non-ambulatory. Without providers willing to treat them in their home, these patients would forgo care until the severity of their illness reached a level where they would require costly transport and more costly care. Excluding these costly patients from the definition of patients harms the patients and the hospital, as well as making the health care system less efficient and effective.

Vulnerable rural patients are very aware of the 340B program discounts provided at their local care facilities and the fact that these discounts mean they will be able to receive medication at a lower cost. For rural facilities, any additionally funds from the 340B program are utilized as an important part of keeping rural facilities open and treating patients. This is especially important since rural America is experiencing a crisis of rural hospital closures, with 85 having closed since January of 2010. Forty-four percent of rural hospitals are operating at a loss, up from 40 percent just one year before. The 340B program serves as a life-line for patients by providing reduced cost medications and assisting in keeping rural facilities operating and providing care.

The patient definition needs to be clear that the patient receiving care via telemedicine is a patient of both the originating site and the distant site. In the context of telemedicine, the patient believes they are a patient both where they are located as well as of the doctor they are seeing at the distant site. This is also supported by the current state of Medicare billing practices, which recognize both locations as having a billable event attributable to the patient being seen – the distant physician for professional services and the originating site for providing the facility and mechanism for the care. Similar billing arrangements are evident with a variety of private insurance companies, as well as state Medicaid programs that utilize telehealth. This is further bolstered by the fact that the physician at the distant site must have privileges at the originating site, and generally has a contractual agreement with the originating site to provide such care to the originating site’s patients. This arrangement would allow flexibility for the patient to receive 340B drugs from either provider, based on whichever is the most logical arrangement for getting the medication to the patient.

The patient definition must recognize that providing a medication in a health care setting is a health care service. The reason these medications are provided in a health care setting is that a provider needs to monitor the patient taking the medication because of difficulties in administration or potential effects of the medication. Medicare has long recognized a difference between medications provided to a patient from a pharmacy setting, generally provided for self administration outside of the direct supervision of a health care provider, and those administered in a health care setting. Medicare, as well as other insurance providers, allow payments for such administrations as a health care service is evidence of this fact. The proposed guidance indicating medication administration or infusion is not a sufficient service for an individual to be a patient of the covered entity providing this service is counter to the long held understanding of these mediations and their administration. A covered entity is responsible for monitoring the patient during the administration, is paid for this service, and is potentially liable if a problem arises during the administration. Administration or infusion of a medication should be sufficient to label the individual receiving these services a patient of the covered entity for purposes of 340B and the guidance should be modified to reflect this fact.

Furthermore,medications intended for use in an outpatient setting, even if ordered in an inpatient setting should be included in the patient definition. Adherence to a prescribed course of treatment is an important part of ongoing outpatient care and ensuring that patients remain healthy enough to avoid additional inpatient admissions. The inability to participate in savings programs related to 340B will increase the price of medications to the patient, potentially leading patients to forego continuous treatment with necessary medications. Such breaks in the proper use of medications has potential health effects for the patients, as well as potential financial implications for the covered entity that could be penalized for the patient’s lack of medication adherence.

Any exclusion of discharge medications in the patient definition encourages providers to leave medication follow-up from an inpatient stay to follow-up treatment with a doctor at the covered entity. Such a decision would assist a patient in affording their medications, while causes potential disturbances in continuity of care and run afoul of the known benefits of continuity of care and proper use of medications.

Thank you for the chance to offer comments on this topic 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. If you would like additional information, please contact Diane Calmus at dcalmus@nrharural.org, or 202-639-0550.

Sincerely,



Alan Morgan

Chief Executive Officer

National Rural Health Association

1. Coukell A, Dickson S, “Reforming the 340B Drug Pricing Program: Tradeoffs Between Hospital and Manufacturer Revenue,” JAMA Internal Medicine (May 21, 2018), <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2681652?redirect=true>. [↑](#footnote-ref-1)
2. Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers, <https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf> [↑](#footnote-ref-2)
3. Id. [↑](#footnote-ref-3)
4. Increases in Reimbursement for Brand-Name Drugs in Part D, HHS Office of the Inspector General, OEI-03-15-00080, June 4, 2018. [↑](#footnote-ref-4)